



Report on a

**Review of the Food Standards Agency Approvals Programme
for Meat Establishments in the United Kingdom**

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1. Background

1.1 Introduction

- 1.1.1 This report outlines the findings of a review of the Food Standards Agency (FSA) meat establishment approval programme for the United Kingdom, which was carried out from October to December 2008. The review was requested by the Chief Executive (CE) following a FSA Board discussion of a paper at its September 2008 meeting on the programme of approval of meat plants¹. The Board discussed the progress of the approval programme and noted *'the lower percentage level of first time full approval in England'* compared to other devolved countries. This resulted in an action point for the CE to *'conduct further investigation and report back in October'*.
- 1.1.2 At the October Board meeting, the CE's report included observations that accounted for the variance in first visit approval levels. The CE concluded with confirmation that: *'this apparent inconsistency of approach [in particular, between England and Wales] is incompatible with our own principles and will now be the subject of further review by the Executive Board'*.
- 1.1.3 Following the October Board meeting, a review was initiated by Audit and Policy Branch (Strategy and Resources Group). David Clarke, Chief Executive of Assured Food Standards was brought into the review team to provide independent oversight of the process.
- 1.1.4 The review considered the approval policies and the implementation of the approvals programme in the UK. It included interviews with relevant FSA officials with policy responsibility for approvals, members of the Approvals Project Board (APB), officials responsible for management and delivery of the approvals programme, a representative group of veterinarians carrying out approvals, official veterinarians (OVs) carrying out official controls at visited establishments, Meat Hygiene Service (MHS) officials and food business operators (FBOs). In addition the review team carried out verification visits to approved establishments, which were selected to provide a range of premises categories, types, sizes and geographical locations. File reviews covered records of approvals in approximately 10% of relevant establishments in Scotland, Wales and Northern Ireland, and 5% in England.
- 1.1.5 The report contains a number of recommendations and observations, balanced with identified areas of effective implementation practice.

¹ Approval of Meat Plants (FSA 08/09/06) – 17 September 2008

1.2 Approval Process

- 1.2.1 Establishments that are engaged in the slaughter, cutting and processing of meat are required to be approved in accordance with Regulation No. (EC) 853/2004 which came into force on 1 January 2006. The responsibility for approval of establishments in the UK is split between the FSA and Local Authorities (LAs). The Agency is responsible for the approval of slaughterhouses, meat cutting establishments, ex-catering butchers (approved as cutting plants), game handling establishments and meat processing establishments that are co-located with these establishments. LAs are responsible for approving stand-alone meat products and minced meat and meat preparations establishments.
- 1.2.2 Approval can only be granted if an establishment complies with hygiene and operational requirements of relevant legislation. These include the general principles of food safety, Regulation (EC) No 178/2002², Regulation 852/2004³ on the hygiene of food stuffs and the specific rules for food of animal origin under Regulation (EC) No 853/2004⁴. On receipt of an application for approval, the Agency is required under Regulation (EC) No 882/2004⁵ to carry out an assessment visit to verify if the establishment complies with relevant legislation. It shall then grant full approval if it complies fully with requirements, may grant conditional approval if it partially complies with requirements, or a refusal to approve.
- 1.2.3 Regulation (EC) No 853/2004 provided for plants that were licensed on 31 December 2005 under the former fresh meat legislation⁶, to continue operating pending approval under the new approvals regime. Where such plants were refused approval, they could appeal the decision and continue to operate until the process was exhausted.
- 1.2.4 In England, approvals are granted by the Veterinary Director on the recommendations of Veterinary Meat Hygiene Advisers (VMHAs) employed by the Agency's Meat Hygiene and Veterinary Division (MHVD). In Scotland, Wales and Northern Ireland (NI) approvals are granted by the respective FSA Directors on the recommendation of veterinarians of the relevant Agriculture and Rural Affairs Departments⁷ (SGRD, WAD, DARD).

² Regulation (EC) No 178/2002 of the European Parliament and Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

³ Regulation (EC) No 852/2004 of the European Parliament and Council of 29 April 2004 on the hygiene of foodstuffs

⁴ Regulation (EC) No 853/2004 of the European Parliament and Council of 29 April 2004 laying down specific rules for food of animal origin

⁵ Regulation (EC) No 882/2004 of the European Parliament and Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

⁶ Until 31 December 2005, meat establishments were licensed under The Fresh Meat (Hygiene and Inspection) Regulations 1995.

⁷ In Scotland and Wales the veterinarians are employed by the Scottish Government Rural Directorate (SGRD) and Welsh Agriculture Department (WAD) respectively. In NI they are employed by the Department for Agriculture and Rural Development (DARD)

- 1.2.5 In anticipation of the current hygiene regulations, an Approval Projects Board (APB) was established in May 2005. The remit of the APB was to develop policies, to plan and oversee the approval of all previously licensed premises, newly opened establishments and premises subject to approval for the first time in the UK. Responsibility for managing delivery of the programme in each country was devolved to managers in the relevant FSA offices. As of January 2006, there were 828 establishments requiring approval in England, 112 establishments in Scotland, 69 in Wales and 58 in NI.
- 1.2.6 With a view to ensuring consistency in the delivery of the approval programme, an Approvals Strategy⁸ was developed by the APB in 2005 and was adopted for implementation by all UK countries. The strategy included a priorities framework for approval assessment visits. In addition it contained general information on the approval process and guidance to field officers on approval procedures and decisions following assessment visits.

1.3 Review of the FSA Approvals Programme

Terms of Reference (ToR) of the Review

1.3.1 The ToR of the review were to:

- (i) Establish the current status of meat establishments approval programmes in England, Scotland, Wales and NI;
- (ii) Review the approval assessment processes, protocols and criteria in England, Scotland, Wales and NI and identify any significant differences;
- (iii) Investigate the apparent inconsistencies between England, Scotland, Wales and NI in the numbers of establishments that were granted full approval at the first approval visit;
- (iv) Identify significant issues in relation to each of the above and make recommendations, as appropriate.

1.4 Methodology and Practical Review Process

1.4.1 The review approaches and methods used to obtain information and evidence included:

- Review of policies, procedures, guidance and instructions on approval;
- Review of approval assessment protocols, records and associated documents;
- Review of the management of the approval process including resource deployment and approaches to prioritisation;

⁸ Post 1 January 2006 Approvals Strategy for UK Meat Establishments.

- Review records of approvals granted, conditional approvals and refusals;
- Key informant and stakeholder interviews;
- Meetings;
- Verification visits to approved or conditionally approved establishments.

1.4.2 The practical review of the policy and implementation issues in relation to approvals (within the context of the ToR) was undertaken through key informant and stakeholder interviews, review of relevant records and documents, and verification visits to a selection of approved establishments in England and the devolved countries. Further details of the practical review process are detailed at Annex 1.

2. EXECUTIVE SUMMARY

- 2.1 The review findings support the conclusion that the differences in the ratio of staff resources pro rata to establishments was a significant factor in the disparities between England and other countries in relation to approvals at first visit. The review did not find evidence to suggest that the higher percentage of first time approvals in Wales was due to differences in approval assessment methodology or standards.
- 2.2 The relatively higher staff ratios in Scotland, Wales and Northern Ireland allowed for more appraisal visits prior to January 2006. Appraisal visits helped to bring about improvements in plants, with the result that generally higher numbers were subsequently approved at first visit in countries where higher proportions of plants received visits.
- 2.3 The availability of grant funding in Wales allowed for improvements and for new plants to be built. Equivalent funding was not available in England. In addition, the historically higher base standards in Northern Ireland and Scotland, where most previously licensed establishments were geared towards the export trade, contributed to the higher numbers of approval at first visit, compared to England.
- 2.4 Whilst weaknesses in the management and supervision of field staff had an impact on the effective delivery of the programme in England, in terms of the overall progress of the approval programme, differing staffing resources was the major factor in the delayed completion of the programme in England. Some Agency officials acknowledged that the available resources could have also been managed better.
- 2.5 An Approvals Project Board (APB) was established in 2005 to develop and oversee the implementation of a UK wide strategy and policy on approvals. The review established that there were no major differences between the countries in the broad implementation of approvals strategy and policy. However, there were variations among the UK countries in the effectiveness of management arrangements, and at the operational level, in the practical implementation of some aspects of the programme.
- 2.6 Quarterly APB meetings provided valuable opportunities to review progress and for the exchange of views and experiences among those responsible for approvals policies and those managing the approvals programmes. Although communication at higher levels was generally effective, improvements were required in relation to communication with field delivery staff.
- 2.7 At country level, communication between relevant FSA offices, field officials and other stakeholders in Wales, Northern Ireland and Scotland tended to be better managed and more effective than in England, however, the process lacked an effective central communication strategy. A strategy for communication would help to ensure effective information flow, facilitate partnership working, improve relations with field staff, key

