

**THE FOOD STANDARDS AGENCY'S APPROACH TO MANAGING THE
INTERESTS OF ITS EXTERNAL SCIENTIFIC ADVISERS**
SUMMARY REPORT OF STAKEHOLDERS' RESPONSES

1. The Food Standards Agency's consultation on its updated Approach to Managing the Interests of its External Scientific Advisers was issued on 25th September 2017 and closed on 18th December 2017.
2. The purpose of this consultation was to seek stakeholders' comments and views on the updated approach and guidance for managing the interests of external advisers including on its effectiveness, clarity and whether the measures specified are proportionate to the risks.
3. The key proposals on which the consultation sought views were:
 - Do you think the criteria for success are an adequate reflection of what the FSA should be trying to achieve in managing the interests of its external scientific advisers? If not, what changes would you suggest and why?
 - Do you agree with the principles of our approach? If not, what changes would you suggest and why?
 - Do you think the process for managing interests meets our criteria for success to a satisfactory extent? If not, what changes would you suggest and why?
 - Is the best practice guidance clear and comprehensive enough for all relevant individuals to understand what they need to do? If not, what changes would you suggest and why?
4. A list of organisations who responded can be found at the end of the document. Responses from individuals have been anonymised.

FSA response to comments received

The FSA is grateful to those stakeholders who responded to the consultation. The responses are set out in the table from page 6 below, in order of the issues considered.

Responses were received through the online survey or email. No responses were received through the post although this was an option. Online survey results are summarised in a graph for each question as not all respondents included comments. Additional comments are included in the table below alongside the comments received via email.

Here the FSA sets out its response to the comments received from stakeholders during the consultation period. There were several cases of similar comments from different respondents. Comment(s) received have therefore been summarised in bold with the FSA response set out underneath. The FSA would like to thank all respondents for their comments and was pleased at the broadly positive response to our proposed approach. We have noted all responses received and will consider them in developing a final version of the approach.

1. How will interests be recorded? What will be the assurance process?

Interests will be recorded in forms completed by advisers in the process of application. Any interests raised and action taken to manage any potential conflicts during meetings of the scientific advisory committees (SACs) will be recorded in the minutes. All SAC minutes are published on the food.gov.uk website. The CSA team will take an overview of these as part of the assurance on how the approach is working in practice. We note that transparency on this aspect of the process is important and will consider how this can best be served.

2. Some expert advisers to the FSA are members of other government departments and agencies and therefore also bound by the civil service code.

The FSA has noted the comment that civil servants from other government departments and agencies, who may act as expert advisers to FSA, are also bound by the civil service code, in addition to FSA employees. We will reconsider the wording in the guidance to ensure clarity.

3. How will the FSA ensure that advisers and potential advisers have sufficient understanding of the process? Should they receive specific training?

As indicated in the consultation document, FSA staff will support potential advisers by discussing the form with them during the appointment process. The FSA is reviewing the induction process for new Scientific Advisory Committee (SAC) members and will consider how to ensure they have an appropriate level of understanding of the approach to interests' and if this should involve specific training. A final version of the guidance will also be provided to potential advisers to accompany the form for recording interests in the appointment process. This can also be made available to existing advisers at their request.

4. The Chair of a Committee leads on assessing interests declared by members at meetings; how will the interests of the Chair be assessed?

For members on most occasions, the Chair will be responsible for determining appropriate actions for any interests declared by members with the support of FSA staff. In the case of interests declared by the Chair, the same process will apply as to when there is an absence of the chair; the relevant FSA staff are responsible for deciding whether an interest is a conflict and if so, how it should be managed. FSA staff may also request input from other committee members on appropriate action. We will update the draft to make this clear.

5. Does the declaration on an interest by an adviser mean their advice will not be considered when advice is being written up?

Declaration of an interest by an adviser does not automatically mean that their expertise will not be considered. This is one option, if their interest is deemed to represent a real or potential conflict. Other options include their advice being requested in the form of an initial statement that is then considered by the other members during the meeting rather than the member being allowed to take part in the discussion and the final recommendation/conclusion. Further evidence from other members may be required to corroborate the evidence of a member with a declared interest.

