FSA Science Council

Working Group 5

Review of the FSA's research programme on food hypersensitivity

Interim Report

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1. EXECUTIVE SUMMARY

In May 2019, the Science Council was asked by the FSA Board to undertake a review of the FSA's research programme on food hypersensitivity (FHS), incorporating food allergy and food intolerance. Much of this work has historically been undertaking through the FSA's Food Allergy and Intolerance Research (FAIR) Programme.

The Science Council appointed a working group led by Dr Paul Turner and Prof John O'Brien. The review was divided into 3 areas:

- A review into the previous and current Research programme, including an assessment of best practice in undertaking such a programme
- A Priority Setting Exercise with wide stakeholder input, to identify research priorities for the FSA in the area of FHS, and a review of the existing literature associated with these identified priorities.
- Identification of future priorities in a 5 to 15-year timeframe, through a horizon scanning workshop.

Consistent with the 2008 and 2012 reviews, the FAIR programme has overall been well-managed, and influential with significant policy implications at a national and international level. These successes are clearly linked to the dedication of FSA staff and contractors, and the extensive and frequent level of stakeholder engagement evident until 2012. Looking ahead, we highlight the following recommendations for the FSA to consider as they develop their future research activities relating to food hypersensitivity:

1.1 Specific Recommendations

i. ***Overall strategy and direction*****:** Historically, the FSA has funded a significant amount of research into FHS in the UK. More recently, there has also been a focus on adult food allergy; the FSA Board requested at the March 2017 meeting that funding research on adult food allergy should not be at the expense of other FSA research activities in FHS. There has been a decrease in investment in the FAIR programme since 2010. In addition, the reduction and turnover in personnel, together with the cessation of annual stakeholder meetings, may have limited the ability of FSA to identify and launch new research activities. The

FSA has funded research that provides less direct impact to protecting consumers with FHS (e.g. by reducing the prevalence of FHS though primary prevention strategies). The success of this work was acknowledged at the March 2017 FSA Board meeting. **With the introduction of cross-governmental ARIs, the FSA Board should again provide a steer as to the role FSA should play in commissioning broader research into FHS** (for example, whether research into the treatment of food allergy or potential environmental causes of food intolerances falls within the FSA remit).

ii. ***Food Hypersensitivity Programme Board***: A new Programme Board was established by the FSA in Summer 2018 to bring together FSA work in the area of FHS under the direct oversight of the Executive Management Team. The process by which science and data are brought to the Programme Board needs to be made more resilient. **We recommend a more structured approach with the necessary staff resourcing to facilitate this, without compromising the benefits of the informal horizontal system currently in place. This could take the form of a multi-disciplinary forum alongside the Programme Board to provide "science push" while the Programme Board creates "policy pull".**

iii. ***Maximising outputs from existing data***: **The FSA should consider allocating additional resource to maximise use of routinely-collected data across the FSA (e.g. post-incident analyses) and avoid the current situation where operational and analysis roles may be combined resulting in limited capacity for data analysis.** This has been previously flagged by the Science Council as a recommendation to the FSA Board (Science Council Report on Capability and Assurance, July 2018).

iv. ***Capturing best practice, supporting staff and building resilience***: There is a critical reliance on "lynchpin" individuals. **This must be addressed through adequate internal resources, succession planning, handover checklists and strategies to capture best practice and protect institutional knowledge.** Thought should be given to the use of expert Project Managers who may be better qualified than FSA scientists to undertake this work.

v. ***Regular external reviews*: The FSA should reinstate regular stakeholder and quinquennial external reviews to ensure ongoing evolution and external monitoring of the FHS research environment.** This would also facilitate:
   - more structured (and regular) horizon scanning
   - wider dissemination of research programme outputs and impact
   - development of more strategic relationships with other funders/stakeholders to maximise potential for early identification of collaborative working/funding and sourcing of high-quality proposals, particularly in new/complex areas.
   - reassurance to FSA with respect to the quality of the programme, its future direction and that the necessary oversight is in place.

