Proposed Changes To The Operational Policy For The Approval

Of Meat Establishments Undertaken By The Food Standards Agency

**SUMMARY REPORT OF RESPONSES TO CONSULTATION FROM STAKEHOLDERS**

A consultation exercise on proposed changes to the Operational Policy detailing the administrative process for approval of slaughterhouses, cutting plants, game handling establishments and wholesale meat markets by the FSA was issued in England, Wales and Northern Ireland on 28 June 2018 and closed on 20 September 2018.

The Food Standards Agency has a published policy providing guidance to food business operators on the requirements for approval and how the application process is delivered. Since the last version of the policy (August 2015) there have been several changes in policy and procedure not yet incorporated into the published document.

In addition to this, in November 2017 the FSA commissioned an external review of operational policy and procedures for the approval of meat establishments. Further to the recommendations made by that review the FSA is also seeking to provide further clarity on how previous poor compliance will be a determining factor in considering new applications for approval.

They key changes being proposed on which the consultation sought views on were:

* Removal of references to Food Standards Scotland. They have produced their own policy since the current joint policy was last published in August 2015.
* Page 6 - There is a change to the governance arrangements following recommendations from John Barnes. The decision maker for Approvals decisions will a Senior Civil Servant likely to be the Head of Operations Assurance or the Head of Field Operations. Reference to a decision making panel is also included for the first time to improve transparency.
* Paragraph 46 – The FSA is now intending to charge for advisory visits which are not required under regulations. These will be on a full cost recovery basis.
* Paragraphs 49-57 – clarifies to FBOs that previous non-compliance is something the FSA will consider when receiving new applications. A disclaimer will also need to be included on the application form to capture previous relevant convictions. This will assist the Agency taking a more robust approach against food business operators who have demonstrated an inability to meet the minimum requirements of food law.
* Para 58 – reference to a food safety management system needing to be in place prior to conditional approval for high risk food items such as minced meat/meat preps intended to be eaten less than thoroughly cooked.
* Para 80 – provides an indication approval numbers can be re-used for a new approval. This allows FBOs to retain their approval number when moving premises
* Para 95 – clarifying that the audit cycle is suspended whilst a review of approval is ongoing
* Para 107 – explains that the Agency will not consider applications for additional activities whilst the FBO has an Urgent Improvement Necessary or Improvement Necessary outcome
* Page 38 – inclusion of the ‘satellite’ exemption which has already been included in the LA Guidance for Approval Officers published in July 2016.
* Page 42 – inclusion of CCTV requirements in the list of serious deficiencies which will allow the FSA to withdraw approval if a slaughterhouse fails to comply with the new requirements.

**Summary of Responses**

A total of 4 responses were received to the consultation in England, Wales and Northern Ireland

Responses:

Association of Independent Meat Suppliers

Wales Food Safety Expert Panel

British Meat Processors Association

Partnership Working Group

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| **SUMMARY OF SUBSTANTIVE COMMENTS TO THE FSA CONSULTATION – OPERATIONAL POLICY**  |

