

UK CONSULTATION ON REDUCING THE RISK FROM *E. coli* O157 – CONTROLLING CROSS-CONTAMINATION

SUMMARY REPORT OF RESPONSES TO CONSULTATION FROM STAKEHOLDERS

1. The consultation on the principles to be applied in controlling the risk of cross-contamination by *E. coli* O157 in order to provide clear guidance for use by all relevant food business operators (FBOs) was issued on 14 July 2010 and it closed on 5 October 2010. The reason for consulting was to obtain comments and views on the proposals described below, where possible accompanied by supporting evidence. The consultation documents were sent to 255 interested parties and all 32 Local Authorities (LAs) in Scotland, as well as being made publicly available via the Agency's website at:
<http://food.gov.uk/multimedia/pdfs/consultation/reducingriskecolio157s.pdf>

Equivalent consultations were also carried out in England, Wales and Northern Ireland. In England the consultation documents were sent to all 354 LAs and 107 interested parties, in Wales to all 22 LAs, the Wales Food Safety Technical Panel, the Communicable Disease Technical Panel, and 63 interested parties and in Northern Ireland to all 26 LAs and 298 interested parties.

2. The FSA is grateful for the comments received and has taken them into account in the decisions it has taken regarding implementation of the proposals on which it consulted.

3. The Agency wants FBOs to be absolutely clear about how to meet their generic obligation in law to produce food safely as well as their specific obligations to comply with the requirements of hygiene legislation (Article 4 and Annex II and Article 5 of Regulation (EC) No. 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs). Authorised Officers undertaking official controls should similarly be clear about whether FBOs are complying with those requirements and the steps that it would be appropriate to take when faced with non-compliance.

4. The key proposals on which the consultation sought views were that:

- Every consumer needs to be protected from the risk of an isolated instance of low level contamination of food by *E. coli* O157.
- The risk to consumers from premises handling raw and ready-to-eat food needs to be reduced by (1) separation to the highest degree physically possible, (2) cleaning and disinfection through heat or through the proper use of effective chemical disinfectants, and (3) hand washing at appropriate junctures, using appropriate technique. All 3 need to be achieved in order to reduce the risk.

- Any loss of control due to lapses in procedures would require action to protect consumers from an imminent risk and should call into question the ability of the FBO to continue to rely on current procedures.
- Whether the proposed approach should be given effect in guidance or through specific legislation.

5. There were 50 Scottish responses to the consultations, including 2 from food business operators/representative industry organisations, 14 from enforcement/government departments, and 34 from consumers. Of the consumer responses received, 30 were based on a template generated by HUSH (Haemolytic Uraemic Syndrome Help) and 2 were based on a template response generated by Consumer Focus Wales.

6. The table below summarises the responses to the consultation in terms of the specific questions posed. The FSA's considered responses to stakeholders' comments are given in the last column of the table.

7. A list of those who responded can be found at the end of the document.

SUMMARY OF CHANGES MADE:

None to consultation letter proposals.

Final IA familiarisation costs recalculated – see responses to IA questions no.2 and no.4.

Comments relating to proposals in the consultation		<u>Response</u>
Q1.	Do you agree that the underpinning principle for the guidance should be that every consumer needs to be protected from the risk of an isolated instance of low level contamination of food by <i>E. coli</i> O157? If not, what alternative would you suggest?	
	There was strong support for this proposal from all sectors with 100% of those who responded agreeing with this underpinning principle. However, a significant proportion of these respondents (60%, all consumers responding using a HUSH letter response template) while supporting the issue of guidance in the short term would also advocate the Agency pursuing ‘Option 3’ of the consultation document, to introduce national legislation legally requiring the controlling measures proposed.	The Agency will be pursuing the option for introducing a legislative requirement further, supported by information gained through implementation of the guidance.

Note - This table provides a summary of the consultation responses only. Copies of the individual responses have been filed with the Agency's Library and Information Service.