6. Should interests be time limited and if so for how long?

The FSA considered having an 'expiration date' for past interests declared or a timeframe from which we would expect interests to be declared. We are aware that some other bodies do use a set cut-off date in their approaches to interests. While this would create a clear cut-off point for declaration, we considered that there could be interests from any point in an individuals' career, which may be or be perceived to be significant, so we were unable to determine a satisfactory cut-off. We therefore propose to encourage advisers to declare all appropriate interests in line with the guidance. FSA staff will be able to advise on specific incidences where an adviser may be unsure to ensure that declarations are proportionate.

7. Should the guidance be entitled 'good' practice rather than 'best' practice?

In finalising the guidance, we will consider whether it is most appropriate to title it 'good' or 'best' practice.

8. It could be unwieldy if the guidance proposes that members are invited to declare interests at each agenda item, the proposed approach needs clarity on this point.

The FSA will reconsider the guidance to ensure clarity over the point(s) in committee meetings at which the advisers will be asked to declare interests. Chairs should ask members to declare all interests relevant to the agenda items at that meeting at the start of the meeting. However, members are encouraged to flag further interests at a later point if they believe there is something else that has become relevant that has not been previously declared.

9. Who will check that the approach is working and ensure appropriate auditing?

As stated in the consultation document, the Chief Scientific Adviser's Team, supported by the FSA's Internal Audit are responsible for checking up that the approach is being followed correctly across the FSA and that any issues are being addressed. Details of this are given in Annex B of the consultation document. To ensure consistency across the SACs, SAC chairs will have the

opportunity to discuss how they adhere to the guidelines at the biannual meetings of SAC Chairs.

10. Should the receipt of research funding from industry or pressure/campaign groups exclude a member from chairing a committee?

While receipt of funding for research should be declared, the FSA does not consider that the receipt of research funding [from industry or pressure/campaign groups] should automatically prevent the appointment of an individual as a Chair of a committee. This is a less direct conflict than personal remuneration and, in line with the principles informing our approach, we feel that any benefits in terms of perceived independence would be outweighed by the effect of significantly limiting the field of eligible applicants with the necessary level of expertise and experience. Receipt of research funding will be considered as a relevant interest in determining suitability for an appointment, on a case-by-case basis, as for other interests.

11. The inclusion of ‘family members’ in the section outlining *Types of interest and examples*

The FSA will consider the inclusion of reference to family members as well as the individual concerned in *Types of interest and examples* to ensure complete clarity of the considerations required and amend the guidance if necessary.

12. The inclusion of an additional principle outlining the FSA’s statutory duty to protect the public health and other consumer interests in relation to health

While this duty is important in everything that the FSA does, we have chosen to include only the principles which relate specifically to the management of interests.

13. Advisers might have intangible interests leading to unconscious biases which are difficult to evidence but can influence the nature of discussions, formation of opinions, and the conduct and conclusions of research.

This is an important point and while, by definition, unconscious biases are difficult to record and mitigate against directly we agree with the comment that some of our measures such as diversity of members should help to mitigate against such biases.

14. How to deal with potential conflicts in the context of assessment of regulated products as part of an authorisation process may need more specific guidance if the FSA takes on a greater role in this area.

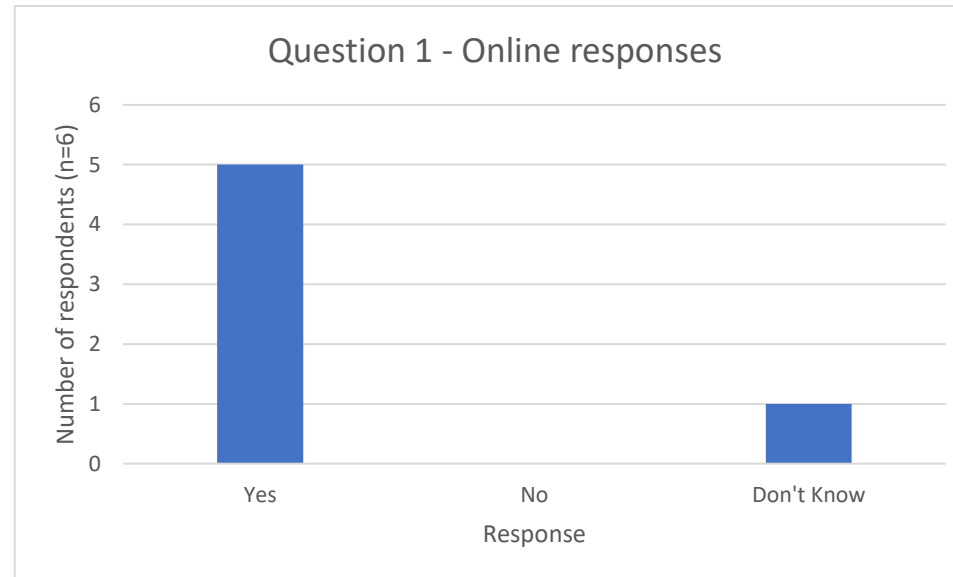
The FSA will need to keep the approach and its application under view and in particular to ensure it remains effective should the nature of FSA’s work and of the advisory roles shift significantly in the future – such as the example of a greater role in regulated products. We believe the principles based approach