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| **Respondent** | **Method of Response** | **Comment** | **Response** |
| Association of Independent Meat Suppliers | Email | **A1.** Paragraph 2.  Regulations 882/2004 and 854/2004 are not hygiene regulations but official control regulations.  They are not part of Food Law but include controls over Food Law and other rules.  They would be better included in a separate paragraph | **A1.** See response for A5.  |
|  |  | **A2**. Paragraph 13.  The proposal for decision making to be delegated to an official who is not a member of the senior civil service is not acceptable.  Withdrawal of approval is the final step in the hierarchy of enforcement and is not an action that should ever be taken in haste, there is therefore no need for such delegation.  If an operation needs to be stopped with immediate effect the appropriate notice should be used, for example an Emergency Prohibition Notice. | **A2.** A review of approval can run parallel to any enforcement action being taken. However, the FSA acknowledges that the process, which affords a food business operator time to provide guarantees over future production, can take time to reach its conclusion and as such should be taken by a SCS. Decisions to grant or refuse approval are often more time sensitive and on occasion may still need to be delegated to the most appropriate available official.  |
|  |  | **A3.** Paragraph 15.  The FSA appear to be confused over what separation is required to ensure independence of decision making.  Although Jan Polley in her report suggested a separation between those responsible for approval and those responsible for audit, her imperative was for there to be separation between those involved in day to day enforcement at an establishment and those involved in approval (see Section 8, Conflicts of Interest).  Staff involved in making approval recommendations should not be involved in day to day enforcement, as they were at the recent case in Norwich Crown Court. | **A3.** There is no material change being proposed to the policy here. The responsibility for Field Veterinary Leaders to be responsible for recommendations on approval decisions has been in place since 2014 following a restructure which was consulted upon with Industry. Since 2014 we are not aware of any issues which have arisen from Field Veterinary Leaders being responsible for making such recommendations and this aspect was not criticised at the recent court case. Moreover, it is Field Veterinary Co-ordinators who are involved in the day to day enforcement activities.  |
|  |  | **A4.** Deleted paragraphs 28 & 29.  Reference to the Commission’s guidance document on implementation of Regulation 853/2004 should be maintained.  In what way is it out of date in relation to cold stores? | **A4**. The proposal to delete reference to these guidance documents was made purely in the belief they were no longer available from the Commission. They are indeed still published and available and therefore reference to these documents will remain.  |
|  |  | **A5.** Paragraph 38.  Compliance with Food Law is the requirement for approval.  Animal health and welfare legislation is not part of food law as is clear from the title of Regulation 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.  Reference to Regulation 1099/2009, which is not part of Food Law should be removed.   Paragraph 49. Regulation 882/2004 Article 31 2 (c) requires operators to demonstrate compliance with food or feed law.  There is no mention of animal health and welfare rules, and references to them should be removed  | **A5.** The FSA considers that animal welfare within slaughterhouses does form part of food law and that it should form part of the procedures for food business operators to follow when applying for approval of their establishments and equally may also be considered in relation to a withdrawal or suspension of approval by the FSA. |
|  |  | **A6**. Paragraph 50.  The legal base is contained in Regulation 882/2004 Article 54. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and that operator's past record with regard to non-compliance. Reference should be made to the Article.  The relevant non-compliances concern Food Law and references to animal health and welfare rules should be removed.  As currently drafted the examples said to be relevant are far too subjective.  They should be limited to proven and serious non-compliances i.e. where guilt has been determined by a Court.  The recent case in Norwich Crown Court demonstrated that using unsubstantiated allegations to refuse approval is contrary to Public Law.   | **A6.** The FSA will consider all applicant’s ability to meet food hygiene and welfare requirements, the purpose of which are clear. If the FSA was to limit its decision making to only those instances where a conviction was secured this would restrict our ability to act quickly as an effective regulator. The recent court case being referred to was not in relation to how previous non-compliances were considered or relied upon. The greater transparency being provided with the insertion of this paragraph is in response to some food business operators whose attitude towards the safe production of food or animal welfare is lacking and for which a further application to operate as a food business operator brings with it no real prospect of improvement.  |
|  |  | **A7**. Paragraph 61.  Following the case referred to above, this paragraph needs expanding to set out a fair procedure for refusing to grant full approval as referred to by HHJ Bate in his judgment.  That procedure must include providing the operator with a report and the reasons why full approval is not being granted as required by Regulation 882/2004 Article 54 3 (a).   | **A7**. The procedure for approval referred to at paragraph is clear and is directed by EU Regulations. When an establishment is refused approval the full reasons are set out.The recent case being referred to dealt with a unique and unforeseen incident.  |
|  |  | **A8.** Paragraph 72.  Granting approval to two operators to slaughter in one slaughterhouse led to the confusion that resulted in FSA having been found to have been procedurally unfair in the Norwich Crown Court case.  It is contrary to the guidance contained in the Commission’s guidance referred to in the deleted paragraphs 28 and 29, which, when referring to wholesale markets advise that a single operator or company should be responsible for common areas.  For slaughterhouses there should only be 1 FBO, who can contract kill for others if need be.  For establishments with shared facilities 1 FBO should be responsible for the shared areas.  The paragraph needs considerable amendment. | **A8.** Two food business operators operating on a time and/or space separation basis is not contrary to law.The FSA is content with the process for contract kills but it should be remembered that in this case, it was not an arrangement that either of the two FBOs wanted or sought.  It is potentially damaging to Industry to restrict the ability for multiple FBOs to maximise the use of an under-utilised premises. Instead the FSA will in future, if presented with the same situation, consider stricter governance around the use of time separation slaughter activities and remove flexibility which was allowed in the referenced case. |
|  |  | **A9**. Annex E.  CCTV being a welfare issue is not part of Food Law and should not be included in the Annex.  | **A9**. It is now a legal requirement that CCTV is required in slaughterhouses. This is intended to protect the welfare of animals. The FSA believes welfare requirements form part of food law and as such we believe it is appropriate to consider the lack of appropriate CCTV as a serious deficiency.  |
|  |  | **A10.** Annex E.  Lack of pest control that does not result in pest infestation is not a serious deficiency and should not be included in the Annex    | **A10.** If this was a singular issue we acknowledge this would not be a serious deficiency and as such the original wording will remain as it is currently. However, it may be considered amongst further examples indicating a poor management attitude and commitment towards a Food Safety Management System.  |