- delivery partners and other stakeholders; and reduce the potential for inconsistency.
- 2.8 A priorities framework developed as part of the approvals strategy was intended to ensure consistency in the implementation of approvals. New start up establishments were given the highest priority for approval visits, followed by slaughterhouses, cutting plants and game handling establishments, on the basis of risk. However, no guidance was provided on the criteria and methodology to be used to risk assess plants. As a result, it was not possible to establish whether the framework was consistently used in planning and identifying priority visits.
- 2.9 In the early stages of the programme, attempts were made in all countries to carry out approvals visits in accordance with the priorities framework. In practice, and as the programme progressed, decisions on the selection of plants for visits were increasingly made by individual field officials. It appeared that decisions on the prioritisation of establishments for approval visits were often based primarily on logistical practicalities rather than consideration of the public health risk.
- 2.10 After January 2006 the APB introduced a number of unplanned changes to priorities which required countries to shift staff resources to new priority areas. The changes in priorities undermined the effective implementation of the programme to varying degrees in all countries. In England, this had a disproportionately greater impact on delivery due to the higher numbers of establishments subject to approval and the relatively lower staff resource.
- 2.11 There was some evidence of ongoing monitoring of programme progress and outcomes but the review found no evidence of policies or supporting procedures for monitoring of approvals assessments carried out by field staff. Enhanced arrangements for the routine monitoring of approvals, including the consistency, and appropriateness of decisions made by VMHAs with appropriate management oversight have been recommended.
- 2.12 The review found some evidence of measures and approaches to aid consistency of approval assessments and decisions by VMHAs/VAs. However, consistency was only partially achieved in practice. The arrangements in place tended to be ad hoc or informal, and were not part of a formal qualitative internal monitoring scheme. Some examples of inconsistent and inappropriate approval assessments and decisions were identified during the course of the review. However, it was not possible to establish the extent to which these could have influenced the outcome of approval visits, because of the limited scope of the review and the relatively small sample of interviews, file reviews and verification visits undertaken. A more strategic framework for ensuring consistency is therefore needed.

3. Summary of Recommendations and Observations

Recommendations	
Paragraph	
4.3.18	A strategy for communication is recommended. This would help to ensure effective information flow, facilitate partnership working, improve relations with field staff, key delivery partners and other stakeholders; and reduce the potential for inconsistency.
4.4.25	It is recommended that the priorities framework should be reviewed to ensure that high risk and/or poor performing establishments are prioritised for approval visits during the remainder of the programme to complete the outstanding approvals.
5.3.12	Management and the APB should take a more strategic approach to dealing with consistency issues and should formalise and implement appropriate measures to ensure that consistency in approval assessments and decisions is maintained.
5.3.13	Further guidance should be issued to VMHAs to ensure a consistent approach to approval assessments and decisions. These should include specific guidelines on partnership-working with the MHS. The use of the OV in establishments as 'eyes and ears' should be emphasised, as an additional resource to monitor progress on outstanding issues arising from assessments visits to facilitate more efficient completion of approval process.
5.3.14	Measures to ensure consistency of approval assessments and decisions should be formalised and implemented - outcomes from these initiatives should be monitored.
5.3.16	All key documents used in the approval process, including the approval assessment aide-memoire, should be centrally developed, officially authorised and issued; their use should be controlled and subject to internal monitoring.
5.4.9	The Agency should develop appropriate UK-wide internal monitoring policies and procedures and implement routine monitoring arrangements covering the qualitative and quantitative aspects of approvals undertaken by field staff in all 4 countries.
5.4.10	The management and reporting lines between relevant FSA countries and VMHAs/VAs should be improved and strengthened.
5.5.9	As part of the current database development project, the MHVD should consider options for digital storage of approved establishments records in a shared central system that is accessible to all relevant FSA and MHS staff in all countries.

5.6.8	During the remaining period of the programme in England, the APB should consider carrying out scheduled reviews of all aspects of the programme. Any significant issues that are identified should be addressed to ensure the programme remains on course for completion by the target date.
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Observations

Paragraph	
4.2.16	The resources needed to meet the demands of the approval programme, particularly in England, should have been kept under review, and any deficiencies addressed, at all stages.
4.4.25	The rationale for decisions on material changes to priorities should have been subject to more formal scrutiny and agreement by the APB and those responsible for managing delivery of the approvals programme.
5.1.14	A Project initiation document (PID) should have been developed and agreed at the commencement of the project, with clear project goals, scope, project organisation, business case, constraints and budgets.
5.2.18	The APB should have played an overarching role with responsibility for delivery of the programme in the UK, and in that capacity should have appointed a project manager at AVH with clear reporting lines and overall responsibility for management of the programme. The role should have included responsibility for liaison with the Board and devolved administrations, managing programme implementation in England, supervision of field staff and management responsibility for support staff.

DETAILED FINDINGS

4.0 Approvals Policy and Strategy

4.1 *Policy and Strategy*

4.1.1 In preparation for the transition to the new EU hygiene Regulations, which required relevant establishments to be approved under Regulation (EC) No 853/2004, an Approvals Project Board (APB) was established in March 2005. The Board was constituted of members from FSA, the Meat Hygiene Service (MHS), Department for the Environment Food and Rural Affairs (Defra), Small Business Service (SBS), Small Business Council (SBC), and Welsh Assembly Government (WAG), with overall responsibility for developing approvals policies and overseeing the programme to 're-approve' all relevant establishments in the UK.

4.1.2 The APB met quarterly and these meetings were the principal fora for review of policies, review of progress with the programme and discussion of approvals implementation issues. The approvals policies were amended in several areas during the life of the programme, mainly due to changing priorities and other factors. Administrative changes at the FSA/Aviation House (AVH) also had some influence on approvals policy. The frequent policy changes, which were regarded as 'reactive rather than proactive' were a source of frustration to affected FSA staff and stakeholders.

4.1.3 An Approvals Strategy⁹ was developed by the Agency in 2005. The strategy was endorsed and adopted for implementation by all 4 UK countries. It provided general information on the approval process and guidance to field officers, including:

- a priority framework for approvals visits;
- guidance on approvals procedures including the application process and scheduling of assessment visits;
- guidance on the circumstances where conditional approval, full approval or refusal were appropriate;
- guidance on enforcement action, and;
- a consideration of resource issues.

4.1.4 The priorities framework in the approvals strategy set out a hierarchy of priorities to be used when implementing the approvals programme. It identified the various establishment types to ensure that new and high risk establishments were scheduled for approval ahead of other types of premises.

4.1.5 During preparations for the approvals programme in 2005, the APB agreed that each country should implement a programme of 'appraisal visits' to selected premises. Appraisal visits were initially offered to all plants. The premises subsequently selected were those most likely to

⁹ 'Post 1 January 2006 Approvals Strategy for UK Meat Establishments'

experience difficulty in meeting the requirements for approval, with a view to carrying out preliminary appraisals and to provide advice on compliance with approval requirements under the new Hygiene Regulations.

- 4.1.6 The review established that there were no significant inconsistencies between the countries in the broad implementation of approvals policy and strategy. There were, however, differences in some operational and practical implementation aspects of the programme, mostly to take account of local priorities. For example, the approach taken in the selection of premises for appraisal visits tended to vary from country to country. The high numbers of game handling establishments (GHEs) in Scotland also meant that policy implementation was modified to reflect their priority in approving these establishments.
- 4.1.7 There was a general consensus among the FSA in England, Wales, Scotland and NI that the strategy and policy development process had been largely participatory and had provided opportunities for the exchange of views which ensured the incorporation of priority issues from each country.
- 4.1.8 Whilst the APB was widely regarded as a useful policy-making and coordinating body, there was some criticism that the Board's project planning was not sufficiently robust because it had not identified key project milestones, and there was no programme budget.

4.2 Resource Issues

4.2.1 Significant disparities were noted between the 4 UK countries in relation to the staff resources available to carry out approvals. The staff resources available in each year since January 2006, and the ratios of staff to establishments are set out in the following table:

	England (FTE)	Scotland (FTE)	Wales (FTE)	Northern Ireland (FTE)
2006	7.1	3	1	3
2007	7.23	2.5	1	2
2008	5.81	1.3	0.75	N/A
Number of establishments requiring approval at the commencement of the project in January 2006	828	112	69	58
Ratio of staff to establishments at the commencement of the programme in January 2006	1:117	1:37	1:69	1:19

Table 1: A comparison of the number of full time equivalent (FTE) VMHAs and the numbers of establishments requiring approval in each country.

4.2.2 The APB experienced difficulties in estimating the magnitude of the demands of the approval programme and the staff resource required to complete it within the planned timeframe. This was in part due to delays in setting a policy to identify, at an early stage, the types of establishments that should be exempted from approval and the time taken to collate accurate data from Local Authorities (LAs) on the total numbers of catering butchers that were expected to be transferred from LA to FSA responsibility.

4.2.3 Nevertheless, using the available information, the APB was able to make some estimates of staff resources required in all UK countries and the expected timescale to complete the approvals programme. This was included in the approvals strategy. The strategy also highlighted resource shortages as an area of concern in England.

4.2.4 Wales and Northern Ireland were able to complete their approval projects with their existing resources, by the middle of 2008. In Scotland, having secured programme funding from within their budget, FSAS was able to negotiate with the Scottish Government and the State Veterinary Service for 2 additional VAs, the programme was completed in mid 2008.

4.2.5 England was not able to secure additional resources at the beginning of the programme, although requests for additional staff had been made following an assessment of resource needs. The programme plan and targets were based on the expected demands of the programme and

assumptions that resource needs would be adequately addressed. The main consequence of the failure to secure adequate resources was the significant delay in completing the programme in England.

