

EVALUATION OF THE RESPONSES TO THE CONSULTATION ON THE FOOD HYGIENE REGULATIONS 2005 AND ASSOCIATED GUIDANCE

Executive Summary

Separate consultations were undertaken in England, Scotland, Wales and Northern Ireland. The consultation was sent direct to 510 interested parties in England, 1100 in Scotland, 100 in Wales and 445 in Northern Ireland. In addition, the consultation was posted on the FSA website to reach a wider stakeholder base.

Responses were received from 67 stakeholders in England, 45 in Scotland, 5 in Wales and 6 in Northern Ireland. Of the total responses, 44 were from enforcement bodies (individual local authorities and groups of authorities as well as national co-ordinating bodies), 52 from industry representative bodies and 27 from other interested parties.

The FSA's aim is to secure an application of the legislation in line with the high-level aims of proportionate, risk-based effective controls which were set for the negotiation of the EU Regulations.

Responses have been summarised in the table overleaf, which brings out the range of opinions given. Where respondents raise significant concerns or maintain a view contrary to the approach suggested these are attributed to the stakeholder concerned.

The full consultation package is available on the FSA website at <http://www.food.gov.uk/news/newsarchive/2004/oct/fhleg>. A summary of consultation responses received will also be available on the FSA website in due course and copies of individual replies will be available in the FSA library.

Question/issue raised in consultation	Summary of responses received	Evaluation of responses/Line to take
<p>a) Links to the Food Safety Act 1990: Enforcement Provisions</p> <p><u>Your views are sought on the approach proposed or whether you would prefer to retain references back to the Food Safety Act, rather than repeating the provisions in the SI.</u></p>	<p>There were mixed views from stakeholders on this issue. Concerns were expressed, particularly by some enforcement authorities, that repeating Food Safety Act provisions in the Food Hygiene Regulations 2005 would lead to confusion. Others considered repeating the provisions in the Food Hygiene Regulations 2005 would facilitate their use. It was suggested that a guidance diagram would help clarify the relationship between different pieces of legislation.</p>	<p>We consider that repeating the Act's provisions in the SI makes for greater transparency by reducing the number of instruments in which the hygiene legislation is contained. We agree that we will need to cover this carefully in the guidance to enforcers so they are clear about what legislative basis they are acting under.</p>
<p>b) Enforcement responsibilities (regulation 5)</p> <p><u>Your views are particularly requested on how best this could be achieved and whether you consider there are ways in which this might be rationalised.</u></p>	<p>Stakeholders views can be summarised as follows:</p> <ul style="list-style-type: none"> • The opportunity to rationalise existing enforcement regimes is welcomed, and clarity of who enforces where is requested. • The “one stop shop” approach to enforcement is considered preferable by most stakeholders to avoid duplication and gaps. Consistency of interpretation of the legislation is important across all sectors. • Clarity on frequency of inspections is important. • Clear guidance should be issued on enforcement responsibilities, particularly the distinction between Agency and enforcement authorities. 	<p>We would certainly agree the need for clarity and avoiding either gaps or duplication in enforcement provision. We continue to have the view that the statutory guidance can clarify the responsibilities in given cases and this is where we would expect to set it out and consult on it in April.</p>
<p>c) Enforcement in respect of ports (sea ports and airports) (regulation 5)</p> <p><u>Your comments are sought on whether the enforcement provisions to apply at ports are sufficient.</u></p>	<p>A number of stakeholders interpreted this question as relating to controls on imported food in general, rather than whether the provisions in the SI were adequate. They therefore commented that enforcement at ports should be strengthened. Some felt that whilst the provisions are adequate, the resources for enforcement are not. The need for consistency of enforcement across the UK was highlighted. Responsibilities for enforcement should be properly established and resourced. Separate legislation for imports would be welcomed. If this is not possible, then clear guidance is requested.</p>	<p>We agree that enforcement as ports needs to be addressed and clear guidance issued. It is unlikely that we will be able to make separate legislation on imports. There was some suggestion that there might need to be something in respect of powers to detain imports. We are still reflecting on this issue.</p>