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| **Respondent** | **Method of Response** | **Comment** | **Response** |
| British Meat Processors Association  | Email | **B1*.*** *Paragraph 46 – The FSA is now intending to charge for advisory visits. These visits are not required under regulations but the FSA still wishes to offer these for prospective new businesses seeking support and advice on gaining approval. These visits will be charged on a full cost recovery basis.* We support the concept, but has the purpose of an “advisory visit” been defined? Are there any guidelines on cost? Is this a commercial agreement in which the FSA is acting as a consultant for the food business and therefore the recommendations are private between the two parties and therefore should not, as a result of data protection, be accessible by the general public as this guidance belongs to the food business? | **B1.** In order to confirm in more detail what can be expected of these advisory visits and the cost the charging of these visits is intended to be introduced next year.As a public sector organisation, all information we hold is subject to release under Freedom of Information unless it is covered by one of the exemptions. These would be subject to a public interest test.  |
|  |  | **B2.** Para 58 – emphasises the need for a food safety management system needing to be in place prior to conditional approval for high risk food items such as minced meat/meat preps intended to be eaten less than thoroughly cooked. Does this also cover ready to eat food types – cooked meats, air dried hams, sandwiches, etc? | **B2**. Yes, ready to eat meat products is considered to represent a higher risk product.  |
|  |  | **B3.** Para 86 – provides conformation that approval numbers can be re-used for a new approval. This allows FBOs to retain their previous approval number in certain circumstances such as when they move to new premises. This allows an existing food business moving to new premises to continue to use its existing approval number - what would happen if both sites continued to run for a period of time?  | **B3**. This policy is already in effect on an operational basis. We are introducing it formally into the published policy to aide transparency. The issue arose when a FBO moved premises and had their approval number on all their packaging and fleet of vehicles. The principal we are keen to maintain is that an approval number is unique to one establishment at any one time. This means we are content for a FBO to retain the approval number when moving premises but it cannot be allowed to span two premises at any one time |
|  |  | **B4.** There are discussions taking place about giving the FSA access to other third-party food safety audits carried out at the manufacturing site – was this considered? | **B4.** This is being considered as part of the review of cutting plants and cold stores. Eventually this may result in changes being introduced into the policy document but it is too soon to introduce such changes into this revision. Recommendation no. 8 Of the Cutting Plant and Cold Store review is; *Test the value in mapping the British Retail Consortium (BRC) Directory open information to the Agencies’ data on establishments and of the Agencies’ officials making use of information in BRC Global Standards (GS) audit reports to inform official controls at cutting plants*  |