will be adaptable to these situations and will allow us to take case-by-case judgements on the extent to which interests represent conflicts and the appropriate approach to managing any conflicts, reflecting the context of the advisory role.

- 15. The FSA needs to maintain an approach that enables its decisions to be effectively scrutinised. Careful consideration also needs to be given to ensuring that there is sufficient balance of expertise and avoiding over-reliance on particular perspectives that could also lead to a particular bias or failure to consider the full range of evidence and perspectives.** The FSA agrees that transparency, scrutiny and ensuring a wide range of perspectives are important aspects of FSA's wider approach to ensuring its work is properly informed by robust science, including through involving wider groups of experts and perspectives, for example through consultation.

Question 1

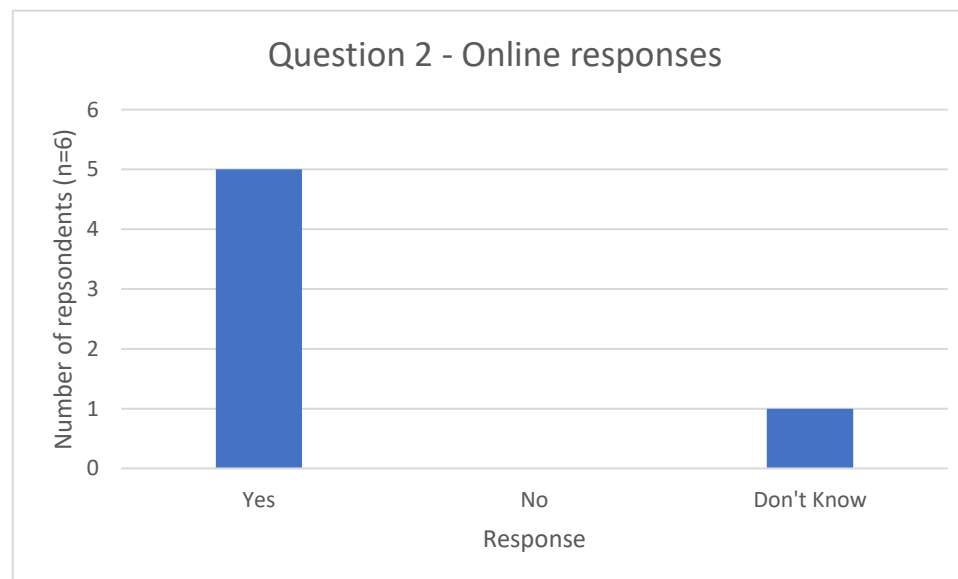
Do you think the criteria for success are an adequate reflection of what the FSA should be trying to achieve in managing the interests of its external scientific advisers? If not, what changes would you suggest and why?



Respondent	Comment
Individual	There is an omission in that it is not clear what happens after a case has been identified and action taken nor is there mention of the creation of a record of the handling of each case that is available (a) for the Agency to understand and if need be review its own precedents or (b) for anyone outside the Agency to have evidence of successful management right to the end of a case.
Which?	We agree with the proposed criteria for a successful approach to managing interests: robust, transparent, consistent, easy to implement and verifiable.
Food and Drink Federation	The criteria for success seem to be appropriate. One additional area that you might want to consider is 'respected'. Meaning, do other organisations who manage such issues, and other stakeholders in general, respect the process that you are using, and thus the quality of outcomes. In addition, you might want to consider and make available the actual process of conducting reviews versus these criteria as this does not seem to be covered at this stage.