vi. ***Tendering process for contracted research***: **The FSA should consider complementary methods to develop tender calls relating to more complex areas of future research e.g. sandpits.** Guidance on the tender process should be developed for the non-commercial sector, emphasising the differences in process of FSA-funded contracted research and that funded through UKRI. A data management plan should be required as part of the tender process, to incorporate details on data flow to facilitate compliance with GDPR and associated legislation.

vii. ***Maximising impact***: Improving the internal and external visibility of previous and existing outputs and impacts will help the FSA build a compelling narrative to inform future business case planning. **A clear process should be developed for data sharing, allowing monitoring by FSA of secondary outputs and impacts. Monitoring of impact should be an integral part of the regular external reviews, which ceased in 2012 due to resource constraints.**

viii. **In response to this report, the Science Council requests that**:

- The FSA develop a strategy setting out how it will address the recommendations from the WG, with clear responsibilities, timelines and resources.

- The FSA provides a report to the FSA Board and then the Science Council on implementation of the WG's recommendations, within 12 months of submission of the WG's final report.

2. INTRODUCTION

The FSA is reviewing its strategy on FHS to ensure it has access to the best available science and evidence and to support the delivery of appropriate and effective actions to improve food safety food safety and widen consumer choice. The FSA has an established policy team and science-led research programme on food allergy and intolerance.

The FSA Board set the direction for the Executive to develop "a comprehensive strategic framework [for food hypersensitivity] for discussion with the Board in autumn 2019. This will include a review of the evidence base and the development of appropriate outcome measures through which to judge progress."

In May 2019, the Science Council was asked by the Board to:

i. Consider and advise on future research priorities and direction in respect to FHS.
ii. Conduct a review of the science and evidence base for addressing FHS
iii. Advise on the role the FSA should play to enhancing scientific knowledge.

At the Science Council's open plenary meeting of June 2019, it was agreed to establish a new Working Group 5 to assess FHS issues in response to the request from the FSA. The Working Group presented and agreed a workplan at the Science Council open meeting in December 2019 (Annex 1):

i. A review into the previous and current Research programme (WG5.1), including an assessment of best practice in undertaking such a programme (WG5.3).

ii. A Priority Setting Exercise, inspired by the James Lind Alliance Priority Setting Partnerships with wide stakeholder input, to identify research priorities for the FSA in the area of FHS (WG5.2), and a review of the existing literature associated with these identified priorities (WG5.4).

iii. Identification of future priorities in a 5 to 15-year timeframe through a horizon scanning activity. (WG5.5)

This interim report describes the process and outputs from the review into the previous and current Research programme (WG5.1) and associated best practice (WG5.3).

3. BACKGROUND

The Food Allergy and Intolerance Research (FAIR) programme was originally established in 1994 by what was then the Ministry of Agriculture, Fisheries and Food, to investigate the causes and mechanisms of severe food allergy, with emphasis on peanut allergy, in order to reduce the incidence and severity.

Since then, the programme has evolved, informed by external programme reviews in 2003, 2008 and 2012, to incorporate funding of research projects to address other areas of policy needs, including the prevalence of food allergy in the UK, identifying risk factors associated with the development of food allergy, and research to review evidence on thresholds for sensitivity to gluten in the context of coeliac disease.

The FAIR Programme has to date encompassed over 60 contracted research projects. (Annex 2). The below table shows the budget of the FAIR project since its formation in 1995.

Table 1 - FAIR Spending on Projects since 1995 to present. Figures reported are not reflective of the financial year spends but of total project costs, allocated into time brackets based on their start date.