<p>d) Requiring compliance with the legislation (regulations 8 to 11)</p> <p><u>We need to know whether the provisions are adequate to provide for enforcement or if there are elements missing which need to be included in order to be able to apply the EU regulations properly.</u></p>	<p>Stakeholders considered enforcement provisions adequate in most cases. Rationalisation of enforcement provisions welcomed although there was concern about potential “gold plating” of the EU legislation. A number of specific issues were raised including :</p> <ul style="list-style-type: none"> • Tampering with/covering up prohibition notices should be a specific offence; • Definitions of “wholesale markets” and “health risk conditions” should be included in the SI; • Powers to issue improvement notices for ships registered in foreign countries should be included in the SI; • the use of remedial action notices should be restricted to certain conditions and there would need to be clear guidance on application. • The requirement for food business operators to identify those associated with their business appears to have been lost in the new SI, make enforcement difficult once again. <p>The Association of Meat Suppliers (AIMS) raised specific concerns that the “stop notice” under Regulation 11 (Remedial Action notices) goes beyond the power of the EU Regulations.</p>	<p>We will consider the points raised further. Tampering with prohibition notices is not an offence under the Food Safety Act so it would be difficult to include it in the Food Hygiene Regulations 2005. “Wholesale markets” are defined in the EU Regulations so there is not need to define them in the Food Hygiene Regulations 2005. “Health risk condition” is in effect defined in Regulation 9(2) of the Food Hygiene Regulations 2005. If an FBO breaches the Hygiene Regulations, an improvement notice may be served whether or not the FBO is a UK ship or a foreign ship.</p> <p>Regarding the AIMS point specifically, Article 54 of the Official Feed and Food Controls (OFFC) Regulation states that the Competent Authority has powers to take whatever measures are necessary in the face of non-compliance. However, the FSA will review this area closely.</p>
<p>f) National provisions contained within the regulations (regulations 29 to 32 and Schedules 3 to 6)</p> <p>Draft regulation 29 and Schedule 3.(bulk transport of oils/fats etc) - <u>Your comments are sought on whether this achieves this.</u></p>	<p>Comments from stakeholders supported the FSA’s suggested approach.</p>	<p>The intention is therefore to retain the current exemptions.</p>

