

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

SCIENTIFIC ADVISORY COMMITTEES WAYS OF WORKING UPDATE

Issue

1. To update the Advisory Committee Novel Food & Processes (ACNFP) on changes to the FSA's approach to managing interests for our expert advisers. This is part of the wider work to develop the FSA's ways of working with their Scientific Advisory Committees in preparation for EU Exit.

Background

2. The identification of potential conflicts of interest of scientific advisers and impacts on the participation of those advisers in the framing of advice to regulatory bodies, has been a focus for scrutiny. The 2016 Triennial Review of FSA SACs recommended that:

'FSA should revise its current guidelines on interests for SACs and their Chairs to ensure they remain clear and fit-for-purpose for the current and future working environment of the committees...considering other models in use across Government nationally and internationally and their efficacy in protecting consumer interests and ensure that its SACs consistently follow the revised framework'

3. This recommendation aimed to ensure that the FSA's approach remained fit-for-purpose for the future, not to address any perceived failings to date.
4. In response, the FSA reviewed its approach, working closely with relevant staff across FSA and with the FSA's SACs. A public consultation on a draft revised approach and guidance was held from 25 September to 18 December 2017, and a range of stakeholders provided comments. These were broadly supportive of the revised approach but did identify some points which the FSA could usefully clarify.
5. The FSA has subsequently taken the opportunity to check the revised approach to ensure it reflects and supports relevant aspects of FSA's work to develop our approach to risk analysis (**Annex A**) and our use of SACs. A final version of the updated approach was agreed by the FSA Board in March 2019 (**Annex B**).
6. The final revised guidance document for managing interests of external scientific advisers can be found in **Annex C**.

Key elements of the approach

7. The updated guidance aims to increase transparency and consistency by bringing guidance together in one place, and updating it as needed to ensure it is future-proof. It applies to all existing and new members of SACs for which FSA is sole or lead sponsor, and their Joint Expert Groups, working groups and other sub-groups.
8. Some key features include:
 - A principles-based approach, which acknowledges that experts (like everyone else) have interests, and that these must be identified with any potential conflicts managed in a proportionate, consistent and transparent way.
 - A proportionate approach to managing risks from potential conflicts which will help us maintain access to the breadth and depth of high-quality experts required while ensuring integrity of both the process and advice they provide.
 - All external expert advisers are in scope, including those on the SACs and contributing to their work, and those providing input through other routes, such as peer review or ad hoc evidence or advice.
 - Explicit coverage of advice in areas where we anticipate making new or expanded use of external expert advisers, as part of our preparations for EU Exit. This includes assessment of applications for approval of regulated products, where the potential for specific conflicts and the need to ensure these are managed effectively and transparently are particularly important.

What has changed in the guidance?

9. The revised guidance builds on existing good practice, with no major policy shifts. There are a few points that are new, or slightly different (as we've moved to a common framework across all SACs) or have a greater emphasis – for example in how we record and report interests and how they have been handled.
10. Secretariats will be more consistently proactive in checking in advance for specific conflicts when planning and assigning new work. This will be particularly relevant for regulated products and potentially contentious issues such as advice to inform trade issues.
11. Reports of work from or informed by the SACs (e.g. committee opinions or reports) will include a summary of relevant interests and how any conflicts were managed, with the rationale for this. This will ensure that information on

interests remains alongside the evidence and advice from the Committee as it handed on and used.

12. The new guidance includes a requirement to declare relevant past interests. In the consultation draft, we did not include a time limit on this, as it is always possible to think of an exception which could be perceived as relevant. However, responses to the consultation flagged that while this is correct, it could lead to uncertainty and a disproportionate burden for reporting. We have therefore set a guide limit of up to 5 years for relevant past interests, with a note to consider including older interests if they are likely to be seen by others as significant.

Committee Action Required

- To ask the Committee if they are clear on all changes to the guidance and the principles set out.
- To ask the Committee to update existing declarations to include any relevant past interests to be included in the 2018 Annual Report by returning the Declaration of Interests Form (**Annex D**) that will be provided by the Secretariat.

**Secretariat
June 2019**

Annexes

Annex A – Risk Analysis Process

Annex B – FSA March 2019 Board paper

Annex C – Guide to Managing Interests of External Advisors

Annex D – Declaration of Interests Form