England

- 4.2.6 In England, it was clear from the outset that staff resources were not sufficient to complete the programme within the estimated timeframe. Some external recruitment was subsequently carried out to fill vacancies created by 2 VMHAs who had been redeployed to another Division. Although there were initial recruitment difficulties, 2 vets were eventually recruited from the MHS, but it took time for them to be trained and to settle into their roles.
- 4.2.7 Although staffing levels were relatively lower in England compared to the other countries, it was acknowledged by the management of the MHVD that the available resources could have been managed better and more efficiently utilised to ensure the bulk of approvals was completed within the timeframe achieved by the other countries.
- 4.2.8 Managers responsible for the project in England also confirmed that there were significant variations in performance among VMHAs in terms of the numbers of visits and approvals completed in each year. This was not previously addressed because, until 2008, there were no formal procedures in place for systematic monitoring of VMHA performance.
- 4.2.9 The original plan in England was to undertake 2/3 approval visits per week but this was not monitored and no specific performance targets were set for VMHAs, who were generally 'left to organise themselves'.
- 4.2.10 To reduce the backlog of establishments requiring approval, the MHS was assigned a number of cutting plant (CP) approval visits, and an external contractor was employed in mid 2008 to carry out advisory visits at catering butchers (CB) establishments. It was intended that the advisory visits would reduce the number of VMHA visits required to secure approval. However, at the time of the review, it was not possible to establish if the advisory visits had achieved this outcome.

Scotland

- 4.2.11 In Scotland, FSAS prioritised programme funding from their budget, and having estimated the staff resources required, worked with the Scottish Government to secure the veterinary resources required to complete the approvals project. The 2 additional full-time VA posts, seconded from SVS (now Animal Health Agency) under a service level agreement, were engaged to carry out approvals on behalf of the FSAS. In addition to the pre-existing VA working in Scotland, these resources were considered to be adequate for the project. A proportion of the time of another veterinarian was also available to provide general veterinary advice on policy matters.

4.2.12 FSAS did not set specific work targets for VAs but each were left to operate in their own areas with general supervisory overview provided by FSA Scotland. Regular staff meetings, also involving MHS Area Managers, were used to monitor progress of the project.

Wales

4.2.13 Wales employed only 1 VHMA, which was considered to be adequate. The VMHA was responsible for prioritising his work in liaison with FSAW colleagues, and all approvals were completed by November 2008.

Northern Ireland

4.2.14 NI employed 3 Divisional Veterinary Officers (DVO) to complete the approvals programme. NI was divided into 3 geographical regions, with each DVO responsible for the completion of the programme in their area.

4.2.15 Although DARD officials had other duties in addition to approvals, the small number of premises per official allowed them to complete the programme within the estimated time frame.

<i>Observation:</i>	
4.2.16	The resources needed to meet the demands of the approval programme, particularly in England, should have been kept under review, and any deficiencies addressed, at all stages.

4.3 Communication and Liaison

- 4.3.1 The review looked at the effectiveness of communication channels and the liaison arrangements between the countries on approval issues. Particular emphasis was placed on the aspects of communication and liaison that were essential for the efficient delivery of the approval programme and for facilitating effective partnership working.
- 4.3.2 At country level, there was a general consensus that the liaison arrangements established in 2005 in preparation for the approval programme had generally worked well. The important role played by the APB in facilitating liaison among countries and sustaining communication channels between the FSA and key stakeholders was highlighted in discussions. These arrangements were instrumental in ensuring coherence in the adoption of approvals strategy and policies that were developed by the APB.
- 4.3.3 At the implementation level the review found that communications at higher management levels, particularly among those responsible for approvals policy development and management of the approvals programme, was generally effective. The APB meeting minutes and other evidence of ongoing communication on approvals issues, confirmed that there were no significant concerns at this level.
- 4.3.4 A number of issues were identified in relation to the communication of policies with the field staff responsible for implementing the approvals programme. One of the methods used to address this was to establish a link between policy and implementation. This was through an initiative to invite a VMHA representative to attend APB meetings and to provide feedback to field colleagues in all 4 countries. The general view was that this was a useful initiative which could have been more effective with better higher level support. In addition, the APB and FSA managers in individual countries issued circulars from time to time for communicating policies and implementation guidance to field officers.
- 4.3.5 Despite the efforts to ensure the smooth flow of communication between managers and implementation teams, variations were noted across countries in the effectiveness of communication channels between management and field staff. The review confirmed the general view that communication between managers and field staff tended to be more effective in the devolved countries.
- 4.3.6 Among field staff responsible for carrying out approvals, there was also agreement that communication channels established to discuss technical issues and facilitate information sharing had generally been effective. The quarterly VMHA meetings were the main fora for discussion of approvals implementation issues. The usefulness of the meetings was acknowledged by most, although there was some feeling that they could have been better structured and more focussed on approvals implementation issues. Feedback from interviews also confirmed that field

staff used email and telephone links extensively to maintain contact and to share experiences.

- 4.3.7 The review also assessed the effectiveness of communication channels between the FSA and the MHS as a key partner in the implementation of official controls in approved establishments. The main finding was that the effectiveness of communication links tended to vary from country to country. In common with other aspects of the approval programme, the relatively large numbers of establishments and the more extensive MHS presence meant that most of the concerns about poor communication were voiced by OVs, contract OV suppliers and MHS officials in England. This is an area for improvement because information held by MHS staff on premises and related enforcement issues is essential in informing approval decisions.

Case Study 1 – A FBO’s view of the approval process

“After the 1st and 2nd visits we had some tense meetings with the VMHA. He raised several relevant issues that we needed to address in order to get full approval. Although we did not disagree with the issues raised, the MHS had never mentioned any of these to us. We ended up following the FSA advice and investing £250,000 to improve the establishment. We eventually gained full approval at the 3rd visit.

Although we thought the VMHA was a bit “tough”, with time we have come to accept that this investment has helped our operational and hygienic standards”.

England

- 4.3.8 In England there were some examples of excellent working relations and effective communication between VMHAs and MHS staff. However it was evident that many OVs, contract OVs, and MHS officials were not satisfied that some VMHA colleagues in England were seeking to work in partnership with them. VMHAs also sometimes experienced difficulties in engaging MHS staff. It was acknowledged by senior managers responsible for the approvals programme at FSA-AVH that the interface between the VMHAs and the MHS was an important area that needed to be addressed.
- 4.3.9 It was also noted that in England it was not always practical for VMHAs to arrange joint visits with MHS officials because of the much higher numbers of premises and the logistical challenges of arranging such visits.
- 4.3.10 Some VMHAs in England were also concerned about the poor communication channels with AVH, which was sometimes caused by problems with the IT and email systems, particularly in areas with poor telephone reception. It was also suggested that the problems were exacerbated by administrative deficiencies.

Wales

- 4.3.11 In Wales, where only 1 VMHA was involved in carrying out approvals, it was generally easier to maintain effective communication. FSAW believed

that the relatively smaller numbers of establishments also made it possible for them to maintain closer working relationships with the MHS and food business operators (FBOs). Attempts were made to ensure that approval visits in Wales were carried out in the presence of MHS officials and that decisions on approval were discussed with them.

- 4.3.12 Verification visits by the review team to 2 approved establishments in Wales yielded mixed results. At one of the visits it was confirmed that working relations and communication between VMHAs, the FBO, contract OVs and the MHS were excellent. However, at the second verification visit, it was claimed that the OV was not informed about assessment visits or asked to provide any information about the establishment. It was suggested that the VMHA might have made a different decision if the OV had been on hand to clarify relevant issues.

Northern Ireland

- 4.3.13 In Northern Ireland, 3 Department of Agriculture and Rural Development (DARD) staff were involved in carrying out approvals. With the relatively small number of personnel it was possible to maintain effective communication lines and working relationships. Regular meetings (every 4-6 weeks) between FSANI and DARD representatives were held to review progress and to discuss issues related to the approvals programme.

- 4.3.14 Strong views were expressed to the review team about the lack of inclusion of Northern Ireland viewpoints in decisions made at FSA-AVH. However, FSA officials at AVH believed that Northern Ireland colleagues had been slow on many occasions to respond to requests for information and to consultations.

Scotland

- 4.3.15 In Scotland, FSAS organised quarterly meetings with Veterinary Advisers (VAs), the deputy Chief Veterinary Officer (CVO) and MHS officials to review progress of approvals, to discuss approval visit programmes and to ensure consistency. The meetings also considered any changes in priorities and any other significant issues in relation to approvals.

- 4.3.16 Regular contact was also maintained with FBOs, OVs and contractors. The review team was informed that the VAs made sure that OVs were always present and participated in approval visits to slaughterhouses. OVs were also invited to attend opening and closing meetings. Feedback from VAs indicated that they always received cooperation and support from MHS staff.

- 4.3.17 FBOs interviewed during verification visits confirmed that they were generally satisfied with the outcome of approval visits and also found the VAs to be helpful and accessible.

Recommendation

4.3.18	A strategy for communication is recommended. This would help to ensure effective information flow, facilitate partnership working, improve relations with field staff, key delivery partners and other stakeholders; and reduce the potential for inconsistency.
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4.4 **Prioritisation of Approval Visits**

4.4.1 The team reviewed the implementation of APB policy on the prioritisation of establishments for approval assessment visits in all UK countries, to establish how effectively this had been undertaken and to identify related issues that had any influence on the delivery of the programme.

4.4.2 At the planning stages of the approval programme, the APB agreed a provisional timeframe to approve all relevant establishments in England and Wales within 2.2 years i.e. by April 2008. In Scotland, time scales were not set until additional resources for approvals were agreed within FSAS. NI estimated that the project would be completed within 12 months. These preliminary targets were subsequently reviewed several times during the life of the project. The most recent target was to complete the programme in England by the end of September 2009.