<p>Draft regulation 30 and Schedule 4 (temperature control requirements) – Your views are sought on retaining these requirements.</p>	<p>Most respondents consider that the temperature control requirements should be retained. A number, particularly enforcement bodies, have concerns that the requirements are difficult to enforce and indicate that clear guidance should be provided. Several authorities remarked about the absence of the general requirement – in regulation 10 of the current Temperature Control Regulations - for all foods to be kept at a safe temperature. Others suggested that this opportunity should be taken to review and amend the requirements, for example, to reduce the chill holding requirement from 8°C to 5°C or harmonise the requirements across the UK. A number of respondents queried the exclusion of ships from the scope while others queried whether some of the textual changes maintained the current requirements. A number of other minor comments and suggestions were made.</p> <p>In Scotland, where different rules apply,</p> <ul style="list-style-type: none"> • Some stakeholders representing gelatine manufacturers queried whether the specific Scottish temperature controls for gelatine remained viable. • There were mixed feelings from Scottish respondents regarding the retention of the current general requirements. A majority of responses indicated that they would like to see the requirements removed as the introduction of the HACCP based requirements negate the need for specific temperature requirements. • Similarly a range of views were received from local authorities in Scotland. Some favoured full removal, and some retention as proposed in the current SI. Some comments requested a re-instatement of regulation 16 of the current control regulations. 	<p>Article 17(3) of Regulation (EC) 852/2004 permits Member States to maintain any national requirements they had adopted in accordance with Council Directive 93/43/EEC on the hygiene of foodstuffs pending the establishment of harmonised EC requirements. This was the basis of the consultation proposal for the national temperature requirements. In England, the intention is to maintain the current national requirements on this basis. Nevertheless, the Agency will review the text of Schedule 4 in light of the comments received to ensure it provides equivalent effect to the Regulations it replaces. In relation to the general requirements in regulation 10 of the current Temperature Control Requirements, these are now contained in Annex II, Chapter IX of Regulation (EC) 852/2004.</p> <p>In Scotland the intention is to retain current national requirements with regards temperature controls. However, it is proposed that in order to bring national measures more into line with those in England and Wales, the provisions relating to gelatine at regulation 15 of Part III of the Food Safety (Temperature Control) Regulations 1995 should be removed.</p>
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<p>Draft regulation 31 and Schedule 5 (small quantities of poultry/lagomorphs) - <u>Your views are sought on whether this is appropriate and whether the requirements give proper effect to that intention.</u></p>	<p>A number of respondents agreed the proposal. Some also suggested that enforcement officers should be allowed some discretion. Other specific points raised were as follows:</p> <ul style="list-style-type: none"> • A number of stakeholders sought clear definitions of “small quantities”, “final consumer” and “local retail establishments” in SI or guidance. • One stakeholder considered that geese should also be subject to small quantities provisions. • would butchers retain ability to sell delayed evisceration poultry. • A call was made for more consultation on “small quantities”. • Why the exemption was needed for poultry was questioned? <p>UNISON did not agree with the proposed approach. Same standards should apply regardless of size. Seriously question public health reasons for exemption.</p>	<p>The FSA proposal would broadly maintain current arrangements and the controls are considered to be proportionate.</p> <p>We are not permitted to define terms such as “small quantities” in the national legislation as they are contained in the EU regulations. We will outline their interpretation in guidance, along the lines originally proposed.</p> <p>Geese are included in the definition of poultry and thus these provisions also apply to them.</p> <p>Butchers would be able to continue to sell delayed eviscerated poultry provided that, as now, such birds were sourced from farms benefiting from the exemption in Article 1(3)(d) of Regulation 853/2004.</p>
<p>Draft regulation 32 and Schedule 6 (restrictions on sale of raw milk) - <u>Your views are sought on the proposal to retain the current requirements and whether the conditions laid down in Schedule 6 are adequate.</u></p>	<p>In England, this issue produced a clear division in the replies as a number of stakeholders agreed the proposal whereas a number called for a ban. Calls were made for consistent rules throughout the UK and the FSA were called upon to review its policy. A suggestion was made for limits on quantities sold.</p>	<p>In England, we are proposing to maintain the present controls, which cover the sale of raw cows’ milk for drinking, without amendment on the basis that it offers consumer choice. There is no evidence to suggest there would be any greater public support for major changes to the controls on raw milk in England than there have been in previous consultations on the issue.</p> <p>In Wales, the proposal to strengthen the labelling requirement for the retail sale of raw drinking milk and cream reflects a decision by Ministers at the</p>

¹ The Scottish Food Advisory Committee felt that the extension of the ban could be seen as disproportionate, and asked that that the Agency engage in an appropriate public communication programme.