Individual	The criteria for success are sensible but it would also be valuable to know how the Agency responds to any challenges it receives on perceived conflicts of interest; how they are resolved and whether the public have confidence in the process.
Public Health England	Yes, we think the criteria are adequate and well described. In Annex B under 1b) Scope it is noted that FSA employees are bound by the Civil Service Code. It is worth noting that external scientific advisors from other Government Departments, such as PHE, are also bound by this code in order to ensure full transparency of approach for experts from outside FSA that are employees of other Government Departments.
Royal College of Physicians	These criteria rightly address the process involved. However, they feel general, although appropriate, and some of the underlying ethos could be expressed later in Principles, and in Responsibilities.

Question 2
Do you agree with the principles of our approach? If not, what changes would you suggest and why?

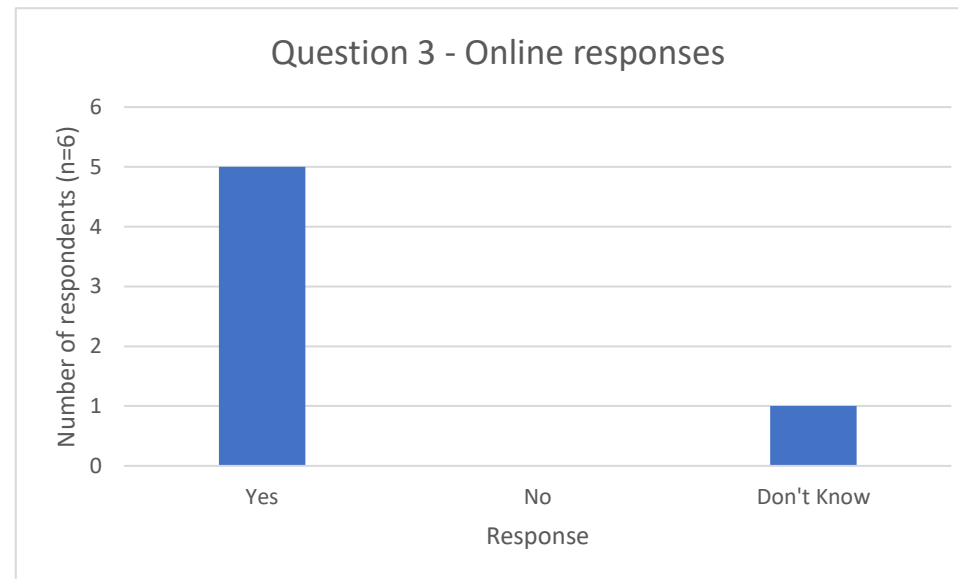


Respondent	Comment
Which?	<p>We generally agree with the five principles proposed to guide the FSA’s approach to managing interests and potential conflicts of interest:</p> <ul style="list-style-type: none"> • Conflicts of interest can lead to bias; risks of bias must be managed effectively. • An interest is not the same as a conflict of interest. A conflict arises when an adviser has an interest that could make them act in a way that reduces the objectivity of the advice. • Conflicts of interest don’t always lead to biased advice, providing they are managed effectively • Perceived conflicts of interest can be damaging, even if they do not lead to bias. People should be aware of how things appear as well as how they actually are. • There must be a balance between managing conflicts, maintaining access to diverse, good quality, and relevant scientific advice, and being practical to implement. <p>In relation to the third principle, expert advisers that may have conflicts of interest may still be able to make a useful contribution because of their expertise, but their bias needs to be carefully taken into account. Other mechanisms for receiving their input, as recognised in the guidance, may also be appropriate so that their input is clearly distinguishable.</p> <p>In relation to the fifth principle, there must be an “appropriate” balance. The focus should be on maintaining the independence and impartiality of the system, but in doing this to ensure that the system does not become so burdensome that the FSA is unable to attract or access the advice that it needs.</p> <p>We also suggest that an additional principle is included. This should state that decisions should always reflect the FSA’s statutory duty to protect the public health and other consumer interests in relation to health. This should always be the priority guiding the FSA’s approach.</p>
Food and Drink Federation	<p>We agree with the principles being used.</p> <p>We particularly agree with the principle that ‘an interest’ is not the same as a ‘conflict of interest’. To further expand on our support for this principle, we recognise that the number of individuals that are available with the specialisms of knowledge you are looking for, are likely to be limited. Given their expertise, such individuals are likely to have a broad range of interests that have informed their knowledge and will enrich their value to your work. Such experience could have been gained in Government organisations, non-Government organisations or in industry. An example of this, that you might consider, is that in the Public Procurement Sub-</p>