Q2	<p>Do you agree that the elements described in paragraph 9 a)-c) are an effective and proportionate approach for FBOs to controlling the risk of <i>E. coli</i> O157 contamination?</p>	
	<p>100 % of consumer responses and 87% of enforcement and other government department respondents agreed with this proposal.</p> <p>Responses from industry also recognised the serious threat that <i>E. coli</i> O157 poses to consumer safety (both respondents agreed). However, enforcement responses reflected concerns about the need for a proportionate approach to control measures.</p>	<p>The guidance may not meet the expectations of some stakeholders in relation to the overriding need for separation and in particular the need to provide separate machinery, such as vacuum packers for raw and ready-to-eat foods. However, in terms of proportionality the approach taken in the guidance is intended to reflect the general proposition set out in the consultation that <i>every consumer needs to be protected from the risk of an isolated instance of low level contamination of food by E. coli O157 as to the degree of protection required.</i></p>

Note - This table provides a summary of the consultation responses only. Copies of the individual responses have been filed with the Agency's Library and Information Service.

<p>Q3</p>	<p>In particular, is achieving separation to the highest degree physically possible, including dedicated (single purpose) use of complex, hard to clean, equipment such as vacuum packers, mincers and slicers a proportionate response to the risk? If not, what alternative would you suggest?</p>	
	<p>100% of consumers, 78.6% of enforcement and other government departments and 50% of industry agreed that achieving separation to the highest degree physically possible, including dedicated (single purpose) use of equipment such as vacuum packers was a proportionate response to the risk.</p> <p>Those disagreeing with this proposal contended that ‘complex’ equipment can be cleaned properly, separation is not practical in very small premises and that HACCP plans are sufficient with further guidance not being required.</p> <p>Enforcement responses called for a clear definition of what ‘separation to the highest degree possible’ means.</p>	<p>Given the strong support for control measures based on separation to the highest degree physically possible the Agency’s guidance will be substantially in line with the consultation proposal and will stipulate the need for dedicated (single purpose) use of complex, hard to clean equipment such as vacuum packers, mincers and slicers, and that dual use of such equipment should never be regarded as a safe practice. It will also state the necessity for separation of raw and ready-to-eat foods and their handling and will describe the circumstances when physical separation is always required. In response to the request for clarity in definitions, the guidance will provide clear advice on separation. In the limited and defined circumstances where separation may not be physically possible, the guidance will describe the key elements required to control cross-contamination.</p> <p>Notwithstanding the overriding requirement for physical separation, the guidance will emphasise the need for appropriate hygienic design of all food equipment and machinery and advice will be given on the applicable standards for hygienic design of machinery.</p>

Note - This table provides a summary of the consultation responses only. Copies of the individual responses have been filed with the Agency's Library and Information Service.

<p>Q4</p>	<p>Is the approach for Authorised Officers described in paragraph 11 proportionate, effective and clear? If not, what alternatives would you suggest?</p>	
	<p>Responses from enforcement interests, whilst generally supportive, requested clarity about the practicalities of enforcing in line with the proposed approach. A significant proportion (43%) of enforcement respondents indicated that they did not agree that the proposed approach for enforcers was proportionate, effective and clear. The majority of these responses sought clarification in a number of areas, particularly in relation to terminology such as ‘physically possible’, when used in the consultation as a factor liable to limit the extent of separation achievable in practice.</p> <p>A large number of enforcement responses reflected on the need for the availability of Remedial Action Notices (RANs) as an enforcement option to deal with non-compliance to be extended to all food premises, rather than just approved premises as is currently the case.</p> <p>Enforcement responses requested separate guidance for enforcers and food business operators to reflect the different needs of the audiences.</p>	<p>The guidance will expand significantly on the general principles contained within the consultation document and will provide clarification to address the specific points raised (see also Agency response to Q.3.). It will include actions that enforcing officers must consider in order to protect consumers in circumstances where a FBO has not identified and controlled hazards appropriately. In particular the consideration of the issue of Hygiene Emergency Prohibition Notices where inadequate control presents a risk of direct or indirect contamination of ready-to-eat foods by <i>E.coli</i> O157.</p> <p>The Agency intends to hold a public consultation on the extension of RANs to all food premises. [This consultation will form part of a separate, but linked, piece of work to review the adequacy of legal powers for local authorities in response to the Public Inquiry.]</p> <p>The guidance will give very clear messages to both enforcers and industry about the assessment of risk and the immediate steps to protect consumers where control measures have lapsed. The Agency will be assessing the need for separate advice in the light of experience from implementing the guidance. See Agency response to Q.6.</p>