	<p>In Scotland there was widespread support among industry, enforcers and public health bodies trusts, for not only maintaining the current ban, but also to extending it to other species.¹</p>	<p>Welsh Assembly Government. This decision followed a recommendation by the Agency in the light of responses to a public consultation carried out by the Agency in Wales in 2002. The proposed enhanced labelling requirement in Wales expands on the current labelling requirement (regulation 31 of the Food Labelling Regulations 1996) by adding a warning for vulnerable groups which reflects the Agency's current advice as stated on its website</p> <p>In Scotland, we are proposing to extend the current ban on the sale of raw milk to other species.</p>
<p>f) Legislation being revoked (Schedule 7)</p> <p><u>Your comments on the proposal to change the right of appeal against approvals to be made to a magistrates' court would be welcome.</u></p>	<p>On changing the right to appeal, general support for FSA proposal, with some concerns raised that this will add extra costs for some industry.</p> <p>Concerns raised by a number of stakeholders that the revoking of legislation should not see the reintroduction of charging.</p>	<p>FSA intention is to abolish the MH Appeals Tribunal. The right of appeal against approvals would be made in the Magistrate's Court as with other foods.</p> <p>Any questions regarding charging will be pursued separately.</p>
<p><u>Application of Regulation 854/2004</u></p> <p><u>The Agency would welcome views on its proposals for the use of company staff.</u></p>	<p>Views on this issue are clearly divided between those who agree the use of plant staff to undertake some inspection duties and those who are against. Of those who object, most do so on the basis of a foreseen conflict of interest. Other issues raised are as follows:</p> <ul style="list-style-type: none"> • Some stakeholders also see the proposal leading to a lowering of standards that would put public health at risk. • Some would like to see the use of plant staff extended to red meat plants. • Other stakeholders agree the proposals on the condition that they are properly trained to undertake the duties and are supervised by the OV. • Some stakeholders made the point that, if allowed, it would need to be determined on a case by case basis. • A call was made to continue and improve links between LAs and the MHS. 	<p>The approach outlined represents current policy and we would intend to go forward with it. The proposed company staff (Poultry Inspection Assistant - PIA) system set out in Regulation (EC) 854/2004 requires that responsibilities for production and inspection be kept separate, in order that no conflict of interest should arise. All PIAs would be supervised by the Official Veterinarian and would have had to have passed the same tests as an official inspector for the tasks they perform. We intend to maintain these arrangements as they are on the basis of proportionality. Each plant wishing to operate the PIA system would need to be specifically authorised by the competent authority and would have had to have been operating Good Hygiene Practice and HACCP procedures continuously and properly for at least a year. There is currently no legal provision to extend the PIA system beyond poultry and lagomorphs. This is a voluntary system.</p>

	<ul style="list-style-type: none"> • There does not appear to be a mechanism of authorisation of the slaughterhouse staff for whatever tasks they take on, nor a mechanism for removing authorisation where necessary. <p>UNISON considers that company staff should be trained across all hygiene sectors rather than certain modules relevant to their subject area.</p>	
<p><u>Draft FSA Guidance on the Requirements of Food Hygiene Legislation applying in the UK</u></p> <p><u>We would particularly welcome your comments on whether this guidance is clear and helpful and presented in a way that helps you to understand what the legal requirements are that food businesses have to comply with. If there are further areas which you think need explanation or clarification, please let us know.</u></p>	<p>Some supportive feedback, but strong sense that stakeholders considered the FSA guidance too complex and not user-friendly. Some terms used too technical (e.g. 'ratites', 'lagomorphs'). A number of negative comments on the constant need to cross-refer to legislation. Support for use of flow diagrams. Does not always help understand what legal requirements food businesses have to comply with.</p> <p>Overall, felt that the guidance more helpful for enforcers than business.</p> <p>Some comments that there should be more sector-specific guidance, including for primary producers</p>	<p>The FSA will look at these suggestions and seek to address stakeholders' concerns that guidance is too complex and technical.</p> <p>The FSA will also consider whether this Guidance would be appropriate in sector-specific versions.</p> <p>The FSA will continue to revise the Guidance on an on-going basis until 1 October 2005, when the document must be finalised.</p> <p>There will be a further opportunity to comment on the interpretation of terms proposed in the FSA guidance during the enforcement guidance consultation (which will need to mirror the approach used).</p>
<p><u>Paragraphs 1 and 3 – Direct supply to the final consumer, or local retail establishment, of small quantities of wild game or wild game meat.</u></p> <ul style="list-style-type: none"> • <u>In the light of the advice from the Committee do you agree that under 300 large wild game carcasses per year remains an appropriate definition of a small quantity?</u> • <u>If not, what figure do you think would represent a small quantity? Please explain the food safety basis for the figure you believe should apply?</u> • <u>What impact do you think a definition of a small quantity of large game as no more</u> 	<p>Opinion is split on this issue although a number agree the proposed limits. Specific points raised were as follows:</p> <ul style="list-style-type: none"> • Clarification is sought on whether this applies singly or collectively by species. Also who does this apply to, tenant farmers running shoots or the estate as a whole? • Some stakeholders would prefer a lower limit of 75 for large carcasses with an additional limit of 2 per week. • One stakeholder would prefer a lower limit of 5,000 carcasses for small game. 	<p>There is no agreed line from respondents. Therefore, the intention would be to go forward as proposed and review in two or three years in the light of experience.</p> <p>Approval dependent on activity not quantities processed.</p> <p>There will be a further opportunity to comment on the interpretation of terms proposed in the FSA guidance during the enforcement guidance consultation (which will need to mirror the approach used).</p>