Projects Starting	Amount Spent (£)	Total Spend (£)
1995-1999	3,829,268.96	3,829,268.96
2000-2004	5,077,840.98	8,907,109.94
2005-2009	5,045,752.95	13,952,862.90
2010-2014	2,558,103.00	16,510,965.90
2015-2019	2,791,822.66	19,302,788.60
2020 - Onwards	644,739	£19,947,527.60

4. METHODOLOGY

The Working Group contracted an independent expert, Alisdair Wotherspoon, to complete a desk study on the previous allergy and intolerance research programme reviews in 2008 and 2012. The desk study sought to identify areas of good practice, and the impact of the programme and implementation of any recommendations into current and future activities. A checklist was developed to support this process (Annex 3). In parallel, a number of interviews were held with FSA staff to examine areas of best practice in the commissioning and execution of the current Research Programme. The FSA staff interviewed are listed in Annex 4.

Further discussions were held with Prof Ian Kimber, the External Programme Advisor to the FAIR Programme, on 12th May 2020. Reported findings were then discussed at thee Science Council workshops, on 24th June, 8th and 23rd July 2020.

5. SUMMARY OF FINDINGS

The WG assessed the following 5 areas:

i. Strategy and Direction
ii. Management and Governance
iii. Research Outputs
iv. Uptake and Impact
v. Review and learning mechanisms

For each area, we outline:

- main observations and elements of good practice
- recommendations for improvement and what they should achieve
- where appropriate, suggestions for how to take recommendations forward.

5.1 Strategy and Direction

Observations

The previous strategy set by the FAIR programme had received broad stakeholder input, with regular reviews at annual stakeholder meetings and quinquennial external reviews. These processes ensured wide stakeholder engagement, although consumer input was mostly limited to Patient Representative organisations and there also appears to be a lack of representation from smaller businesses. These reviews were comprehensive and served to provide regular monitoring of the FAIR programme. The programme was also informed by a number of systematic reviews in addition to the commissioning of original research. Significantly, regular stakeholder and external reviews ceased after 2012. This appears to have been a consequence of resource limitations, which adversely impacted upon capacity/ capability within FSA, and a shift of emphasis of the research programme from food allergy in infants and children to adults.

Subsequently, the FSA has undergone internal restructure to separate “policy” from “research”. The Science Council view this as a positive development, as this has facilitated a “science push” to inform and challenge policy via an iterative process. However, the interviews gave the impression that there seems to be more “science push” than “policy pull” in determining research directions. The optimum would be a balance between the two. While the Science Council were reassured that there are frequent exchanges between policy and research, it was not entirely clear as to how this now occurs in the area of FHS.

There was evidence of prioritisation of projects, and review of the need for ongoing projects, at Divisional/FSA level as part of business/budget planning, with linkage back to FSA strategic aims.

More recently, there has been recognition of a need to increase the focus on social science-based research to help understand target groups etc. and inform policy/legislation/implementation. There is a current focus on the prevalence of characteristics of adult food allergy, though we note a clear mandate from the FSA Board that this should not be at the expense of other research into FHS (FSA Board meeting, March 2017).

The establishment of the Food Hypersensitivity Programme Board is a positive development to facilitate coordination of activities in the area of FHS, ensure appropriate resourcing and give visibility to activities across the Agency. A new Head of Food Hypersensitivity strategy and policy was appointed in spring 2020, along with a new Programme Manager, and they have been reviewing the Programme structure and ways of working of the Programme Board. In order to maximise the available opportunities, we would highlight the following:

- The Programme Board is focused on delivery of strategic outputs and thus has limited visibility of the scientific pipeline. It would be helpful to consider how the Programme Board can have an awareness of future science direction, while not becoming engrossed in detail.
- The Programme Board is being refocused as a smaller, delivery-oriented Board, with a consequential reduction in membership. There is currently a single, senior representative from the Science, Evidence and Research Directorate (SERD), in line with the more focused approach going forward. However, it is very important that the SERD representative is well supported and able to represent the full range of scientific disciplines. The Programme Board should consider how best to involve the right scientific expertise at the right time, in addition to that lead representative. This will reduce the risk of relying too heavily on a single individual and creating a 'bottleneck' in communication, and mitigate against the possibility that the Programme Board misses key expertise during important discussions.
- There are important opportunities to improve the wider awareness within the FSA about the Food Hypersensitivity Programme. There is an awareness that discussions at the Programme Board may directly impact the work of SERD, but less knowledge of the Terms of Reference for the Programme Board, and how decisions, directions and actions from meetings are communicated. Improving communication, both to and from the Programme Board, is likely to empower those members of FSA staff who work in the FHS arena.