Note - This table provides a summary of the consultation responses only. Copies of the individual responses have been filed with the Agency's Library and Information Service.

Comments relating to proposals in the consultation		Response
Q5	We would intend to issue guidance based on these principles to provide clarity to FBOs and Authorised Officers, so that both can be clear about how to comply and how to address non-compliance. Do you agree that such guidance would be useful for FBOs and/or for Authorised Officers?	
	There was overwhelming support for the issue of guidance with 100% of those who responded to this question agreeing to this proposal even where respondents also wanted the agency to pursue national legislation (see also responses to Q.1).	The Agency is pleased to note the positive response from all sectors and will be issuing detailed guidance covering the proposals outlined in the consultation for use by all FBOs and Authorised Officers.

Note - This table provides a summary of the consultation responses only. Copies of the individual responses have been filed with the Agency's Library and Information Service.

<p>Q6</p>	<p>Do you have any views of the form or format that the proposed guidance should take? In particular, what would help in relation to the suitability and use of cleaning and disinfection materials?</p>	
	<p>A large number of enforcement and industry respondents offered a broad range of suggestions on the style, format and content of the guidance. For example, the guidance should be in plain English, available in a number of languages, should include pictorial guides, should be detailed enough to ensure consistency and that separate guidance is required for different sectors.</p> <p>With regard to the suitability and use of cleaning and disinfection materials a total of 23.5% of enforcement and other government departments, and industry suggested that the Agency should produce a prescribed list of cleaning products with appropriate contact times. 59% suggested that information should be provided on existing European Standards for cleaning chemicals.</p>	<p>The Agency has, as far as possible, considered the suggestions offered in formulating the guidance. The guidance is intended as a source document for both industry and enforcers from which messages can be taken to produce further targeted guidance for specific audiences. This recognises the emerging findings from our work on understanding behaviours which emphasised the need for effective, targeted messages. The Agency will be taking forward a further programme of work to consider how best to target specific audiences. To inform this, we will be actively seeking feedback from FBOs and enforcers on implementation of the guidance.</p> <p>The guidance will provide advice on the selection and use of chemical disinfectants by reference to existing European standards. It is not considered practical for the Agency to produce, and most importantly, keep up-to-date, a prescribed list of cleaning products.</p>

Note - This table provides a summary of the consultation responses only. Copies of the individual responses have been filed with the Agency's Library and Information Service.

Comments relating to proposals in the consultation from the Impact Assessment (IA)		Response
Q1	Whether the suggested list of categories of premises likely to be affected is accurate.	
	Of those who addressed this question the vast majority believed that the Agency's estimations of the types of business involved in raw and ready-to-eat food processing was accurate.	Due to the lack of evidence or referencing to support the alternative estimate and in the light of the support given by the majority of stakeholders to the Agency's estimate, the Agency will prepare the final impact assessment in line with its estimation for the number of establishments effected.
Q2	The likely cost to businesses (with supporting evidence where possible) in terms of familiarisation with proposed guidance, the purchase of additional equipment to comply with physical separation and/or necessary changes to business' premises to achieve complete physical separation of raw and ready to eat foods.	
	<p>Scottish responses to this question were limited, with only 4 responses. These responses indicated that the costs to small business could be disproportionate, will vary from plant to plant but would not be significant to SMEs supplying major multiples. Of those who addressed this question across the UK all suggested that it is estimated that it will take 2 hours per business to read and familiarise themselves with the guidance document and disseminate this through the business rather than the one hour suggested in the consultation IA.</p> <p>The Agency received very limited information from responders in relation to costs for the purchase of additional equipment to achieve physical separation.</p>	<p>Accepted. Final IA amended to reflect respondent's views on familiarisation and costs recalculated.</p> <p>Due to the lack of evidence supplied the Agency was unable to estimate costs in relation to the purchase of additional equipment.</p>

Note - This table provides a summary of the consultation responses only. Copies of the individual responses have been filed with the Agency's Library and Information Service.

