

RESPONSE TO THE CHIEF MEDICAL OFFICER'S REVIEW OF THE OUTBREAK OF E.COLI O157 IN SOUTH WALES FROM SEPTEMBER 2005

The Food Standards Agency has welcomed the Chief Medical Officer's review and is committed to addressing the recommendations within it. This document sets out the Agency's initial response to the recommendations, which are numbered as in the review itself, for ease of reference.

Recommendations addressed to the Food Standards Agency

4.1.1 The FSA ensure that all local authorities in Wales have a clear understanding regarding –

- **The timetable for the implementation of the new EU food hygiene regulations.**
- **The material changes to be implemented by the regulations and**
- **The transitional arrangements for their introduction.**

The new regulations were not in force at the time of the outbreak, or at the time the review was conducted.

The Food Hygiene (Wales) Regulations 2005 were approved by the Assembly on 29 November and came into force on 1 January 2006. These Regulations provide for the execution and enforcement of the new EU food hygiene legislation, which applies directly across the EU from 1 January 2006. This EU legislation has as its primary objective the optimisation of public health protection, by improving and modernising the previous sector specific EU legislation. **The EU legislation emphasises that it is the responsibility of food businesses to produce food safely.** It introduces more risk based and flexible procedures, better matched to the needs of individual businesses and to enforcement, and facilitated by the introduction of food safety management procedures based on the application of Hazard Analysis and Critical Control Points (HACCP) principles.

The Food Hygiene (Wales) Regulations 2006 came into force on 11 January 2006 and revoked and remade the Food Hygiene (Wales) Regulations 2005. The 2006 regulations were necessary to apply some transitional and implementing measures not published by the European Commission until 22 December 2005 and which could not therefore be implemented in UK law by 1 January 2006. Training has been provided to Welsh local authorities in December 2005, and local authorities were notified as soon as the 2005 Regulations were approved by the Assembly, and were kept updated throughout December on the timetable for the coming into force of the second set of regulations. Written guidance has also been issued and is available on the Agency's website and more will follow. This guidance has been subject to wide consultation, including with local authorities. The Agency is continuing to liaise with local authorities and the industry over the legislative requirements and enforcement responsibilities.

Both the 2005 and the 2006 Regulations were brought into force at the same time as parallel regulations in the rest of the UK.

4.1.2 The FSA should examine in detail, and provide a report for the Minister for Health and Social Services, as to whether –

- **In relation to the premises of John Tudor and Son, the appropriate Food Hygiene Legislation was correctly applied by the Local Authority to those premises.**
- **The existing Food Safety Legislation was adequate to enable the local authority effectively to control the operations at those premises.**
- **Whether designation as a meat products plant would have provided alternative controls.**

A factual report on the inspections carried out by the local authority at the premises concerned was provided to the Minister for Health and Social Services on 7 October 2005. A full assessment along the lines of the recommendation was not possible at that stage and the Minister was briefed on this. The local authority did apply the correct legislation. The Agency agrees with the statement in the CMO's report that "the current legislative framework if properly implemented, appears to be fundamentally satisfactory to protect public health".

The Agency will shortly submit a further report to the Minister on the local authority's enforcement action in this case.

The review asks whether designation as a meat products plant would have provided alternative controls. The business concerned could not, however, have been designated as a meat products establishment, as the relevant legislation did not apply to those supplying the final consumer and the term 'final consumer' was defined to include caterers. The premises was a catering butcher, subject to butchers' licensing, and was correctly identified as such at the time of the outbreak. Notwithstanding this, the essential food hygiene tenet applied by both sets of regulations is that hazards must be identified and controlled.

4.1.3 The FSA provides an assurance to the Minister for Health and Social Services that guidance and practice in respect of butchers' premises, both now and in the future reflect the importance of a fully implemented HACCP system as an integral part of a good food safety management system and not as an end in itself.

HACCP and good management should be consistent. The legislation in place at the time of the outbreak required food safety management based on HACCP principles in licensed butchers' premises. The Agency agrees that relevant guidance should highlight the importance of such food safety management systems.