4.4.3 The prioritisation of establishments for approval assessment visits was based on the priorities framework in the approvals strategy. The framework identified new and start-up plants as the highest priorities for approval assessment. Next were slaughterhouses, cutting plants and game handling establishments, which were to be prioritised on the basis of their audit risk ratings¹⁰. Exceptions to these priorities were made to allow inclusion of the following;

- the early approval of plants known to have serious deficiencies;
- establishments with histories of consistent compliance with regulations, and;
- low throughput plants requiring approval in order to access export markets.

4.4.4 During the course of the programme, the APB introduced a number of changes to priorities. The review confirmed the general view in all the countries (held by those responsible for management of the approvals programme, field staff responsible for implementing the programme and other stakeholders) that progress of the approvals programme had suffered as a result of unexpected changes in priorities. Some of the changes were said to have been introduced in response to external factors (for example prioritisation of game handling establishments approvals in response to demands by the trade for early approval, and the need to respond to issues arising from the Wales E coli Inquiry), in addition to internal factors.

4.4.5 The most significant changes in priorities included the requirement introduced in the autumn of 2006 to grant conditional approval to all game handling establishments by September 2007, and in the summer of 2007 when all catering butchers (CBs) were prioritised for approval visits.

¹⁰ The risk assessment system operated as part of FBO audits by OVs. It is used to determine the frequency of audit at each establishment.

- 4.4.6 The unexpected changes required countries to shift staff resources to the new priority areas and this impacted on the delivery of the approvals programmes by varying degrees in all 4 countries. The impact was greatest in England, because it has the highest number of establishments requiring approval and had relatively fewer staff resources than the other countries. Scotland also experienced some challenges in complying with changes because of the disproportionately higher numbers of GHEs and CBs in the country.
- 4.4.7 The prioritisation of all relevant establishments within the approval programme could not be finalised pending policy agreement on the types of establishment that were subject to exemption from the requirement for approval.
- 4.4.8 The review established that there was no consensus among the countries on the rationale for the changes to priorities for approval, particularly when new priorities were introduced at later stages of the approvals programme. For example, some countries did not agree with the rationale for prioritising CBs, on the grounds that, apart from those handling both raw and ready to eat products, they were not a 'high risk' priority.
- 4.4.9 The review team also noted that, whereas early attempts were made in all countries in to carry out approvals visits in accordance with the priorities framework, in practice the final decision on prioritisation was, in most cases, made at the discretion of VMHAs/VAs and DVOs. The veterinarians frequently made decisions based on travel practicalities, their knowledge of establishments in the area, findings from appraisal visits and in some cases information obtained from the MHS. It was not possible to establish conclusively the extent to which public health risk was considered and, if it was considered, how this was weighted against other factors.
- 4.4.10 There was general agreement among those interviewed that subsequent reviews of priorities had undermined the effective implementation of the initial prioritisation framework
- 4.4.11 The prioritisation framework required slaughterhouses (SHs), cutting plants (CPs) and GHEs to be prioritised in accordance with risk, but did not set out a clear basis for risk assessment to ensure identification and prioritisation of establishments with serious structural and operational deficiencies.
- 4.4.12 Lists of establishments selected in accordance with the guidance on priorities were provided by some countries but there was no evidence to confirm that these were consistently used in planning and identifying priority visits.
- 4.4.13 The prioritisation strategy also included a number of 'exceptions' and allowed scope for discretionary decisions on priorities by field staff. It also emphasised the need to respond to requests from FBOs for early

assessments for commercial reasons. These exceptions made it difficult to achieve consistency in the planning and scheduling of approval visits, and probably diluted the effectiveness of the priorities framework as a risk-based system for prioritisation.

4.4.14 Attempts were also made at an early stage, starting from 2004, to identify establishments that were likely to experience difficulties in achieving full approval. Hygiene Assessment System (HAS)¹¹ scores, local knowledge and MHS information were used to identify these premises. Three categories of establishments, A, B and C, were initially identified¹². These premises were offered an advisory/appraisal visit in order to allow adequate opportunity to rectify deficiencies prior to the official assessment visits from January 2006. The table at Annex 2 details the numbers of establishments offered approval visits and those that were visited. Following advisory/appraisal visits, establishments were re-categorised as A, B, C and D¹³.

England

4.4.15 In England 144 out of the 828 premises (18%) subject to approval received an appraisal visit. In addition, requests for appraisal visits were received from more than 50 premises which were not initially included among those to be visited.

4.4.16 At the start of the approvals programme in January 2006, attempts were made to ensure that priorities for the approvals programme were set out in accordance with the original strategy. However, as the programme evolved, there were changes to priorities when it was realised that establishments with a poor history of compliance were not being adequately prioritised. It was also necessary to introduce changes upon realisation that the original framework was not sufficiently risk-based to ensure that prioritisation decisions were based on food safety risk.

4.4.17 Another problem recognised in England and acknowledged by managers responsible for the approval programme, was the difficulties experienced in ensuring that VMHAs visited poor performing establishments, which should have been priorities for early assessment visits. VMHAs sometimes deferred visits to such establishments on the grounds that the MHS needed to address all issues and contraventions before the assessment visit.

¹¹ Hygiene Assessment System scores – a scoring system for slaughterhouses based on a detailed evaluation of structural and operational hygiene of establishments and to monitor hygiene on different premises to provide a means of comparing standards and to identify and encourage improvements. Premises were given a score out of 100. The system was replaced in January 2006.

¹² A category were those likely to take longer to address the deficiencies, while C category were likely to correct deficiencies in the shortest time.

¹³ A = major deficiencies, B = lesser deficiencies, C = minor deficiencies, and D = mostly compliant

Wales

4.4.18 In Wales the strategy was to carry out appraisal visits to plants that were most likely to fail to secure approval. These were selected in consultation with the MHS and taking into account the results of audit risk assessments. A total of 32 that had been identified as likely to experience difficulty in securing approval were offered appraisal visits. By the end of the appraisals programme 25 premises initially identified had received appraisal visits and 7 declined the offer.

4.4.19 It was recognised that Wales was able to get around the country more quickly and to reach stakeholders more easily because there were fewer establishments requiring approval, which were spread over a smaller geographical area than England. The high percentage of establishments that had received appraisal visits also meant that many establishments had been able to carry out improvements, which improved the likelihood of early approval. The FSAW relied on the VMHA's experience and knowledge of establishments to prioritise visits. A deliberate decision was also made not to visit premises that officials knew were likely to be closed because they could not meet the requirements for approval.

Scotland

4.4.20 In Scotland the initial target to complete the approvals project by March 2008, was largely achieved. It was confirmed that Scotland initially worked in accordance with the prioritisation guidance in the approvals strategy, but later this changed when UK-wide policies were amended. Of greatest significance to Scotland was the period when GHEs became a priority, as Scotland had a disproportionately high number of GHEs compared to the other countries.

4.4.21 In 2005, 33 plants were visited with the aim of identifying those that were likely to experience difficulties in meeting approval requirements, these were then prioritised for appraisal visits. Ultimately it was possible with the available resources at the time to carry out appraisal visits to 25% of establishments in Scotland.

4.4.22 It was also recognised in Scotland that priority was not always given to poorly complying establishments because, in some cases, the larger plants requested to be assessed early as a matter of priority for 'commercial reasons'.

4.4.23 FSAS officials believed that the VAs employed to carry out approvals in Scotland had very good contact with OVs and generally considered the issues raised by OVs when prioritising establishments for approval visits.

Northern Ireland

4.4.24 In Northern Ireland, officers endeavoured to schedule approval visits in accordance with the priorities framework. However, it was acknowledged that it was not always possible to adhere fully to the framework as they needed to exercise some flexibility to take account of logistics.

Recommendation:

4.4.25	It is recommended that the priorities framework continues to be reviewed, as necessary, to ensure that high risk and/or poor performing establishments are prioritised for approval visits during the remainder of the programme to complete the outstanding approvals.
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Observation:

4.4.26	The rationale for decisions on material changes to priorities should have been subject to more formal scrutiny and agreement by the APB and those responsible for managing delivery of the approvals programme.
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5.0 Programme Implementation

5.1 Programme Planning

- 5.1.1 At the start of the approvals programme in January 2006, all UK countries had planned to schedule approvals visits in accordance with the priorities framework in the approvals strategy. However, over time it became necessary to adjust the scheduling of assessment visits to take account of local priorities and changes in UK-wide priorities.
- 5.1.2 The review confirmed that in practice the scheduling of visits was mostly determined by VMHAs/VAs. The levels of central input into scheduling decisions varied from country to country. The approaches used by VMHAs/VAs to prioritise visits were not consistent and in some cases were not risk-based.
- 5.1.3 The review team learned that the approval programme did not always proceed according to plan because of new or previously unforeseen factors, and changing national priorities. With hindsight it is possible to say that the implementation of the programme suffered as a result of inadequate forecasting and limited planning for contingencies during the project planning phase.