<p><u>than 75 (or 150) carcasses per annum would have on existing local trade in wild game meat?</u></p>	<ul style="list-style-type: none"> • A suggestion was made for 1000 small game and 250 per week. • A point was made that a lower limit of 75 large game would drive trade underground. 	
<p><u>Paragraph 4 – Retail-to-retail supplies and the interpretation of “marginal”, “local/localised” and “restricted”</u></p> <p><u>It would be useful to have a more precise indication of the number and size of butchers' shops that would be affected.</u></p>	<p>Very little information received on the numbers of butchers shops that might be affected.</p> <p>Views Differ on the interpretations. Some support definitions, exemption for butchers shops and EHO inspection of low throughput. A number of stakeholders call for lenient interpretations of the terms to allow for continuation of existing practice. Some stakeholders thought the interpretations might be too broad.</p> <p>A number of different suggestions were made in relation to <u>“localised”</u>:</p> <ul style="list-style-type: none"> - 30 miles from the premises; - 50 miles from the premises; - the authority plus 1 or 30 miles from the supplying establishment whichever is the furthest; - LAs having discretion to widen the 30 miles; - it should be own district and 5 miles or within neighbouring district whichever is the lesser; - own district and 30 miles from establishment. - For NI – supply within the province of NI should be considered local or local should be the county of origin plus the neighbouring county. Consideration needs to be given to the ROI being the neighbouring county . <p>Proposed interpretation does not allow for traditional products for which the main market is London (e.g. meat from rare breeds sold to London restaurants).</p> <p>Unlikely to achieve a universally accepted notion of ‘local’. Concerns over local as it would allow someone in the home counties to supply the whole of London.</p>	<p>No universally accepted answer put forward.</p> <p>There is a judgement call to be made between the proposal and the alternatives put forward by respondents.</p> <p>We should proceed and review in light of experience. Guidance to enforcement authorities should emphasise a common sense approach.</p> <p>The EU Commission's draft interpretation paper states that, in the case of a <u>large</u> Member State, the notion of marginal, localised and restricted supply should not extend to the entire territory. This implies that our proposed interpretation of “localised” (own County plus greater of <u>either</u> neighbouring county or counties <u>or</u> 30mile/50km from the boundary of the supplying establishment's county) would be acceptable. It is liberal enough to satisfy most suppliers while affording proportionate public health protection.</p> <p>We would need to consider further, in light of Commission guidance, whether interpretation of “localised” could be waived for small amounts of high value or traditional products with a limited market, where application would limit consumer choice.</p> <p>Will be limited by interpretation of “marginal”.</p>