Q3	Whether it is agreed that large business are unlikely to incur significant cost in complying with the proposed guidance due to the existing nature of their operations.	
	This view was supported by all of the consultation respondents who specifically addressed this point.	Noted and text of Final IA amended.
Q4	Whether the estimated cost to local authorities is considered accurate or if there are any additional costs that will result from the proposed guidance	
	<p>Of those who addressed this question the majority (80%) suggested that the time allocated for and reading and dissemination was inadequate. It is estimated that an Environmental Health Officer (EHO) will invest one hour reading and familiarising themselves with the guidance document and a further hour training other key staff (other EHOs) in the organisation, meaning a total of two hours for familiarising and training of the technical requirements for the primary EHO and additional hour of training time for each EHO within the authority of how the proposed guidance should be applied by an FBO.</p> <p>Respondents believed that the Agency had also not considered the Officers role in providing expert advice to food businesses on how this guidance should be implemented. The Agency would need to cost for this technical support role.</p>	<p>Accepted. Final IA amended to reflect respondents view and costs recalculated.</p> <p>Accepted. Final IA amended to reflect respondents view and costs recalculated.</p>
Q5	Whether local authorities agree with the described benefits and/or consider that there will be additional benefits from the introduction of the proposed guidance.	
	Of those who addressed this question 100% agreed with the described benefits.	Noted.

Note - This table provides a summary of the consultation responses only. Copies of the individual responses have been filed with the Agency's Library and Information Service.

ACTIONS TO BE IMPLEMENTED:

Guidance to be published, with the Agency taking forward a further programme of work to review its implementation and consider how best to target specific audiences. The Agency will be pursuing the option for introducing a legislative requirement further, supported by information gained through implementation of the guidance which sets out how FBOs are to meet their legal obligations.

Note - This table provides a summary of the consultation responses only. Copies of the individual responses have been filed with the Agency's Library and Information Service.

Respondents to the consultation

	Respondent
1.	Peter Anderson
2.	Frank Feechan- Dundee City Council
3.	Lyn Farmer
4.	Sara Meissner
5.	Claire Dishon
6.	Ian Anderson- Scottish Association of Meat Wholesalers
7.	Dr John Cowden- HPS
8.	Dr Margaret Hannah- HPS
9.	Craig Brown- South Lanarkshire Council
10.	Dr Ken Oates- NHS Highland
11.	Consumer
12.	Consumer
13.	Consumer
14.	Consumer
15.	Consumer
16.	Consumer
17.	Consumer
18.	Consumer
19.	Consumer
20.	Consumer
21.	Consumer
22.	Consumer
23.	Consumer
24.	Consumer
25.	Consumer
26.	Consumer
27.	Consumer
28.	Lorraine MacGillivray- Stirling Council
29.	Ken Jones- Scottish Borders Council
30.	Consumer
31.	Consumer
32.	Consumer
33.	Consumer
34.	Consumer
35.	Consumer
36.	Consumer
37.	Consumer
38.	Consumer
39.	Consumer

40.	Consumer
41.	Consumer
42.	Consumer
43.	Andrea Carson- Aberdeen City Council
44.	George Fairgrieve- SFELC
45.	Graham Ross- West Dumbartonshire Council
46.	Mary Lawton- Consumer Focus Scotland
47.	John Sleith- Falkirk Council
48.	Kenny Riddoch- Fife Council
49.	Kaarin Goodburn- Chilled Foods Association
50.	Alan Morrison- Argyll & Bute Council