It was not clear to the Science Council as to what the FSA categorises as research.

- In addition to the FAIR programme, there are additional activities that are managed under social science (e.g. Food & You) and as part of evidence gathering and synthesis that may not be considered or classified as “research”.
- There is a strong framework of evaluation for externally-commissioned research, but the value of “non-research” data generated routinely within FSA (such as data pertaining to food incidents/root-cause analysis and commercial contracts) may not be fully recognised, nor a similar process of evaluation applied. This may be due to a lack of infrastructure, resource and/or capacity to process and analyse these data in a timely manner. A small investment might enable more rapid analysis of incidents data, deliver improvements in incident prevention, and facilitate real-time analysis in incidents epidemiology as changes to food supply chains occur in the future.
- A more joined-up coordinated approach to data collection and analysis in the area of FHS is an opportunity.

The success of the previous/existing FAIR programme has very much depended on “lynchpin” individuals. The programme has been adversely impacted by internal staff changes, which risks loss of institutional knowledge. To a large extent, the role of the external programme advisor has mitigated against this, however in doing so this role has itself become a “lynchpin”.

- The availability of the external programme advisor has also provided a high value of expert insight in its own right, in addition to helping the FSA to see interconnections between activities and the wider FHS arena. However, the success of role has much to do with the knowledge and approach of the current incumbent. The absence of a succession plan and current dependence on a single individual is a significant risk.

The Science Council were left with the impression that while the FAIR programme had delivered an integrated and proactive research programme, the value of other FSA activities within the FHS arena (but outside FAIR, such as data from Food and You and incidents) has not always been considered as FHS data which can be integrated with other research to inform FSA policy. The 2008/2012 annual reviews included an element of horizon scanning, but it was not always clear as to how these

inputs evolved into ideas which could then be taken forward into an appropriate research response.

There was limited evidence of input from SACs, whose role has historically been more of responding to specific questions rather than a general review of science and contributing to research inception. This may reflect a lack of awareness as to how food hypersensitivity comes within the remit of some of the SACs. The interface with other relevant organisations such as Scientific Advisory Committee on Nutrition (SACN) and Public Health England (PHE) has been important in the area of FHS, but previous initiatives to establish foundations for joint working have had limited success. In part, this is due to different approaches to risk assessment: PHE takes primarily an epidemiological-based approach, while the FSA approach is more focussed on risk to individuals.

Attempts to co-fund projects with other funders, with the FSA funding applied research and Research Councils funding the underlying basic research, have had limited success. A joint workshop was held in 2009 with the MRC to identify opportunities for synergy between basic immunology and food allergy research, which resulted in a subsequent joint FSA/MRC call. However, the focus of the MRC tends to be on immunological mechanisms, and therefore no applicants to this joint call received the level of priority needed to achieve funding under MRC assessment. The differences in funding models and procurement routes employed by Research Councils versus FSA are not always easily compatible, and may have contributed to the gap in research funding identified by the House of Lords Science and Technology Committee in 2007 for food allergy in the UK with respect to translational research.

