COMMITTEE PAPER FOR DISCUSSION **ACNFP/149/05**

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES

Update on Regulated Products & Risk Analysis Processes

Issue

1. Not all ACNFP members may be aware of content on the FSA website (www.food.gov.uk) and ACNFP website (acnfp@food.gov.uk) in relation to regulated products and the authorisation process.

2. Since exiting the EU there has been further work across the FSA to support risk analysis processes. Whilst the ACNFP is focused on the risk assessment piece this paper aims to provide an update on some of the other aspects which are being considered by others in the Agency. The paper is for information and to provide context of what the ACNFP does, as part of the wider regulated products and risk analysis processes.

Background

Food.gov.uk

3. In order to support applicants in providing high quality dossiers for assessment the FSA has put together a package of information that has been published on the FSA website.

4. The UK left the EU on 1st January 2020 and in line with this the FSA food.gov.uk website was updated accordingly. Details of the pre-market approval procedure for food and animal feed products and processes requiring authorisation can be found on the Advice on the Authorisation Process webpage.

5. Detailed information on authorisation requirements for different product type such as novel foods and genetically modified organisms (GMO's) as food and feed can be also be found here.

6. Information on what an applicant needs to submit as part of their regulated product applications can be found on the Guidance on the Application Requirements webpage.

7. All of this information can also be found on our dedicated ACNFP website under Food Assessments.

Other aspects being considered by FSA

8. The assessment and authorisation of regulated products sits within the wider FSA risk analysis process. This allows risk managers in considering the way forward for an issue or dossier to take account of wider factors such as economics and trade known as Other Legitimate Factors in developing their recommendations. The Advisory Committee for Social Science (ACSS) was asked by the Chief Scientific Adviser (CSA) to advise on principles for developing recommendations on **Other Legitimate Factors (Annex A)** to include in complex risk analysis questions.

9. This paper had two aims:

   - to set out how evidence on other legitimate factors should be assured; and
   - establish mechanisms for ensuring that FSA's analytical consideration of other legitimate factors within the risk analysis process is guided by the most appropriate high-quality evidence.

10. The paper is being incorporated into the FSA Risk Analysis Playbook which is to be used as a resource to support FSA staff when responding to situations where stress (e.g. unexpected time pressures, or a lack of information) is placed on the risk analysis process. The Playbook will include a series of cards which will define broad issues that may arise in a range of different scenarios, providing helpful pointers towards the way in which the FSA should respond and the people that should be involved, rather than setting out specific scenarios themselves or seeking to detail the full process.

11. The ACSS and Science Council felt that the Other Legitimate Factors paper complemented the Science Council's **Third Party Evidence Review** well (**Annex B**).

12. The aim of the Science Council for this review was to provide a framework that can guide those seeking to submit uncommissioned evidence to the FSA on its scientific principles and standards. The Science Council's proposed framework is based on the principles of quality, trust and robustness.

13. To note, Regulated Products were out of scope of this review, as there are specific requirements to be met in these areas.

Committee Action Required

- Members are asked to note the wider information for applicants on the regulated products assessment requirements and process.
- Members are asked to note the wider ongoing work on the risk analysis process of which assessment of regulated products is a component.

- Members are invited to raise questions or share reflections on this work to inform the Secretariat's contributions to wider initiatives on the risk analysis process.

ACNFP Secretariat

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Annex A: ACSS Other Legitimate Factors paper

Annex B: Science Council's Third Party Evidence Review