3. Areas for consideration in implementing the models

In this guide

44. The ACNFP also considered how the Models could be implemented in order to ensure the data requirements could be practically applied. Some recommendations for consideration by risk managers in deciding on the approach to regulation are outlined below.

45. The Committee considers that the responsibility for the data being provided sits with applicants. Applicants are accountable for the accuracy and conclusion of any statement they provide in support of their application. Being able to navigate an applicant’s argument on how the data presented supports their conclusions on the safety of their product has been important in other regulatory regimes. The Committee recommended that a structured explanatory narrative should present the information and detail supporting the application, the reasoning behind the interpretation of accompanying data and a clear conclusion that answers the requirements. The FSA should reserve the right to request or examine further data and should have powers to seek more data or review where

potential risks are identified.

46. Decisions on when and where in a process additional data can be requested from applicants has been key in the effective operation of other regulated product regimes. The Committee recommends that opportunities to request additional data is built into the regulatory process, where pivotal to enable decision-making or where clarification is needed. This should be limited to data expected to be available to the applicant as part of normal due diligence to ensure safety under food law. This holds true for both Model 1 and Model 2.

47. It was commented that where larger data sets are deemed necessary to better understand the safety profile of a PBO, particularly where commissioning of further studies is required, this is more in alignment with Tier 2 of the assessment and would need to be justified as being necessary for decision-making.

48. It was noted that to ensure Tier assignment is working as initially intended, the process may benefit from an audit or review of the first applications after 2-3 years. This could be helpful in establishing precedents and ensuring the guidance is achieving its aims. One approach to achieve this would be that initially all PBO applications are assessed by the ACNFP to ensure the adopted approach is effective and proportionate. Depending on the model chosen by the FSA, this could then move to an approach where the internal FSA science team completes the triage process based on data in initial submissions; applications that require expert advice on more technically challenging aspects would be completed with the support of the ACNFP.

49. Given the potential for the application of technology in this area to evolve quickly, it was suggested that there be a mechanism to ensure the guidance and support materials can be updated. The Committee suggested that the process is subject to regular review every 3 years to ensure the assessment process remains appropriate and fit for purpose in light of technological and political developments.