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| **Respondent** | **Method of Response** | **Comment** | **Response** |
| Wales Food Safety Expert Panel | Email | **C1.** The document appears to be a combination of operational guidance and policy. We assume that there is a guidance document for FSA Ops staff as there is for LAs. In order to facilitate a consistent approach for food businesses there should be one set of guidance for the approval process. | **C1.** The document is an operational policy document so by its nature is used by both FSA Operational staff and food business operators for reference.The document represents a high level viewof the processes which are to be followed.  |
|  |  | **C2.**  **Page 6 point 13**  If a senior civil servant is to authorise approvals we would assume that they are competent in food matters. As food is currently devolved in Wales then should approval be authorised by someone with knowledge of devolved matters? | **C2.** Field Veterinary Leaders are responsible for conducting assessments at food establishments as they are competent in these matters. Where matters of concern are raised the SCS can ask for a panel to provide further input into their decision. This will include input from colleagues who are also competent in this area and where the establishment is located in Wales the FSA Director for Wales will also be invited to contribute.  |
|  |  | **C3.** **Page 6 point 14** What would the initial enforcement process be if a decision for withdrawal of approval needs to go to the panel? In order to protect public health an instant decision may need to be made on site. For example are the OVs competent and authorised to serve a RAN to ensure that any risk to food safety is removed? How timely would the panels be convened? | **C3.** If a RAN is required to be served in order to safeguard public health then these will of course be served. OVs are authorised to serve these as indeed are other veterinary officials and meat hygiene inspectors.The use of enforcement notices such as a RAN is the appropriate enforcement mechanism when immediate action is required. As such, a panel to decide whether an approval needs to be withdrawn can be arranged once the evidence has been collated by a Field Veterinary Leader and considered carefully.  |
|  |  | **C4**. **Page 17 point 58** “the CA may grant **conditional approval** if the establishment meets all the infrastructure and equipment requirements. The food business may not have recognisable fully developed and documented HACCP based procedures but the planned method of operation must not constitute a risk to public health and there must be adequate provision to control any such risks that have been identified. This is particularly so for high risk food items such as ready to eat meat products and minced meat/burger intended to be eaten less than thoroughly cooked. In such cases, the FBOs food safety management system needs to be available to the CA but if the establishment is not operational, it will not be possible to assess how effectively this works in practice”. This is contrary to the FSA approvals guidance issued to LAs which states that “FBOs to demonstrate compliance with the requirements of Article 5 of Regulation 852/2004 and to gain approval establishments will have to fully meet the requirements of Regulations 852 and 853/2004”. *E. coli* O157 is a hazard that needs to be controlled through the business' food safety management system. We feel that a fully developed and documented HACCP system which is commensurate with the nature and size of the proposed operation should be in place prior to issuing conditional approval. We understand that HACCP is a live working document and will be subject to ongoing review as the business develops. | **C4.** The FBO needs to demonstrate the production of food is safe. It is for the Field Veterinary Leader to determine this at the initial approval assessment visit. If they feel the nature of production requires the food safety management system to be fully documented prior to making this determination they are fully entitled to request this. If however, the process is relatively straightforward and the Field Veterinary Leader is content with the description provided to them of how the food safety management system is going to operate then the Agency is content for them to provide conditional approval provided the lack of a documented FSMS is raised as a deficiency for which we would expect this to be resolved at the next approval assessment within three months. If the FBO has not demonstrated clear progress towards the full requirements of food law at this second approval assessment then approval will not be extended and full approval will be refused.  |