Recommendations

- The FSA Board has previously agreed (at its March 2017 meeting) that the FSA should continue to fund research that does not necessary contribute directly to protecting consumers, but identifies interventions that can prevent the development of FHS at a population level. There is a clear gap in funding translational research into FHS in the UK; while it may well be appropriate for

the FSA to fund public health research in FHS, this should now be clarified in 2020 in terms of cross-governmental ARIs. The FSA should investigate whether the restructuring of Research Councils into UKRI provides a fresh opportunity for greater cooperation and research integration, with visibility of FHS research across government agencies. This may be facilitated by building access to expertise within FSA, such as that relating to epidemiology and public health. This is relevant to FHS, since routinely-collected health data relating to FHS might be able to inform FSA policy.

- The role of the Food Hypersensitivity Programme Board is to provide "policy pull", in which case consideration needs to be given as to which part(s) of the FSA should provide "science push" and filter the science which is reviewed by the Programme Board. The FSA should consider the formation of a panel, perhaps alongside the Programme Board, to fulfil this role – something which is currently done informally, and as a result might not be sustainable. This panel could also assist in the improving the visibility of the Programme Board across the FSA, and protect institutional knowledge relating to FHS science. Ensuring a more robust means of capturing key outcomes and learnings from FHS research activities can then inform strategy and direction. There may be merit in inviting additional science representation to the Programme Board on an ad hoc basis. The Programme Board has financial oversight over the FSA budget on FHS (including research) and should use this to coordinate and facilitate sufficient resourcing to promote future FSA research activities.
- The FSA should consider investing in additional resource to maximise its own internal data (e.g. post-incident analyses) and avoid the current situation where operational and analysis roles are combined (and the former takes priority at the expense of the latter). Such data are likely to be a significant benefit to the FSA as food supply chains evolve in the future. This has been previously flagged by the Science Council as a recommendation to the FSA Board (Science Council Report on Capability and Assurance, July 2018).
- There is a critical reliance on "lynchpin" individuals which must be addressed through succession planning, handover checklists and strategies to capture and protect institutional knowledge. The role of the External Programme Adviser has reduced but not mitigated this risk; plans must be made for the

eventuality where no future suitable candidate can be identified. There may be a role for SAC members (or individuals on the Register of Specialists) to provide input as an alternative strategy. There is need for oversight in order to ensure availability of appropriate expertise on the Register.

- The traditional role of the SACs in responding to specific requests for scientific advice is now being complemented by horizon scanning activities. Wider input from SACS into the FHS research agenda should be facilitated and welcomed.
- The FSA should reinstate regular stakeholder reviews (e.g. biennial) and quinquennial external reviews to ensure ongoing evolution and monitoring of the FHS research environment, including horizon scanning and wider dissemination of research programme outputs. This should be complemented by broader consumer representation (not just patient groups) and inclusion of SMEs.

5.2. Management and Governance

Observations

The previous external reviews (2008, 2012) both indicated that overall, the FAIR programme was managed well and had resulted in outputs of good to high quality with associated impacts. There was evidence of regular, structured management of the programme internally, identifying issues and actions and seeking wider advice (both internal and external) if needed (something which has continued to the present). Later reviews also highlighted any lessons to learn/issues which the FSA needed to consider. Overall, the programme had provided value for money. The Science Council agreed with this assessment, although the lack of external review since 2012 is concerning. The creation of the Food Hypersensitivity Programme Board can now address internal oversight, but an element of external review is advisable.

The Programme has benefited from having an External Programme Adviser, who has provided continuity despite significant staff changes and loss of institutional memory over time. However, the oversight and governance of this role is unclear, particularly following cessation of the external reviews after 2012.

The transition from small to larger, more complex projects (such as the TRACE Peanut study) revealed that the management time needed had been underestimated. Central to this was not the presence of unforeseen risks, but rather, an underestimation of the magnitude and complexity of those risks. There has been a positive shift towards an emphasis on project management within the contracted study teams, but matching this with better support for project management for FSA staff would have helped.