	<p>Groups (PPSG) where an individual within the industry is used as part of such groups, this is not a conflict of interest. That individuals’ have this experience and knowledge, is to be welcomed in helping you conduct scientific evaluations. However, understanding the detail of these interests is essential in managing any potential real or perceived conflicts of interest. Therefore, we also agree with the principle that ‘conflicts of interest don’t always lead to biased advice, providing they are managed effectively’.</p> <p>We also strongly agree that ‘perceptions of conflicts of interest can be damaging’. This impact can be on a wide range of individuals and organisations and thus the importance of managing such issues, should be treated with the utmost care and consideration.</p> <p>We also strongly agree that ‘There must be a balance between managing conflicts, maintaining access to diverse, good quality, and relevant scientific advice, and being practical to implement’. I would refer you back to our first point in this section that describes our reason that we also support this point.</p>
Individual	<p>It might increase confidence in the process if newly-appointed members of SACs received training in how to recognise and resolve potential conflicts of interest as part of their induction process. At the interview stage, many applicants seem to have a very sketchy knowledge of the subject.</p> <p>While it is the Committee Chair’s job to decide if members have a Col, who is responsible for checking the Chairs?</p>
Public Health England	<p>Yes we agree with the principles as described.</p> <p>It is worth noting that assessing the objectivity of a specific scientific advisor may be made more difficult by a declared apparent conflict of interest.</p>
Royal College of Physicians	<p>More consideration should be paid to the nature of interests. In the supportive text appropriate examples are given for which objective and tangible evidence may be available. However, advisers might have intangible interests leading to behaviours, and biases that cannot be easily evidenced, but which can, none the less, influence the nature of discussions, formation of opinions, and the conduct and conclusions of research. The FSA’s SAC system mitigates some of these points and this should be considered as a component in the section on the Roles and Responsibilities in managing interests.</p>

Question 3

Do you think the process for managing interests meets our criteria for success to a satisfactory extent? If not, what changes would you suggest and why?

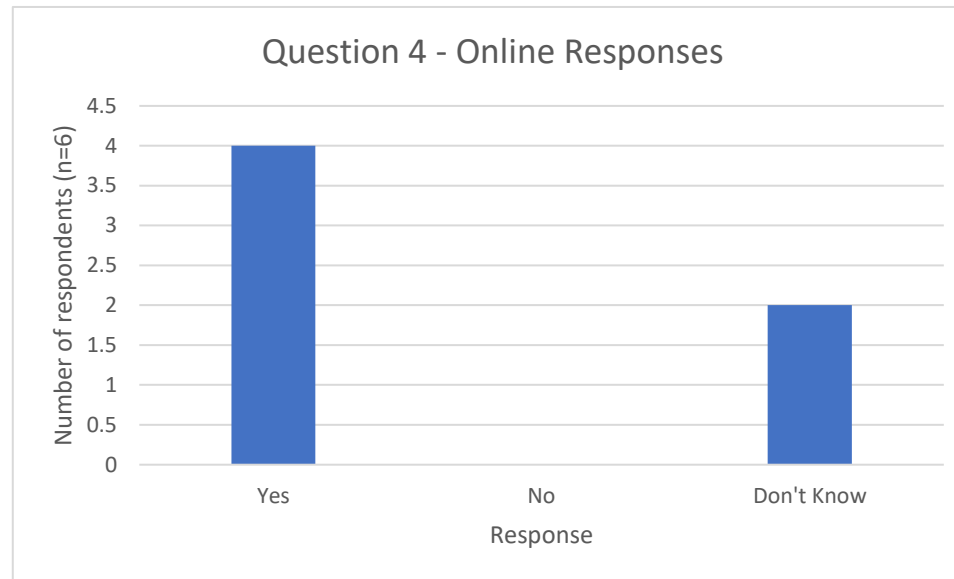


Respondent	Comment
Individual	A chair of a SAC ought to be open to hearing comments of committee's members on the matter when deciding how to manage a case
Individual	The final paragraph detailing when the advice from an adviser is written up raises some questions. It could be interpreted as meaning that advice that from the adviser that appeared to reflect the declared interests would be rejected and only evidence that conflicted with the declared interests given weight. If the advice does appear to reflect the interests of the adviser, then a justification could be provided as to why this is considered to be good advice. Declared interests are only one potential source of bias and this should be acknowledged. None of us are without prejudice and bias, however objective and evidence-based we try to be. The principle of engaging with people from different backgrounds e.g. academic, medical, industrial is a good one and should be encouraged.