|  |  | **C5. Page 19 point 72** “3. Until conditionally approved by the FSA/FSS, responsibility for enforcement action remains with the LA or DC. When assessing for approval the FSA/FSS, where possible in consultation with the relevant LA or DC, will consider whether any enforcement action for the protection of public health is needed and communicate this to the relevant LA or DC responsible official.” We strongly believe that as soon as the FSA becomes aware that a business falls within their enforcement responsibility then the FSA should assume responsibility for enforcement. There should be a clear transparent process, with guidance available that doesn’t confuse businesses or overburden LAs in an area which ultimately falls outside their remit. There is no timescale specified for handing the premise to the FSA. In circumstances where enforcement responsibility has transferred from FSA premises to LAs this has been with immediate effect. It is important that a collaborative approach takes place between the LAs and FSA were required, to ensure that a consistent approach is taken to applications, interpretation of statutory requirements and guidance. It would also be helpful if training was readily available to LA and FSA officers on the implementation of 852/2004 and 853/2004 in order to aid consistency in relation to interpretation of requirements and guidance in the appropriate areas. | **C5.** The regulatory responsibility is set out in the Food Law Code of Practice. The Code of Practice is also currently subject to consultation and this comment has been passed to the FSA team responsible for this. In addition to this, recommendation no. 7 is:*Invite a small, representative number of LAs to participate in a trial to evaluate the use of single organisation to deliver all Official Controls in a geographic location*   |
|  |  | **C6. Page 28 point 101** Where a “minded to” Notice of Review of Approval has been served the FBO may provide the CA, within 14 calendar days from the date of service, with any guarantees regarding future production that it will resolve the deficiencies within a reasonable time. What is the rationale for the FSA and LAs having a different approval processes? LAs do not use “minded to” Notices of review of approval. If an enforcement body is considering withdrawing an approval then there must be serious deficiencies, which is an actual or potential risk to public health. The “minded to” process is a lower standard to that enforced in LA approved premises. The process should be brought up to the LA standard. Use of these notices adds complexity and extends the time taken to resolve the serious deficiency. The definition of within a reasonable time is not consistent with that given in the LA guidance which is within 14 days. | **C6. The review of approval process is described in Article 31(2) (e) of Regulation (EC) 882/2004***‘The CA shall keep the approval of establishments under review when carrying out official controls. If the CA identifies serious deficiencies or has to stop production at an establishment repeatedly* ***and the feed or food business operator is not able to provide adequate guarantees regarding future production****, the CA shall initiate procedures to withdraw the establishment’s approval. However, the CA may suspend an establishment’s approval if the feed or food business operator can guarantee that it will resolve deficiencies within a reasonable time‘*There is an inference in the bold text that a food business is provided an opportunity to provide such guarantees. This process is also described in the LA Guidance document*The* ***provisional decision*** *to withdraw the approval must be communicated in writing to the FBO. The FBO must provide the LA with any guarantees that it will resolve the deficiencies within a reasonable time.* The intention is that the FBO provides a response within 14 days. This response must provide guarantees of how the serious deficiency is to be resolved within a *reasonable* time. It is the timeframe for rectifying the serious deficiency which needs to be “Reasonable” and it is this which is *relative to the nature and magnitude of the deficiencies present.* This point needs greater clarity in the LA Guidance document and these comments have been forwarded to the team responsible for the publication of this.  |
|  |  | **C7. Page 31 point 112** On change of FBO an establishment can continue to operate under the existing approval for a short period of time, but not exceeding a maximum of **25 working days** after the change of FBO, until an approval assessment is carried out by the CA. This flexibility is not afforded in the LA approvals guidance. There needs to be a level playing field for businesses. | **C7.** The process for approving establishments which have changed ownership was established in late 2011/ early 2012 in consultation with industry. The FSA acknowledged concerns made by Industry at the time that a business changing ownership being required to cease production pending a new approval could prevent the sale of such a business. As such it introduced the procedure to allow, in certain circumstances described in the policy for a new owner to continue the same production pending a new approval assessment. This comment has also been forwarded to the team responsible for the publication of the LA Guidance as this requires rectification.  |
|  |  | **C8. Annexe H Flowchart** This flowchart would be useful for the LA guidance. | **C8.** This comment has also been forwarded to the team responsible for the publication of the LA Guidance |