- The FAIR programme has adopted a project risk register which is a positive development.
- It was not clear whether the FSA's Programme Management Office (PMO) provides a central repository of support for staff with Project Management duties to tap into, and how this might be accessed.
- More complex projects were supported through Independent Trial Steering Committees and Data Monitoring committees. However, the remit of these committees was not always clearly defined at the outset, which led to later difficulties.
- The commissioning of more complex clinical trials also raises the need to ensure that the data generated adheres to the quality assurance dictated by Good Clinical Practice (GCP). We were unable to identify documented processes in place, nor were decisions taken on data curation always transparent and minuted.

The current FAIR Programme manager is responsible for 11 different projects, in addition to their day-to-day operational responsibilities. While policy is now separate from science within FSA, there are clear benefits to maintaining a flexible approach to having shared staff overseeing both Programme management and day-to-day operational (science) matters, in order to maximise synergies. Adequate staff resourcing would be needed for this to happen without compromising either activity.

Some academic contractors perceive projects as grants rather than contracted research with strict management expectations (deliverables, timelines, milestones).

This should be flagged up strongly in advance, perhaps in a more uniform and transparent manner across the FSA.

- The previous programme had frequently involved dialogue with external stakeholders to formulate the remit of tender calls (perhaps the best example of this was for the Adult Food Allergy call). However, we were unable to assess how that advice then impacted on the final tender specification.
- A number of interviewees mentioned that separate guidance for tendering for research contracts by the non-commercial sector might be helpful.
- We were unable to identify how learning from risk mitigation with the previous and existing programme had been captured.

A recent concern has been the impact of GDPR on FSA-commissioned research, which has in turn impacted on study timelines, recruitment and feasibility. Whilst there has been learning as a result of this, the issue is likely to remain problematic and this needs to be built into the commissioning of future research.

Recommendations

- The FSA should consider re-instituting a mechanism for external review. We would recommend annual or biennial peer-review, and quinquennial independent external review, as this formula has previously been very successful.
- Project (and contract) management is very time consuming, and currently, there appears to be little internal support for this. Although the Programme Management Office has some resources available, this does not seem to extend to active input to FSA staff, and likewise, there appears to be a low level of awareness in terms of the support the PMO can offer. The FSA would benefit from creating a central research knowledge and expertise core, which could provide tools and expertise on project management, literature searches, etc. A register of experts might be a useful contribution when external input is required e.g. trouble-shooting. There is significant dependence on the good will of FSA staff, and it is important to support staff with formal processes and to build resilience.
- The FSA should consider complementary methods to develop tender calls e.g. sandpits. This could be done at the same time as the annual/biennial workshops.

- Separate guidance should be developed for the non-commercial (e.g. academic) sector in terms of submitting tenders for research to the FSA. This should include a requirement for a data management plan as part of the tendering process, to incorporate details on data flow to facilitate compliance with GDPR and associated legislation. FSA should consider confirming tenders only after a formal Data Protection Impact Assessment (DPIA) has been completed by the host institution, to avoid delays downstream.
- In conjunction with other Governmental Agencies, FSA should continue to request the Information Commissioner's Office to provide clarity on the application of GDPR and associated legislation on research activities.
- When external independent advisors are used e.g. for Data Monitoring committees, the remits of these committees should be established up-front in writing, using a committee charter and in line with UKRI guidance. FSA should follow established guidance (e.g. from NIHR, UKRI) in drawing up these charters, and should ensure that membership of Data Monitoring committees is fully independent (this may require recruitment of some members from other scientific disciplines).
- Where there are differences of scientific opinion between external independent advisors, FSA should have a clearly documented process to reach a final conclusion. This may require the involvement of international experts to advise the FSA.
- The FSA should consider introducing a common standard for data management and curation to be applied to all research activities across the FSA, based on based on existing external standards.
- The FSA should consider ways of capturing best practice in terms of project management and governance, and the implementation of regular reviews of lessons learnt, as a continuous cycle.