England

- 5.1.4 In England approval visit plans were initially developed in accordance with the priorities framework. Once a priority list had been produced, premises were allocated geographically to VMHAs. The initial plan was for each VMHA to carry out 2 to 3 approval visits per week. 224 establishment visits were undertaken in 2005 prior to the commencement of the approval programme.
- 5.1.5 All VMHAs in England were aware of the priorities framework and at the beginning of the project had sought to work in accordance with the framework. However, it was widely acknowledged by VMHAs that they did not always follow the priorities in all cases, with the majority of establishments being identified and targeted based on individual VMHA's experience, local knowledge and sometimes geographical location. Although attempts were made to give priority to premises considered to be 'high risk', this was considered to be 'not always possible or practical'.

Wales

- 5.1.6 During the initial planning stages the FSAW and the MHS discussed ways of encouraging FBOs to invest and bring their plants to full compliance with approval standards. In all cases FBOs were given as much time as necessary to carry out improvements, on condition that the MHS were satisfied that public health risks were being effectively managed.

5.1.7 In consultation with the VMHA and in liaison with the MHS, a decision was made by the FSAW not to visit plants that had been identified during appraisal visits as not complying with requirements and therefore likely to be refused approval.

5.1.8 The planning and scheduling of of approvals visits in Wales was the responsibility of the VMHA in liaison with FSAW colleagues who also provided administrative support. This was thought to be the most appropriate approach to the planning and delivery of the project objectives because the VMHA had long experience and extensive personal knowledge of establishments in the country. In the process of scheduling visits, the VMHA identified the following categories of establishments in discussion with FSAW and MHS colleagues:

- establishments that were unlikely to meet the requirements for approval;
- establishments expected to close because they could not be brought up to the standards required for approval;
- establishments that required extensive improvement works to achieve approval, and;
- establishments that were close together and could be grouped together for visits on an 'area' basis.

5.1.9 The FSAW advised operators of establishments that required extensive works of the opportunity to apply for grant funding from the Welsh Assembly Government. Applications were in some cases referred by the Welsh Development Agency (WDA) to the VMHA for comment and advice. In Wales it was thought that the availability of grant funding was instrumental in helping many FBOs to improve their premises and subsequently to secure full approval. The FSAW also believed that grant funding was a significant contributory factor in the numbers of establishments that achieved full approval at the first visit.

5.1.10 Visits to other categories of premises were scheduled in accordance with a priority list agreed by the VMHA and FSAW, although this was not strictly followed. In many cases visits were carried out on an area or regional basis, for reasons of practicality and logistics.

Scotland

5.1.11 In Scotland, most of the approvals project planning was completed before January 2006. An approvals visit programme was then developed on a spreadsheet containing a list of all plants, from which a priority list was produced, and agreed with VAs. The list was also used to monitor progress of the approval programme and reviewed as necessary.

5.1.12 Establishments were initially categorised into those that were likely to achieve approval requirements and those that were not likely to do so. A priority list of visits was then developed on the basis of risk. However this was not always adhered to in many cases where selection and scheduling

was on the basis of practicality, geographical location and other considerations.

Northern Ireland

5.1.13 In Northern Ireland the programme was completed by August 2007. It was planned that each DVO would carry out at least 2 visits per week to allow sufficient time to produce the reports and if needed to attend other duties. It was also agreed at the planning stage that the plant OV should be present at all approval visits, but in practice this was not always possible. In addition, more than half of the approval visits were 'joint visits' attended by more than 1 DVO.

<i>Observation:</i>	
5.1.14	A Project initiation document (PID) should have been developed and agreed at the commencement of the project, with clear project goals, scope, project organisation, business case, constraints and budgets.

5.2 Programme Management and Administration

- 5.2.1 Whilst the APB had UK-wide responsibility for developing policy and overseeing the delivery of the approvals programme, responsibility for management and administration of approvals projects was devolved to the FSA offices in each country.
- 5.2.2 The review team noted some variations in the effectiveness of management and administration of approvals in the 4 countries. At the level of the APB the review found a lack of clarity of roles and accountability for programme outcomes. As a result there was no clear responsibility for setting programme targets and for addressing any variance.
- 5.2.3 It was also apparent that the APB did not take effective control and direction of the approvals system to ensure that policies and targets set were adhered to. There was a lack of effective higher level coordination to support the management of the programmes at individual country level. It was established that no ToR had been drawn up at the inception of the APB so its roles and responsibilities were not clearly set out. It was suggested that the APB should have played an overarching oversight role, and in that capacity, should have appointed a project manager with responsibility for coordinating the management of approvals delivery.
- 5.2.4 Within individual countries the effectiveness of management and administration arrangements varied depending on the magnitude of the task. In all countries, VMHAs and VAs were generally left to organise their own work programme with minimal supervision from the FSA. In smaller countries with fewer establishments, FSA managers could maintain closer contact and more effective control of programme implementation by field officers.
- 5.2.5 The effective delivery of programme goals depended on strong coordination of approvals policy development and implementation. The essential linkages between the APB and officials responsible for managing programmes, and also with field staff carrying out approvals, were found to be weak and therefore did not always ensure effective translation of policies to the desired outcomes.
- 5.2.6 The weaknesses in overall control of the approvals system was illustrated by the suggestion that FBOs were able to use the conditional approval and appeal provisions to buy time. It was also suggested that VMHA's in some areas may have delayed the granting of full approval in order to prolong the programme. Where management controls were ineffective, these weaknesses could not be identified or effectively addressed at an early stage.

England

- 5.2.7 In England the Veterinary Director had overall management responsibility for the approvals programme until his departure in October 2007. This created a management vacuum that undermined the effective management of the approvals programme until the Deputy Veterinary Director assumed responsibility for approvals. A VMHA was asked to take an overall lead in the co-ordination of the approvals programme, but the initiative had limited success because he had no management responsibilities and the arrangement was never formalised.
- 5.2.8 In addition the management of the VMHAs carrying out approvals in England had always been challenging for managers. It was frequently stated that VMHAs operated with little or no central supervision or control. Until 2008, few measurable outcome and output targets were set for VMHAs and there was no formal monitoring of performance against targets.
- 5.2.9 Reductions in field officer and administrative staff resource levels in England also resulted in the loss of administrative support to out stationed VMHA's. In addition, there was a lack of clarity of roles and responsibilities among managers and administration staff responsible for over-seeing and supporting the implementation of the approval programme.

Wales

- 5.2.10 With only 1 VMHA to carry out approvals in Wales, the process was generally easier to manage and to provide the necessary administrative support and back-up. A system for monitoring progress of approvals, which would flag up any outstanding or overdue visits was set up for the purpose.
- 5.2.11 However, it was also not always possible to carry out visits in accordance with priorities because logistical considerations sometimes determined which visits were made. For example, if the VMHA was in a particular part of the country he would endeavour to visit nearby establishments.
- 5.2.12 Overall, Wales was able to achieve the targets set by the APB, and completed the approvals programme by November 2008. It is likely that the high proportion of appraisal visits carried out in 2005 enabled more establishments in Wales to be approved first time, compared to other countries where more visits were required after-January 2006 to achieve full approval.
- 5.2.13 A number of VMHAs were of the opinion that the approval programme was much better managed and more focussed in Wales than in England. Comments identified better and more effective communication and liaison between FSAW, and the MHS, better planning and foresight in carrying out appraisal visits.

Scotland

5.2.14 In Scotland, day to day management of the approval programme was the responsibility of a small team at FSAS. The team discussed and agreed work programmes with VAs and the deputy CVO on a quarterly basis. Once programmes were agreed VAs were left to manage their individual workloads, with FSAS monitoring progress against agreed work plans.

5.2.15 The VAs interviewed confirmed that they had received excellent and consistent administrative support from FSAS, including notification of FBOs and the timely completion of related administrative formalities.

Northern Ireland

5.2.16 In NI, the FSA was responsible for the production of the approval letters based on the DVO recommendations and DARD provided the remainder of the administrative support. Management of the programme rested with FSANI, but the day to day running of the programme rested with DARD.

5.2.17 There was close liaison between DARD and FSA officials during the implementation of the programme, with meetings every 4 to 6 weeks to discuss programme delivery issues.

Observation:

5.2.18	The APB should have played an overarching role with responsibility for overseeing delivery of the programme in the UK, and in that capacity should have appointed a project manager at AVH with clear reporting lines and overall responsibility for management of the programme. The role should have included responsibility for liaison with the Board and devolved administrations, managing programme implementation in England, supervision of field staff and management responsibility for support staff.
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5.3 **Consistency of Approval Assessments and Decisions**