Which?	<p>We agree with the roles and responsibilities as described, including that the use of multiple advisers is also an important factor in ensuring the breadth and impartiality of advice. Advisers should be responsible for declaring their interests, but the FSA needs to have a proportionate way of “policing” this. Chairs have a crucial role in ensuring that interests that may arise during scientific committee or working group discussions are handled appropriately. Their independence and integrity is therefore especially important.</p>
Food and Drink Federation	<p>We agree with the process for managing interests. We would suggest that you are very clear about the timeframe within which people are asked to consider when they are answering the questions that are to be posed. For example, with family members, would they need to declare interests of parents, if this was before the individual themselves was an adult themselves? Are there any circumstances under which interests early in an individual’s career or educational experiences should not be declared?</p> <p>It seems somewhat unsatisfactory to say that these are not exhaustive lists of examples. But given the inclusion of this phrase, will you provide expert advice to individuals in case of questions of what should be included?</p>
Public Health England	<p>Yes we agree with the processes as described. However, we note that no timeline is given over which the interests of external scientific advisors need to be considered and declared.</p> <p>We would suggest a period of five years as consistent with the approach taken by other organisations, including international organisations such as the European Centre for Disease Control. Alternatively, as in the approach taken by the European Food Safety Authority, the period of time during which the activity which could result in a conflict of interest is undertaken could be requested but then it is suggested that this is clearly and unambiguously added as a separate column in the Appendix A document.</p>
Royal College of Physicians	<p>This deals appropriately with accountability in relation to coping with interests, but the culture of an organisation throughout all levels of responsibility should be that there is an institutional appreciation of the possible detrimental effects of interests. This requires an expertise and insight of risk assessment and risk analysis overall and of the potential for bias and interest in the topics dealt with by SACs, research programmes and projects. Therefore it may be difficult, given the reduction of staff and the attenuation of experience and expertise within the FSA, to expect FSA staff and Chairs of SACs etc. to have the expertise to be aware of all potential adverse effects of interests, and to act on their concerns. Therefore it might be helpful for the SAC as a whole to consider any interests of concern.</p>

Question 4

Is the best practice guidance clear and comprehensive enough for all relevant individuals to understand what they need to do? If not, what changes would you suggest and why?



Respondent	Comment
Individual	I would perhaps put more emphasis on the importance of over-declaring possible interests as a precautionary principle.
Individual	What is missing is whether there is a sort of statute of limitations for the declaration of a one-off interest which could give rise to a conflict, which, as time goes on, gets increasingly out of date. This was one of the queries raised in a meeting of GACS and which the secretariat noted, indicating it would be reviewed when the documentation about managing interests was updated. I do not find this point anywhere in the consultation document.
Individual	In principle, yes, but implementation is open to Chair's judgement on SACs. It will be useful for the Chairs of the SACs to have a briefing session with the FSA collectively to consider consistency of implementation of this guidance, and for the Chairs to include a session on the agenda of a future SAC to brief SAC members fully.