5.3. Outputs

Observations

It is clear that the FAIR programme has generated extensive outputs which have had far-reaching impacts on both clinical practice, science and policy. Final reports are subject to external peer review and extensive internal FSA review. Most completed

projects have a final report and/or published papers on the FSA website, together with public-facing summaries of the project background results/implications, although we note that for most studies the website does not provide details as to what study data are available, and how these can be accessed. The quinquennial programme reviews are also available on the FSA website, which helped ensure a level of transparency and a synthesis of programme evolution over time.

In a number of projects, a significant number of indirect outputs were likely, but it was not clear as to how these are currently being captured. The availability of raw data seems to be a principle that underpins much of the research undertaken by FSA, but in the case of the FAIR programme, it is not clear as to how these data might be accessed, and under what circumstances. In addition, it was not clear as to whether the FSA is able to capture the *impact* these indirect outputs have.

A summary of the FAIR programme was published in the peer-review literature in 2010 (Toxicology 2010;278(3):319-25. doi: 10.1016/j.tox.2010.08.007) as a means of communicating outputs to the scientific community. This was viewed as an important means of communicating the success of the FAIR programme to the scientific community. However, no subsequent follow-on manuscripts have been submitted; this might enhance recognition by the international allergy community of the crucial role the FSA has had in facilitating a paradigm-shift in strategies to prevent food allergy, away from strict allergen avoidance towards tolerance induction through primary prevention.

Recommendations

- There would be significant benefit to improving the internal and external visibility of outputs and telling a more complete story of how research has evolved from inception to outputs and impact. FSA should consider a public-facing communications strategy (similar to that used for the CSA report) published every 3-5 years. A follow-up to the 2010 summary published in the peer-review literature should also be encouraged.

- The FSA website is a very useful repository of material with respect to the FAIR programme, however some re-organisation and restructuring would improve accessibility, particularly with respect to archival material.
- A more transparent policy on how FSA-funded data are made available to other researchers would be very welcome. It might be best for this to occur through a controlled-access data repository, rather than the main FSA website, as this would allow FSA to capture impact too.

5.4. Uptake and Impact

Observations

There was evidence in both Programme Reviews of the impact of the FAIR programme on policy/actions, at a national and international level. The external review panels considered the impacts to be “impressive” considering the size of budget. These included:

- Data informing COT to update/revise advice on infant feeding
- Informing the UK position at CODEX and EFSA
- Changes in advice in the UK management of coeliac disease
- Evidence to assist the ASA in upholding complaints
- Input to a House of Lords Science and Technology Committee on food allergies in the UK.

However, little formal evaluation has occurred since 2012, despite some very significant outputs of international impact since then. For example, the FSA has had a key convenor role in discussions and the commissioning of research which has radically impacted on infant feeding advice and food allergy prevention, but there is under-recognition of this in the public and medical/scientific arena.

It was unclear as to how impact is communicated internally, and success celebrated/lessons learned. Addressing this would help demonstrate how research/science can impact on day-to-day FSA activities, and assist the FSA in placing science at the centre of its work.

It was also unclear as to how external impact is monitored by FSA. There are a number of potential means of doing so, which tap into existing FSA activities, e.g.

through the Food and You survey, by monitoring data relating to prevalence of incidents, confidence in labelling, industry compliance etc.

Recommendations

- The FSA should consider re-instituting a mechanism for external review, to include an assessment of impact and to allow for longer-term monitoring for both projects and the overall programme.
- There is an invaluable opportunity to increase awareness of the impact of prior FSA research, which should be communicated both internally and externally. FSA should develop a communication strategy for the research it commissions, which is able to provide a longitudinal view of impact as well as highlighting current activity.
- We would encourage FSA to develop an Agency-wide approach to data sharing and use of data repositories to monitor secondary outputs and resulting impact.
- We did not identify any clarity over who within FSA has responsibility to review policy impact, and the need to refresh the evidence-base, although a number of interviewees referenced HM Treasury Green Book which recommends 5-yearly cycles. Within the FSA's FHS work, it would make sense for this role to be taken on internally by the Food Hypersensitivity Programme Board. Consideration needs to be given as to the need for external review to provide the necessary assurance of this process.
- Thought also needs to be given to capturing recommendations which are often made as part of Research project reporting, to ensure where appropriate these can inform both future research and policy.