- 5.3.1 Consistency in the application of policies and the implementation of approvals requirements is clearly essential for confidence and the integrity of the approval system. Responsibility for ensuring consistency in the approval process was considered by interviewees at regional FSA offices and at Aviation House to lie with the Meat Hygiene and Veterinary Division (MHVD) and the APB. The review considered the consistency of approval assessments and decisions, and consistency between countries in the management and delivery of approvals.
- 5.3.2 Consistency issues were explored with members of the APB, senior managers of the MHVD, managers responsible for managing approvals programmes in all 4 countries, field staff responsible for carrying out approvals, MHS field staff and managers and meat industry stakeholders. This was done through interviews, reviews of file records of approval assessments visits, decisions following assessment visits, and verification visits to 10 approved and conditionally approved establishments.
- 5.3.3 During the life of the programme consistency issues were discussed at APB and VMHA meetings with the aim of identifying areas for improvement. However, a member of the APB thought that the body had not always acted promptly or effectively to address consistency issues raised at meetings.
- 5.3.4 The review found evidence of a number of measures in place to ensure consistency in dealing with approval applications by VMHAs/VAs. These included measures to ensure consistency in the approval assessment visits, records of approval assessment and post-assessment decisions. Examples of the main approaches include:
- a) *Quarterly VMHA meetings:* These meetings were attended by UK VMHA/VAs and MHS and FSA officials and veterinarians involved in approvals. The main focus of the meetings was to discuss technical and practical issues in relation to approvals and to review progress of the programme;
 - b) *Shadow/joint visits:* A number of ad hoc arrangements for shadow and joint approval visits were made by VMHAs and VAs in England and Scotland. The shadowing arrangements were particularly beneficial to new VAs who had been seconded to FSAS and those appointed from the MHS. In Northern Ireland joint visits were made in at least 50% of approval visits. The review noted that some joint visits were arranged in Scotland at establishments that were known to be 'difficult';
 - c) *Use of an Approval Assessment Checklist (aide memoire):* This was used to ensure that assessments consistently covered relevant requirements of the legislation. The use of the checklist helped to achieve some level of consistency but some areas for improvement were identified;

- d) *Email circulation list and telephone forums*: Outside of the quarterly VMHA meetings, an Email discussion forum and telephone links were used to maintain contact, to share information and to discuss technical approvals issues;
- e) *VMHA training*: All VMHAs/VAs attended a HACCP course in 2004. This was aimed at improving consistency in the assessment and auditing of HACCP-based food safety management systems. A number of H 1, 2 & 3¹⁴ courses and seminars for FSA and MHS veterinarians were run by the FSA and MHS prior to the coming into force of the new hygiene regulations.

5.3.5 The review team found these measures to be useful for sharing of information and experiences, however arrangements needed to be developed further to address the following areas:

- There were no procedures in place to check and monitor if consistency was being achieved in practice. Other than for refusals, VMHA decisions were not subject to scrutiny or management oversight. Recommendations to address this deficiency and to strengthen internal monitoring arrangements have been made under the section on Internal Monitoring;
- Some existing measures, for example the use of an assessment checklist/aide memoire, the email circulation lists and the shadow/joint visits have tended to be ad hoc arrangements undertaken at the initiative of individual field officers, rather than as part of a formal qualitative monitoring scheme;
- It was suggested by some VMHAs that their meetings needed to be better structured to ensure more focus on technical issues. Liaison with the APB also needed to be strengthened in order to facilitate more joined-up working with the APB.

5.3.6 Overall, the review found that whereas some attempts were made to promote consistency, in practice this had only been partially achieved because of a lack of effective arrangements for independent scrutiny of approval assessments, decisions and associated reports and records.

5.3.7 Examples of positive feedback, citing good practice, were counter-balanced by examples where the approvals system needed to be more consistent. An example of positive feedback was received from a FBO who had interacted with a number of different VMHAs and had found the advice and issues raised to be generally consistent. VMHAs and VAs were also of the view that the use of the checklist had helped to ensure more consistency in assessing compliance with requirements.

¹⁴ H 1, 2 & 3 refer to Regulations (EC) No 852/2004, 853/2004 and 854/2004 respectively.

5.3.8 Some evidence of inconsistency in the assessment and determination of approvals was obtained from interviews, file reviews and verification visits to establishments. However, it should be emphasised that these findings were based on the limited file reviews, interviews and verification checks that were possible during the review. This was an insufficient evidence base to establish if the issues identified could have significantly influenced the outcome of the approvals programme. The issues raised are important nevertheless and require appropriate management interventions to reduce the potential for inconsistency in the future.

5.3.9 The issues identified in relation to the consistency of approval assessments and decisions included:

- Variations between veterinarians in approval decisions on similar issues, particularly in relation to cases where HACCP compliance was raised;
- Inconsistency in the interpretation of approval requirements;
- Lack of consistency in prioritisation of establishments for approval visits;
- Inconsistencies in utilising MHS input during the approval process;
- Inconsistent use of the approval assessment checklist/aide memoire;
- Variations in approval reports and letters to FBOs;
- Lack of measures to minimise the potential for gold-plating of approval requirements.

5.3.10 The use of approval assessment checklists/aides-memoire is important for ensuring that the checks carried out consistently covered relevant requirements of the legislation. The aide memoire were adapted, initially for personal use by a VMHA from an earlier version that was based on the old hygiene regulations. It was first circulated to other VMHAs in 2006. Subsequent revisions continued to be circulated without central control. It was learned that its suitability was not assessed or validated centrally by the management of the MHVD or the APB. There were suggestions that there was a reluctance to circulate the document to managers and other stakeholders.

5.3.11 Although most VMHAs found the document to be useful for consistency, other VMHAs and some senior managers of the MHVD were of the view that it did not adequately reflect the risk basis of the new regulations. It was also suggested that some of the compliance criteria included in the checks had the potential to 'gold-plate' the regulations. The latter point was supported by findings from some of the file reviews undertaken during the review. It was also suggested that the assessment criteria in the aide-memoire needed to be more consistent with the 'Meat Industry Guide'.

<i>Recommendations:</i>	
5.3.12	Management and the APB should take a more strategic approach to dealing with consistency issues and should formalise and implement appropriate measures to ensure that consistency in approval assessments and decisions is maintained.
5.3.13	Further guidance should be issued to VMHAs to ensure a consistent approach to approval assessments and decisions. These should include specific guidelines on partnership-working with the MHS. The use of the OV in establishments as 'eyes and ears' should be emphasised, as an additional resource to monitor progress on outstanding issues arising from assessments visits to facilitate more efficient completion of approval process.
5.3.15	Measures to ensure consistency of approval assessments and decisions should be formalised and implemented - outcomes from these initiatives should be monitored.
5.3.16	All documents used in the approval process, including the approval assessment aide-memoire, should be centrally developed, officially authorised and issued; and their use should be controlled and subject to appropriate internal monitoring.

Case Study 2 – FBO's experience of the approval process

"The approval visit was not very useful because we disagreed with the VMHA's interpretation of the HACCP requirement and his reason for deciding not to grant full approval at the first visit – on the grounds that our HACCP had not been reviewed and that he disagreed with the CCPs we had identified. This was despite the fact that our HACCP system was found to be satisfactory by the BRC and major supermarket customers who frequently audited us. We were even more disappointed that on the second visit it was decided to extend the conditional approval, although we had verified, validated and reviewed the HACCP system. After 6 months with a conditional approval, we decided to amend the HACCP system in accordance with the VMHA's wishes because we did not want to risk a refusal.

Whilst we do not agree with the decision not to grant us approval at the first visit, we found some aspects of the process to be useful. Perhaps there should have been more sharing of experiences to help us improve how to do things and there should have been better forward planning. Apart from this, the VMHA was quite approachable and has given us useful advice at various stages of the development of our business at this site".

5.4 Internal Monitoring of Approvals Programme

- 5.4.1 The review considered the management policies for monitoring the approvals programme and the arrangements for management monitoring of approvals delivery by field staff, including the qualitative and quantitative aspects of approvals work.
- 5.4.2 Overall, the review team concluded that there was no clear policy or supporting procedures for monitoring the approvals assessments carried out by field staff although there was some monitoring of overall progress of the programme. There was little evidence of systematic monitoring of the assessments undertaken by VMHAs during approvals visits including the consistency, and appropriateness of decisions made by VMHAs.
- 5.4.3 The only quality monitoring checks undertaken by the VMHD at AVH were limited to reviews of decisions to refuse approval, which included refusals from Scotland and Wales. However, in all the countries there was evidence of some monitoring of VMHA/VA approval outputs including numbers of visits and approvals completed by VMHAs, but the extent of monitoring varied from country to country.
- 5.4.4 With the exception of Northern Ireland, the devolved administration FSA offices had no 'in-house' veterinary expertise. It was therefore not possible to carry out the appropriate level of qualitative monitoring. At Aviation House where such expertise existed, and which was frequently provided to other countries, there were no formal arrangements for monitoring checks on samples of approval files from England or the other countries. There were also no arrangements for formal verification checks at approved establishments. The review team was informed that monitoring checks were not undertaken because of insufficient management resources to cope with the demands of monitoring VMHA work.
- 5.4.5 Checks on a sample of approved establishment files supported the approvals outcome in most cases. However, some inconsistencies and deficiencies that could have influenced approvals decisions were identified across the UK,. These could have been identified if appropriate levels of qualitative monitoring were in place. Many veterinarians interviewed during the review recognised that there needed to be better accountability from VMHA colleagues.
- 5.4.6 In England, records of management oversight or monitoring of VMHA activities were requested but these were not available. Senior MHVD managers acknowledged that there needed to be more effective central monitoring of both qualitative and quantitative aspects of the approvals work undertaken by VMHAs.

Case Study 3 – A FBOs experience of the approval process.

The VMHA was familiar with the site as he had been here several times before. We got the full approval at the first visit. To us the process did not make any difference, it was a “paperwork exercise”. We did not need to invest any money during the approval process as the VMHA was satisfied with both the structure and the food safety systems we currently have in place.

We are a very small establishment and were quite surprised when for the approval visit the VMHA was accompanied for at least 3 more people! This is as much as our workforce in the premises.