Which?	<p>It is important that interests are not defined solely as an advantage or obligation that an expert owes or feels they owe another person or organisation, or is owed to the individual from that person or organisation. Experts may have an interest that creates a conflict of interest without them necessarily consciously seeking to act on this. Individuals are not always going to be in a position to appreciate that they are influenced or conflicted. The definition should recognise that interests include experience that may affect an advisor's advice or judgement in a particular way.</p> <p>The guidance sets out a non-exhaustive list of a wide range of interests that need to be declared, both personal and non-personal. A challenging, but important issue is how to deal with non-direct interests eg. those interests which go beyond current employment or personal remuneration and may be more subtle. This is also an important consideration when selecting Chairs, and deciding whether membership, or balance, on a particular panel is appropriate. We agree that previous employment or other relationships, support or funding that could affect or be perceived to affect independence should also be declared and taken into account.</p> <p>The FSA must also develop a transparent approach to dealing with specific interests that may relate to a company, sector or product, for example, and how it will be determined whether this could present a conflict when dealing with other related products or more generic advice and vice versa in the case of non-specific interests. The issue of how to deal with potential conflicts in the context of assessment of regulated products as part of an authorisation process may need more specific guidance if the FSA takes on a greater role in this area. More generally, it would be useful to develop some specific scenarios to help with the consistent and appropriate application of the guidance, reflecting some of the complex situations that may arise across the FSA's areas of responsibility.</p>
Food and Drink Federation	<p>We agree with the best practice guidance, in particular the intentions around making such information publicly available.</p> <p>We would strongly suggest that the guidance is an integral part of the declaration form so there can be no doubt about the points for consideration when completing the submission.</p>
Individual	<p>I don't think it's practical for committee Chairs to ask for declarations 'at each agenda point' (page 11) - a reminder at the start of each meeting, covering all agenda points, should be sufficient (as seems to be the advice on page 16). There seems to be some inconsistency here.</p>

	<p>The inclusion of 'current and past interests' (page 12) raises the question of whether interests are time-limited and, if so, for how long?</p>
Public Health England	<p>Yes the guidance is generally clear and comprehensive. The categories of interests are particularly well defined.</p> <p>It is noted that <i>“the FSA has a long-standing position that Chairs of its Scientific Advisory Committees should not be employed by, or receive personal remuneration from, industry or pressure groups during their terms of appointment”</i>.</p> <p>PHE recommend that there should also be consideration of receipt of research funding in these restrictions.</p> <p>It may be worth addition of text in section 2 prior to section 2b(ii) indicating that the consideration of conflicts of interest refer to family members as well as the individual concerned in considering conflicts of interest in relation to relevant organisations and individuals (ie from page 11) in order to ensure complete clarity of the considerations required.</p>
Royal College of Physicians	<p>If this Guideline is going to be used to generate contractual terms for service as an external scientific adviser, it is suggested that occupational law advice be taken. It is arguable that 'Best Practice' should be replaced by 'Good Practice', because the latter can be substantiated in law, the former may not be.</p> <p>Reflecting on the Criteria for Success, these address the process, but not its effectiveness. The proposed system can be expected to be effective, and taken for granted. However there will be instances when risk assessments, research outcomes, and opinions will be found to have been compromised by the interests of external scientific advisers. These should be acknowledged in the Approach Guidance so that the role of audit process in exploring such events and, if necessary, advising on any amendments to the approach to and monitoring of interests.</p>

Additional comments

Included below are comments which were not specific to an individual question but refer to the proposed plans in general.

Respondent	Comment
Individual	<p>In general, I support the FSA's approach as laid out in the consultation document.</p> <p>As indicated, any adviser, be it from an academic, industry or lay background is by definition coming in with 'baggage' and the potential to exhibit a degree of bias. It is important that they consider each topic discussed and whether or not there could be a potential conflict of interest. In the committee on which I sit, it is indeed routine to declare any interests at each meeting and we are encouraged to make such a declaration even if we are not sure it is relevant.</p> <p>The bias can be largely negated by having committee members with a range of backgrounds and experiences. It is my experience that a personal opinion can be swayed by the input of others with different perceptions of the same issue. It is important to remember that the committee chairs themselves will have a view and it is imperative that they do not try to influence the committee discussion in any particular direction. I will not provide a response to all of the individual questions as I believe the document to be acceptable.</p>
Which?	<p>A robust approach to safeguarding independence by dealing with conflicts of interest is essential. Alongside this, the FSA needs to maintain an approach that enables its decisions to be effectively scrutinised. Transparency is emphasised as a principle and this should extend to open meetings of scientific committees and the continued appointment of public interest and lay members of committees and other forms of expert panel to provide challenge.</p> <p>Careful consideration also needs to be given to ensuring that there is sufficient balance of expertise and avoiding over-reliance on particular perspectives that could also lead to a particular bias or failure to consider the full range of evidence and perspectives. It may sometimes be the case that leading experts that the FSA could benefit from involving, may have limited time available to contribute to regular advisory bodies. The FSA must therefore ensure that it develops a range of mechanisms to ensure that it is involving and consulting the most relevant experts in line with the principles in the guidance.</p>

List of organisational respondents:

Food and Drink Federation

Public Health England

Royal College of Physicians

Which?