|  |  | **C9.** In light of recent food fraud incidents the Panel suggests that matters relating to food standards such as labelling should be considered at the approval stage. | **C9**. The approval process does require the food business operator to demonstrate compliance with all relevant requirements of food law. The relevant requirements would include all those for which the FSA are the competent authority. The Cutting Plant and Cold Store Review (Oct 2018) includes the recommendation*Inviting a small, representative number of LAs to participate in a trial to evaluate the use of single organisation to deliver all Official Controls in a geographic location.* By removing the multiple competent authorities and as such this suggestion could be incorporated into that process.  |
|  |  | **C10**. The Panel are of the opinion that as both FSA and LAs have the responsibility for dealing with approved premises there should be one set of guidance. This would ensure consistency of enforcement and a level playing field for business. It is imperative with EU exit on the horizon that the UK is able to demonstrate that the food it produces is of a standard acceptable in the global market and the system is able to respond to international scrutiny. | **C10.** The two documents were originally produced with different audiences in mind. One is clearly a guidance document instructing LA Officers whereas the other has additional focus on the requirements on slaughterhouses operations and is directed towards slaughterhouse and cutting plant operations. However, this has raised some unintended areas of inconsistency and as such this suggestion will be taken forward for further consideration.  |
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| **Respondent** | **Method of Response** | **Comment** | **Response** |
| Partnership Working Group | Verbal | **D1.** Why is CCTV being dealt with differently to other non-compliances in being considered a serious deficiency | **D1**. The policy document provides non-exhaustive examples of non-compliances which could be considered as serious deficiencies, depending on the severity. Non-compliance with the CCTV is therefore being treated in the same way as other requirements for which the FSA is the competent authority.  |
|  |  | **D2**. It is natural justice to await a prosecution before instigating a withdrawal of approval. If a food business operator is trying to comply with the CCTV requirements but an Official Veterinarian is not satisfied with the CCTV coverage it is unfair for this to potentially result in a withdrawal of approval for what may be a disagreement.  | **D2**. The process for keeping establishments under review is described in regulations as, *‘The CA shall keep the approval of establishments under review when carrying out official controls. If the CA identifies serious deficiencies or has to stop production at an establishment repeatedly and the feed or food business operator is not able to provide adequate guarantees regarding future production, the CA shall initiate procedures to withdraw the establishment’s approval. However, the CA may suspend an establishment’s approval if the feed or food business operator can guarantee that it will resolve deficiencies within a reasonable time’*It would be inappropriate and against its regulatory responsibility for the FSA to permit a serious deficiency it has identified to remain in existence whilst a prosecution is sought.  |
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|  |  | **D3**.If a food business operator is trying to comply with the CCTV requirements but an Official Veterinarian is not satisfied with the CCTV coverage it is unfair for this to potentially result in a withdrawal of approval for what may be a disagreement. | **D3**. An OV is not responsible for making recommendations to withdraw approval. These recommendations are made by Field Veterinary Leaders. If such a recommendation is made the SCS decision maker would need to consider if the non-compliances does indeed represent a serious deficiency as described in the policy. To this end they would need to consider whether withdrawal is proportionate with the level of non-compliance being identified. To this end, where the FBO has largely met the requirements, alternative enforcement would likely be more appropriate. However, if a slaughterhouse FBO has not installed CCTV and does not provide adequate guarantees on the timescale they intend to meet this requirement withdrawal of approval would likely be more appropriate than a prosecution. The MOC instruction on enforcement of CCTV issues states, ‘*All enforcement action must be proportionate and reasonable. You should encourage the business operator to inform you of any issues or problems with any CCTV equipment and the likely timescale that problems will persist. Verbal advice is likely to be the most relevant action in such circumstances.**Formal written enforcement action will be more appropriate where the business operator has failed to comply with the legislation throughout a significant part of the operation’.*   |