- 5.4.7 In Wales FSAW carried out routine monitoring work targets but did not monitor technical aspects of approvals because VMHAs were considered experts in their field. However it was recognised that this should have been done by AVH.
- 5.4.8 A similar view was reflected in Scotland where FSAS officials said they did not have the required qualitative monitoring capacity or arrangements because the VAs were considered to be experts. The monitoring carried out was limited to the quantitative aspects of VA approvals.

Recommendations:

5.4.9	The Agency should develop appropriate UK-wide internal monitoring policies and procedures and implement routine monitoring arrangements covering the qualitative and quantitative aspects of approvals undertaken by field staff in all 4 countries.
5.4.10	The management and reporting lines between relevant FSA countries and VMHAs/VAs should be improved and strengthened.

5.5 Approvals Records and Databases

- 5.5.1 The review considered the approved establishments record keeping arrangements in all countries. The accuracy of data and progress reports on approvals is dependant on the reliability of the systems used to collect and process information collected by each constituent FSA office.
- 5.5.2 All the FSA offices in England, Scotland, Wales and Northern Ireland maintained approvals databases which contained records of approved establishments and were in all cases updated regularly. These databases were routinely used to monitor progress of the approvals programme in each country. Monthly reports were submitted to a central database in AVH for the same purpose.
- 5.5.3 At the time of the review, database systems in the different countries were mostly maintained on spreadsheet programmes. Although the spreadsheets had similarities in terms of data content, it was noted that there were some differences which contributed to the difficulties experienced in obtaining database reports requested by the review team. In some cases this resulted from differences in the way data inputs were made or variations between countries in the interpretation of data. In England, approvals data was maintained on several different databases.
- 5.5.4 All countries used the spreadsheet records for a range of functions. These included, maintaining records of premises information, scheduling visits and revisits, allocating plants for approval visits, recording approval visit outcomes and monitoring progress of approval programmes. The systems could also be used to monitor the progress of individual VMHAs/VAs and to remind them of target dates for re-visits.
- 5.5.5 The databases systems were capable of generating management reports on approvals but these could only be collated manually because of the limited data input and reporting capability of the systems. There were also difficulties in maintaining accurate data given the frequent changes in the numbers and status of approved establishments.
- 5.5.6 The management team at AVH acknowledged that there were some concerns about the accuracy and value of some of the data, and difficulties in understanding reports created from the system. It was suggested that the used of a common spreadsheet template should have ensured that all countries maintained similar data.
- 5.5.7 In addition to the databases maintained at country level, a 'central database' was maintained at AVH to which all countries submit monthly progress reports. However, it was difficult for the devolved countries to access remotely the database containing all UK data. At the time of the review a bespoke system was being developed, which would merge FSA and MHS data and is expected to provide more robust data input, data handling and management report generating capabilities.

5.5.8 In addition to the electronic databases, all countries also maintain hard copy file records of approved establishments in their respective FSA offices. Home-based field officials (VMHAs/Vas) also kept files containing premises information and approval activity records for establishments in their area. The practice of maintaining separate file records in a variety of locations was identified as a weakness in current arrangements. The use of digital imaging technology to integrate file records with the proposed database would ensure more effective document control and improve accessibility of information.

Recommendation:

5.5.9	As part of the current database development project, the MHVD should consider options for digital storage of approved establishments records in a shared central system that is accessible to all relevant FSA and MHS staff in all countries.
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5.6 Programme Review

- 5.6.1 The review of progress of the approvals programme was a key focus of APB meetings. The meeting minutes confirm that the review of the progress of the approvals programme was a standing item at the quarterly meetings. The meetings also considered the need to review policies in the light of any emerging programme implementation issues.
- 5.6.2 By November 2006, 40% of approvals assessments had been undertaken across all countries with an expected termination of the programme in March 2008. In March 2007 it was reported that 50% of plants had been re-approved across all countries, but only 40% in England. The reason given for this was the number of second and third visits to conditionally approved plants, although it was expected that the programme would still be completed by Spring 2008.
- 5.6.3 Some guidance to address the delays caused by second and third visits to conditionally approved establishments was issued to VMHAs. However, it was not clear if any other steps were taken or recommended by the APB to investigate and establish the rationale for the repeat visits.
- 5.6.4 In November 2007 the APB reported that in England only 60% of re-approvals had been carried out. It was again mentioned that progress was being hampered by the large numbers of second and third visits to conditionally approved plants. In addition there was a further requirement for VMHAs to focus on those plants that had been highlighted as poorly performing by the MHS.
- 5.6.5 By March 2008, when the programme should have been completed, Scotland had only 3 plants outstanding; Wales had largely completed the programme, but England still had 'a fair amount'. The loss of 3 VMHAs had had an effect as had the number of repeat visits. There were in addition concerns being expressed by the industry as to the length of time the project was taking.
- 5.6.6 In July 2008 it was reported that England had completed 72% of the re-approvals. There were 168 plants yet to be visited, most of which were previously licensed red meat CPs and a further 150 CBs to be approved.
- 5.6.7 Some FSA and MHS staff interviewed during the review considered that reviews of the programme had mostly been carried out on an 'ad hoc' basis and tended to be reactive, but not scheduled or planned.

	<i>Recommendation</i>
5.6.8	During the remaining period of the programme in England, the APB should consider carrying out scheduled reviews of all aspects of the programme. Any significant issues that are identified should be addressed to ensure the programme remains on course for completion by the target date.

6.0 Programme Outputs and Outcomes

6.1 Approval Outputs

- 6.1.1 At the time of this review, the approvals programme had been completed in Scotland, Wales and Northern Ireland, while England still had a significant backlog of approvals to be completed. Although the deficiencies and weaknesses in management and execution of the approval programme observed in England are likely to have contributed to the delays, the review team is of the opinion that the significantly lower resource level was probably the main contributory factor.
- 6.1.2 Disparities were also noted in the numbers of approvals granted at the first visit. This was highlighted at the 17 September 2008 Board meeting, which discussed an update report on the progress of the approvals programme. Following a request from the APB in October 2008 the Director FSAW¹⁵ provided a written explanation for the marked difference between Wales and other countries, especially England.
- 6.1.3 Explanations for the differences between UK countries in the percentage of premises not granted full approval at the first visit were then provided by the Chief Executive in a report to the Board on 15 October 2008¹⁶. The table below shows data on approvals at first visit from the CE's October 2008 report:
- 6.1.4 The review explored the differences highlighted and the findings were consistent with the explanations provided by the Chief Executive and the Director FSAW. There was no evidence to suggest that the differences, particularly between Wales and England, in the percentage of approvals at first visit was due to differences in approval assessment methodology or standards.
- 6.1.5 Findings in relation to consistency of the approval system have been covered in previous sections of the report. Inconsistencies in the application of approval requirements, which could influence the outcome of the approval process, tended to be among individual veterinarians rather than between countries. The differences observed between countries in the management of approval programme were unlikely to influence the outcome of the approval process to the same extent, and therefore had little bearing on the disparities observed.

¹⁵ Approval of Meat Plants in Wales – October 2008

¹⁶ Chief Executive's Report: FSA 08/10/03 15 October 2008

6.2 Progress of the Approval Programme

- 6.2.1 A table has been included at Annex 3 detailing the status of the approvals programme at 31 October 2008. Scotland, Wales and Northern Ireland had completed most of their programmes while there was a target to complete the programme in England by the end of September 2009.
- 6.2.2 At 31st October 2008, 142 establishments were still due for a first approval visit in England. As mentioned previously in the report, the MHS and a contractor had been engaged to carry out approval and advisory visits that should improve the prospects of completion within the estimated timescale.
- 6.2.3 Since the programme started in January 2006, 30 establishments have been refused approval. Of these, 22 subsequently gained full approval after FBOs had completed the corrective works.

7.0 ANNEX

Annex 1 – Practical Review Process

Practical Review Process

The practical review of the policy and implementation issues in relation to approvals within the context of the TOR was carried out mainly through key informant and stakeholder interviews, review of relevant records and documents, and verification visits to a selection of approved establishments in England and the devolved administrations. The main components of the review are set out in the table below:

Policy on Approvals	Implementation of Approvals programme	Outputs/Outcomes of Approvals
Policies developed/implemented in relation to approvals; Prioritisation of approvals; Communication of policies: Guidance, Instructions or Circulars on Approvals VMHA Training; Resource issues	Consistency issues: <ul style="list-style-type: none"> • Approvals process • Approvals protocols and checklists • Internal Monitoring of Approvals • External Monitoring Timescales for approvals	Numbers/percentage of establishments fully approved ¹⁷ , conditionally approved or refused Numbers/percentage of establishments with full approval at first visit; FBO feedback

Key informant/stakeholder Interviews

The aim was to obtain information and views on approval policies, the implementation of the approval programme and the outcomes of approvals. Key interviews involved the following:

- FSA (Aviation House), FSA Wales, FSA Scotland & FSA Northern Ireland interviews:
- Official(s) with management responsibility for approvals in each country;
- Veterinary Meat Hygiene Advisors (VMHAs) and relevant Agriculture Department officials who were directly involved in the approval process in the devolved administrations (1 – 3 in each country)

Approved Establishment (plant) level interviews:

- Team Leader;
- Plant Official Veterinarian (OV) – preferably at time of approval;
- Food Business Operator (FBO).

¹⁷ Since 01 January 2006

These interviews depended upon the involvement of interviewees during the approval process and their availability at the time of the verification visit to the establishment.

