General

Assessment Process and Ways of Working

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1. The Risk Analysis Process

The work of the Committee will focus on the risk assessment stage of the risk analysis process. The majority of the risk assessment work of the Committee will relate to the evaluation of feed additive dossiers seeking authorisation in Great Britain (GB). In line with legislation requirements, the additive will be assessed regarding safety risks to the target species, consumers, the user and the environment. The Committee will also assess whether the additive has the intended effect, in line with Article 4.(3) of Assimilated Regulation 1831/2003.

It is recognised that risk assessment is one of the major components in determining whether or not to authorise a feed additive. However, risk managers (the FSA Policy team that considers risk assessment conclusions to determine conditions of authorisation) will need to consider a range of other aspects, known as ‘other legitimate factors’, which include economic, public health, technical, and consumer-related factors. Therefore, in line with best practice and to maintain the separation of roles, the Committee will provide its assessments as independent scientific advice to the Food Standards Agency (FSA).

2. The Dossier Stages

Every feed additive dossier follows a similar route before it reaches the Committee, which is here summarised:

2.1 Validation stage

The dossier is submitted by the applicant through the online portal.

The Regulated Products Approvals Team (RPAT) check for any administrative inconsistencies, and send to the Feed Additives (FA) Policy Team (Risk Managers).

The FA Policy Team does an initial check of the dossier to ensure the applicant has submitted information in the relevant sections as described in Assimilated EU Legislation (REUL) of Regulation 429/2008 on the preparation of dossiers. The FA Policy Team and the ACAF Secretariat work together to evaluate the applicant's request for confidentiality and whether input is needed from the National Reference Laboratories for evaluation of the application's analytical methods.

After this suitability check, the ACAF Secretariat carries out an in-depth completeness check based on the requirements laid out in the EFSA scientific guidance and REUL 429/2008. At this point information may be requested from the applicant, including missing documents and sections, clarifications and corrections.

2.2 Assessment stage

After the FA Policy Team and the ACAF Secretariat agree on validating a dossier, a proposal is formulated by the FA Policy Team describing the type of risk assessment required to be carried out by risk assessors. This is agreed by both teams and a problem formulation statement (PFS) is then signed. The PFS is a formal written record describing the assessment type requested by Policy to risk assessors.

If an ACAF-led assessment is required, the application is presented at the next available Committee meeting, with relevant cover papers and summaries from the secretariat to support the Committee (see section below).

3. Committee meetings and ways of working

3.1 Meetings

The Committee is expected to meet six or seven times a year, approximately every 6-8 weeks. Some meetings will be conducted face-to-face, but the majority are expected to be carried out online.

The content of the meetings will be composed of a main component of dossier assessment, followed by a review of applicant's responses and opinion drafts, where relevant. ACAF will have a chance to give feedback and provide

assessment on other issues related to animal feeds and pet foods, which have been the remit of other Scientific Advisory Committees (SAC) prior to the reinstitution of ACAF.

Agendas, non-confidential versions of the minutes, and conclusions of the ACAF's assessments (Committee's Advice Documents) will be published in the ACAF website as early as possible.

3.2 Secretariat and external support

The meeting dates are agreed the previous year, based on the availability of members, and attempts made to evenly space them throughout the year.

The Secretariat will support the Committee at each meeting by preparing cover papers, summarising information and providing early assessment of certain aspects of the dossier.

The ACAF can access external niche areas of expertise when required. This expertise can be drawn from the Register of Specialists, internally within FSA, other SACs members or external specialists.

3.3 Rapporteurs

Every dossier is assigned to an ACAF member, who acts as 'rapporteur'. Rapporteurs are expected to take ownership of the assessment process of the dossier, from facilitating the discussion and input from ACAF experts, to reviewing the final opinion written by the Secretariat based on the Committee's discussion. Rapporteurs have the support of the Secretariat and the Chair when carrying out their responsibilities.

Rapporteurs are chosen based on a variety of factors, including conflicts of interest, current workload, expertise and authorisation type.

While the rapporteur acts as an overseer of the dossier, the assessment is carried out by the Committee as a whole, with members contributing to the assessment of their relevant area of expertise.

3.4 Committee-led assessments

The type of feed additive risk assessments carried out by the Committee are as follows:

Feed additive dossiers: The Committee’s main area of responsibility is the evaluation of application dossiers for the authorisation of feed additives for use in Great Britain. This will be carried out in line with the principles laid out in Assimilated Regulation 1831/2003, 429/2008, and Scientific Guidance.

PARNUTs (feed for particular nutritional uses): ACAF has the responsibility of evaluating the safety and efficacy information provided by the applicant supporting the PARNUT application in line with Assimilated Regulation 2020/354. There is no specific guidance or legislation determining what information should be included in the application, however, general principles of safety and efficacy are taken into consideration for the evaluation of PARNUTS.

Feed detoxification processes: ACAF has the responsibility for evaluating the validity of feed detoxification processes for their use in Great Britain. There is no specific guidance available for detoxification processes’ applications. However, any dossier should demonstrate that the detoxification process meets the acceptability criteria established in Assimilated Regulation 2015/786.

3.5 Request for information by ACAF

The Committee may request further information (RFI) from the applicant to inform the assessment. It is expected that the applicant will provide the right information within the first response to the RFI. After that response, the Committee will be able to conclude based on the information available or ask for a further RFI to be sent out. The same RFI question is not expected to be extended repeatedly if not answered successfully on the first occasion.

The assessment of the dossier is expected to be carried out in line with EFSA guidance or legislative requirements and, therefore, requests for information are generally based on these requirements. However, as an independent assessment body, the Committee may request information based on their own expert evaluation.

3.6 The Committee’s Advice Document / Safety Assessment

Once all the necessary information has been provided and conclusions reached by the Committee, the Secretariat will draft a Committee’s Advice Document which, once finalised and agreed by ACAF, will serve as the formal conclusions of the Committee on the application.

The FSA/FSS will consider the ACAF's advice on the application and produce a second document, named "Safety Assessment", which forms the official opinion of the FSA/FSS, and will include other considerations relevant to the assessment. The Safety Assessment draft will also be shared with applicants for confidentiality information review.

The FA Policy Team will then send the document out to a consultation process (open to members of the public) for the application and consider the conclusions of the Committee as the basis for their risk management decisions. These will be captured in the legal mandate that authorises the additive for its commercialisation in Great Britain.

3.7 Conflicts of interest

All Committee members are bound the Civil Service Code of Practice. In addition, members are asked to declare any conflicts of interest whenever these may interfere with their ability to provide unbiased assessment on any matter. To this regard, the FSA guidance on declaration of interests captures how these can be identified, declared and managed. Furthermore, ACAF will adhere to the following practices to ensure that all conflicts of interest are identified and managed timely and transparently:

a) A full professional biography will be publicly available for all ACAF members in the Committee website. All interests for each member will also be listed here.

b) Members will be asked to declare any potential conflicts of interest when being assigned the role of rapporteur for a dossier.

c) Members will be asked to declare any potential conflicts of interest at the beginning of each item in the agenda during Committee meetings.

d) The Chair and Secretariat will manage the conflict of interest on a case-by-case basis, potentially limiting the participation of the Committee member in the assessment partially or totally.

i. If a member directly works with or for the company that submitted the application, they will declare a direct conflict of interest and will not be able to remain or participate at any point of the assessment process.

ii. Other potential conflicts are generally declared as indirect, however, this categorisation will depend on the particularities of the situation and managed accordingly.

e) All conflicts of interests declared will be captured in the minutes, which will later be made public in the ACAF website.