	<p>On “<u>marginal</u>”, a number suggested that a weight limit be applied in addition to the 25% of turnover. This would allow small suppliers to supply a greater proportion of their total output. Some said that there should be an additional qualification of 1 tonne. NAMB – 25% should apply to the volume of foodstuffs produced not turnover. Will 25% refer to turnover or weight? Limit of 25% is too low.</p> <p>Other suggested that the % of turnover meant nothing and that there should only be a weight limit (1 tonne).</p> <p>A number said that the onus to prove exemptions should be on business.</p> <p>Some asked for further clarification of the terms. How is turnover of a business to be measured? How to deal with small amounts of high value product? Is volume of sales by weight or value? Do all three apply? Do they apply to the business as a whole or individual units?</p> <p>“<u>Restricted</u>” should be given generic examples. Is the intention to exempt all butchers shops? Would all three definitions have to apply to get the exemption? Guidance unclear and difficult to understand. Need further guidance.</p> <p>Some supported proposal to replace vets with EHOs in low throughput. Some asked for more clarification on low throughput. Why replace VO with EHO when concept of low throughput is being abolished?</p> <p>HUSH – licensing scheme should be kept. Do not agree with replacing vets with EHOs in low throughput establishments. Do not agree that cutting plants should be charged on risk based frequency.</p>	<p>We are restricted by Recital 13 which interprets “marginal” as “only a small part of the business”. We have made representations to the Commission to the effect that it should be interpreted as meaning a <i>small amount</i> of food in absolute terms, as well as a small part of the business. This would allow us to exempt butchers who produce only a small amount but supply in excess of 25% to caterers. It is hoped this will be covered in the next version of the Commission’s interpretation paper.</p> <p>Turnover is the only possible measure where a variety of food products which are measured in different ways are involved, e.g. meat and milk.</p> <p>Butchers supplying the final consumer will be exempt. Those supplying other establishments with over a quarter of their production will require approval (subject to the possibility that if this is a small amount in absolute terms, the exemption will still apply). All three apply.</p> <p>Businesses with a low throughput are referred to in reg. 854/2004, but the terms are not defined.</p> <p>If the EU Commission accept our recommendation on the interpretation of marginal, we will consider further the desirability of seeking agreement to replace veterinary control with EHO control in low throughput establishments.</p>
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<p><u>Draft Summary guidance on the new food hygiene regulations</u></p> <p><u>We would particularly welcome comments on whether this guidance is of help. Are there further types of food business for which you think this type of summary guidance should be produced?</u></p>	<p>Summary guidance generally welcomed by those stakeholders who commented, but strong call for more sector-specific versions.</p> <p>A number of comments requested more detail whereas others considered they were too complicated. general dislike of the use of technical terms (e.g. ratites) and of the need to cross-refer.</p> <p>One stakeholder suggested that the titles of the documents need to be made more clear.</p> <p>Suggestions were made that the summary guidance should be produced in a wide range of languages.</p>	<p>The FSA will consider the format and content of the draft Summary Guidance on merit.</p> <p>There was a call from some stakeholders for a larger number of sectors to be covered by the Summary Guidance, including the voluntary sector. This will be considered by the FSA as will the possibility of translating the guidance into different languages.</p> <p>Farmed game will be covered in Meat Industry Guide as will wild game activity in approved premises. An industry guide covering wild game activity <i>outside</i> of approved premises will be produced for use by industry and enforcers.</p> <p>The FSA will continue to revise the Summary Guidance on an on-going basis until 1 October 2005, when these documents must be finalised.</p>
<p><u>Partial Regulatory Impact Assessment</u></p>	<p>Some areas of increased cost to stakeholders were identified, but not quantified.</p>	<p>We will continue to update and refine the partial RIA based upon comments from stakeholders.</p> <p>It should be borne in mind that some costs will be the result of the direct application of the EU legislation. This will be reflected in the Main RIA.</p>

<p><u>Primary production issues</u></p>	<p>The following points were made.</p> <p>Vital to know who will be enforcing and the regularity of inspections ASAP. There should be a single enforcement authority.</p> <p>Inspectors must interpret the requirements in a uniform manner and be trained. Consistency is most important. Need appropriate verifiable standards. Auditing of inspectors needs to be put in place. Enforcement responsibilities need to be made clear. Opportunity to rationalise enforcement. Need pragmatic, realistic and consistent enforcement. Do not 'gold plate'.</p> <p>Need very clear guidelines on interpretation of requirements. Different interpretations needed in different activities. Essential for the development of guides to good practice. Industry led guides must be compatible with inspection regime.</p> <p>Will there be an appeals panel? Are number of inspections likely to increase?</p> <p>Should use existing systems for registration requirement. Will farmer have to re-register for hygiene purposes or will existing CPH information be taken? Registration information likely to improve due to cross compliance.</p> <p>Should use e.g. assurance scheme information to meet the food chain information requirement.</p> <p>LACORS - It should not be assumed that local government could easily take on any increased role in primary production sector. FCI needs addressing.</p>	<p>We will take these points on board as we continue to develop the arrangements to apply at the level of primary production.</p>
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