Meat Hygiene Service Interviews

- Officials at the Veterinary and Technical Directorate

Verification visits to Approved Establishments

Verification visits to a sample number of meat establishments in each country explored the practical conduct of the approvals process at establishment level, verified the rationale for approval decisions and obtained information on field officers' and FBOs experiences of the process. The review team endeavoured to select a representative sample of establishments for the verification visits, based on the type of operation (e.g. slaughterhouse, cutting plant, catering butcher), species handled, a mix of establishments approved at first visit and those approved at subsequent visits, and approvals processed by different VMHAs/VAs.

Verification visits were made to approved establishments as follows:

Country	Establishments that were approved at first visit	Establishments that were conditionally approved	Total Number of Establishments to be visited
Scotland	1	1	2
Wales	1	1	2
Northern Ireland	1	1	2
England	2	2	4

Review of Records/documents

Records/documents reviewed in each country:

- Total numbers and types of establishments requiring approval in England, SW&NI (as at 31 October 2008)
- Establishments approved (as at 31 October 2008);
- Establishments granted approval at first approval visit;
- Establishments conditionally approved (31/10/2008)
- Establishments refused approval (31/10/2008);
- Approvals Board meeting minutes;
- Approved Establishments files (file checks on a minimum 10% of establishments requiring approval);

Review of Policies, Central Guidance or Instructions and the implementation of Approvals

- Policies, instructions, circulars and guidance on approval - issued since 2005 in each country;
- Checklists/protocols to assess compliance with approval requirements;
- VHMA resources provided for approval;
- Training provided to VMHAs on approval;
- Procedures for internal monitoring of approvals process and decisions;
- Records of internal monitoring of approvals process and decisions;
- Results of Customer Satisfaction questionnaires sent to FBOs after approval.

Annex 2 – Summary of Appraisal Visits Progress Report

APPRAISAL VISITS PROGRESS – 16 SEPTEMBER 2005

		Eng	Scot	Wales	NI	Total
Selected premises offered appraisal visits		191	24	32	18	265
Visit refused or not required (<i>e.g. plant closed, licence revoked, involved in OTM or OTMS</i>)		12	0	7	0	19
Date agreed for appraisal visits		160	24	25	18	227
Appraisal visits carried out		144	21	24	17	206
Appraisal reports sent to operator		135	21	24	17	197
VMHA post-appraisal assessment (see below for explanation of each category)						
VMHA post-appraisal assessment (see below for explanation of each category)	Category A	56	6	8		70
	Category B	53	9	9		71
	Category C	32	13	7		52
	Category D	0	0	0		0
Priority A premises						
Priority A premises to receive appraisal visits		65	2	9		76
Priority A premises given appraisal visits		64	2	8		74
Requested appraisal visits						
Premises that requested appraisal visit		38	13	1	0	52
Date agreed for appraisal visits		29	8	1	0	38
Appraisal visits carried out		25	8	1	0	34
Appraisal reports sent to operator		21	8	1	0	30

VMHAs have categorised plants in GB that have been reported on so far as either:

Category A

- major structural or layout deficiencies (*e.g. problems generally requiring over 3 months to remedy*);

Category B

- lesser structural or layout deficiencies; and/or
- major maintenance deficiencies; and/or
- deficient Pre-requisites Programme (PRP) and HACCP in complex operation (typically in large to medium slaughterhouse) (*e.g. problems generally capable of being remedied within 3 months*).

Category C

- minor maintenance deficiencies;
- deficient PRP and HACCP in simple operation (typically in low throughput slaughterhouse and cutting premises) (*e.g. problems that could be resolved relatively quickly and easily*).

Category D

- compliant

Annex 3 – Approval Statistics (as at 31 October 2008)

		England	Scotland	Wales	Northern Ireland
Number of establishments to be re-approved at 01 Jan 2006		828	112	69	58
Number of establishments fully re-approved at 31 Oct 2008		445	89	48	49
Number of establishments conditionally re-approved at 31 Oct 2008		60	1	1	2
Number of establishments awaiting 1st re-approval visit at 31 Oct 2008		142	3	1	1*
Total number of plants to be re-approved at 31 Oct 2008		202	4	1	3
Number of establishments re-approved at	1st visit	114	26	28	19
	2nd visit	208	32	8	14
	3rd visit	113	29	12	16
Number of establishments refused re-approval from 01 Jan 2006 to 31 Oct 2008		25*	2*	1	2
Number of establishments that have closed/ceased trading since 01 Jan 2006		174	19	18	6
Number of establishments that have closed/ceased trading since 01 Jan 2006 prior to receiving any approval visit (if this data is available)		148	13	15	2
New establishment approval requests from 01 Jan 2006 to 31 Oct 2008*		109	14	8	4
Estimated end date of the re-approval process (i.e. Sept 2008)		Sep-09	Dec-07	Nov-08	Aug-07
FTE field officers directly involved in the re-approval process on	2006	7.1	3	1	3
	2007	7.23	2.5	1	2
	2008	5.56	1.3	1	
Ratio number of establishments/VMHA in 2006		117	37	69	19
Appraisal visits offered in 2005		255	24	32	Not available
Appraisal visits completed in 2005		224	16	24	22
% over establishments to be reapproved at 01 Jan 2006		27%	14%	35%	38%
% of Establishments approved at 1st visit against establishments fully re-approved		26%	29%	58%	39%
% of Establishments approved at 1st visit against establishments fully re-approved including sites that closed prior to any visit		19%	25%	44%	37%
% of Establishments that have closed		21%	17%	26%	10%

Annex 4 - WHAT could have been done better?

The following are extracts of *comments made and views expressed to review team members, mainly by FSA and MHS interviewees.*

- Programme could have been better managed
- Should have had explanations and formal reviews of why it was taking so long.
- Priorities should not have shifted and changed in the unplanned manner, that it did.
- The interface between the different UK countries, mainly at delivery level, could have worked better.
- VMHAs needed a better understanding of approvals requirements.
- Resource issues should have been considered and should have been subject to scheduled reviews. E.g. decision to re-deploy VMHA resources elsewhere affected delivery of the programme.
- Did not predict the scale of the challenge – some establishments required 3 or more visits because appraisal visits were not as far-reaching as could have been. Better outcome in Wales where more appraisal visits were carried out.
- The programme could have achieved more with adequate resources and more effective management.
- Communication has improved and things would have been better still if this had been the case from the start.
- Concerned about how much the programme including the current review were costing.
- There was not the desired level of coordination between the FSA – AVH and MHS Regional offices.
- Perhaps there should have been a 'holistic' decision on policy priorities at the very start of the programme.
- More timely policy development.
- A bit ambitious to expect completion of programme within 12 months.
- England was allowed to 'drift away'.
- Should have taken account of all sectors, including CBs and GHEs at the very start of the programme and to have developed appropriate policies, including prioritisation policy.
- Some FBOs 'played the system' to stretch out approvals.
- VMHA could have visited earlier than March 2008 when he made the first visit.
- The VMHA's interpretation of the law appears to be different from others.
- Maybe the VMHA should have been assisted by someone else.

- VMHA's should have taken responsibility to enforce the conditional approvals
- Project manager should have been in place at the outset as should a Project initiation document.
- Plan should have been in place supported by MHS/FSA
- Approval level should have been 'set' to ensure all parties knew what the standard was before approval would be given.
- Concern was expressed by the FVO in some establishments that they had been approved
- Poor plants took time to bring up to speed, these were due to poor technical staff (OV) within them, high turnover and poor retention.
- Scotland had higher standard as did Northern Ireland due to export markets.

- **Annex 5 - Report Circulation** [To be advised]

Annex 6: Glossary

APB	Approvals Project Board
AVH	Aviation House
CB	Catering Butcher
CE	Chief Executive
CP	Cutting Plant
CVO	Chief Veterinary Officer
DARD	Department of Agriculture and Rural Affairs
DVO	District Veterinary Officer
FBO	Food Business Operator
FSA	Food Standards Agency
FSA-AVH	Food Standards Agency- Aviation House
FSANI	Food Standards Agency Northern Ireland
FSAS	Food Standards Agency Scotland
FSAW	Food Standards Agency Wales
GHE	Game Handling Establishment
HACCP	Hazard Analysis and Critical Control Point
MHS	Meat Hygiene Service
OFFC	Official Feed and Food Controls
OV	Official Veterinarian
SBC	Small Business Council
SBS	Small Business Service
SGRD	The Scottish Government Rural Directorate
SH	Slaughterhouse
SVS	State Veterinary Service

ToR	Terms of Reference
VA	Veterinary Adviser – Scotland
VMHA	Veterinary Meat Hygiene Advisor
VMHD	Veterinary and Meat Hygiene Division
WAD	Welsh Agriculture Department
WAG	Welsh Assembly Government

Annex 7: Acknowledgements

The Agency is grateful for:

- *the help, support and contribution of the following who participated in the review:*

The Veterinary and Meat Hygiene Division, FSA, Aviation House, London;

The Food Standards Agency, Scotland;

The Food Standards Agency, Wales;

The Food Standards Agency, Northern Ireland;

The Department for Agriculture and Rural Affairs, Belfast, Northern Ireland, and;

The Meat Hygiene Service (MHS), York

- *The cooperation of FBOs at the approved establishments that were visited as part of verification checks undertaken during the review;*
- *The cooperation and assistance of field staff including, VMHAs, VAs, OVs, OV contractor suppliers and field managers, who helped to facilitate visits and/or attended interviews.*