5.5. Review and Learning Mechanisms

Observations

Review and learning are a key part of research governance. Previous Programme reviews (2008 and 2012) demonstrated clear best practice in terms of project and programme review (both internally and peer-review at the Annual workshops), and summaries relating to process and likely future themes. The reviews also incorporated an assessment of scientific quality and productivity, delivery against aims and impacts on policy. There was some evidence of outcomes and recommendations from the External Review Panels feeding into future planning, both

in terms of research topics and management. However, external review has mostly been lacking since 2012 when the annual stakeholder meetings stopped.

Previous external reviews have identified the clear importance of assessing the scientific merit of a project independently of potential policy relevance and/or project delivery. This was partly addressed between 2008 and 2012, but there is no clear evidence of external review and oversight since then. Thus, the FSA has missed out on opportunities to be at the centre of FHS research in the UK, undertake horizon-scanning activities, enlist the academic community to assist with dissemination and maintain external oversight as part of governance. Furthermore, this may have contributed to a perception of a narrowing in focus in the current FAIR programme to adult food allergy.

Recommendations

- The FSA should consider re-instituting a mechanism for external review, as highlighted above, not just to capture best practice, but also monitor its success in applying this learning to future work.

6. GENERAL CONCLUSIONS

Consistent with the 2008 and 2012 reviews, the FAIR programme has overall been well-managed, and influential with significant policy implications at a national and international level. These successes are clearly linked to the dedication of FSA staff and contractors – something which should be acknowledged by the FSA Board – and the extensive and frequent level of stakeholder engagement evident until 2012. However, after this time, it has been difficult to track how specific issues have evolved over time and been dealt with, and whether best practice has been captured. The previous annual meetings provided a key "convenor" role, a "value-added" output which has been under-estimated. The Science Council consider the annual meetings were invaluable to the success of the programme, with considerable indirect benefits to the UK Food Allergy research community, and also helped with dissemination and a greater awareness of the FSA's work in this area.

The science team within FSA has undergone a restructuring and will benefit from support to enable optimal impact on future policy in the area of FHS. Previous success has very much depended on lynchpin individuals; more support is needed to build resilience so that success is not dependent on the good-will of a few individuals. There is a need to consider how best to coordinate research into FHS, assuring quality, sharing outputs and translating diverse research activities currently conducted in different parts of the organisation. The formation of the Food Hypersensitivity Programme Board is a positive step, but science representation to the Board is limited. There is clearly a role for SERD to input into future strategy and ensure that the FSA maximises its use of routinely-collected data, avoiding the trap of acute day-to-day activities adversely impacting on science capability. A short project to assess expertise, capacity and succession plans in this area of work is necessary. It would be useful to use a RACI/RAPID perspective to help organize workflows.

Our review gave the impression that there seems to be more "science push" than "policy pull" in determining research directions. The optimum would be a balance between the two. The FSA now has an opportunity to articulate the means by which

impacts are hoped to be realised, for example through a direct pathway to policy impact. However, a second pathway to impact – at risk of being overlooked – is the use of insights to drive research questions and research investment as a means to sustain the credibility, authority and reputation of the agency. The FSA should therefore implement a pipeline of projects (perhaps with recourse to the FSA's Strategic Evidence Fund), supported by appropriate scientific horizon scanning.

7. LIST OF ANNEXES

1. Working Group 5 – Overview.
2. Published projects under the FAIR research programme.
3. WG5.1 and 5.3 Programme Review Checklist
4. List of interviewees
5. Case Studies:
    i. EAT (End Allergies Together) Study
    ii. Prevalence of Adult Food Allergy (PAFA)
    iii. Survey of allergen labelling and allergen content of processed foods