4.1.4 The FSA provides an assurance to the Minister for Health and Social Services that the repeal of licensing provisions for butchers' premises will not diminish the legislative controls available to Local Authorities.

The Minister was advised of the Agency's decision to end the licensing scheme for butchers' shops selling raw meat and ready to eat foods from the same premises once the Food Hygiene Regulations came into force. Detailed briefing was provided about practical aspects of the new Regulations, including the role of food safety management systems and requirements for premises handling raw and ready to eat foods, and the end of butchers' licensing.

The Agency considers that Butchers' licensing as envisaged by the Pennington Group (which was set up following the 1997 E.coli outbreak in Central Scotland) has served its original purpose. The Pennington Group recommended butchers' licensing as a temporary measure until new EU hygiene legislation required all food businesses to operate HACCP procedures. Such new rules took effect on 1 January 2006. Full details of the new hygiene legislation can be found on the Agency's website (<http://www.food.gov.uk/foodindustry/hygiene/>) and the Minister was briefed on the issue.

FSA evaluations of butchers' licensing showed that the initiative had achieved a good measure of success in raising hygiene standards and supporting the introduction of HACCP procedures in butcher shops, to the point that butchers' were now well placed to comply with the new EU requirements. And because the new EU hygiene rules impose substantially equivalent hygiene requirements on butcher shops as applied to them under licensing, public health will remain protected provided the new EU requirements (as with the licensing regime) are properly applied and enforced.

The Agency's Board considered this issue at its open meeting in March 2005 following wide consultation. A substantial majority of consultation responses from across the UK supported ending butchers' licensing, and responses to the consultation did not indicate opposition by Welsh local authorities to the ending of licensing. The butcher referred to in the CMO's report had been licensed from August 2002 and this licence was renewed by the local authority concerned 2 months before the outbreak following an inspection.

The Agency does not consider that this outbreak gives cause to change the decision to replace licensing with the EU hygiene legislation. This was confirmed in discussion at the Board's open meeting in February 2006.

4.1.5 The FSA should consider whether additional guidance on appropriate food safety measures should be provided to food businesses handling both raw and cooked meats.

The Agency has, on a number of occasions, issued advice to local authorities and food businesses on the importance of the proper segregation of raw and cooked food. The Agency's food hygiene campaign emphasises in particular the need to avoid cross contamination. The Agency will consider whether additional guidance would be

appropriate, and will continue to reinforce messages about avoiding cross contamination between raw and cooked meats, and in any other circumstances where there is a risk of contamination of ready to eat products.

4.1.6 The FSA should reappraise their advice to Local Authorities in respect of inspection frequencies.

The Agency keeps under continuous review its advice to local authorities in relation to inspection frequencies and as part of the review of the statutory Code of Practice currently underway, we will consider this once more. The inspection frequencies set out in the Code of Practice are clearly minimum frequencies and we would expect authorities to plan to achieve 100% of inspections due in high risk premises. The Agency recognises that other activities to increase compliance or tackle imminent food safety risks, such as the provision of appropriate advice, also have a role to play in ensuring compliance, and supports an integrated approach with the appropriate enforcement mix. The rationale for this recommendation referred to the possibility of judicial review where a local authority chose to conduct more than the minimum number of inspections. This has not been raised with the Agency before and is not seen as a reason to limit the numbers of inspections where these are judged appropriate on a risk basis. This will be discussed with LACORS and local authorities, as recommended.

4.1.7 The FSA reviews the operation of their current auditing regime of Local Authorities in Wales.

The Agency announced in October 2005 that it would review its UK audit programme and the Minister was advised of this. Arrangements for this review are underway. Full audits of the whole range of food safety and standards functions in every local authority in Wales were conducted between July 2001 and February 2005 and reports are available on the Agency's web-site.

Although, owing to competing priorities there were delays in finalising the formal reports, all authorities were given detailed feedback at the time of audit.

4.1.8 The FSA should clarify to the Minister for Health and Social Services, what it considers its own role in food poisoning and foodborne infections outbreak control to be and the basis upon which this has been established. Any anomalies

or variance with existing plans or guidance should be resolved and agreed with their partners.

At the time of the outbreak, the Agency had just commenced a review on the Management of Outbreaks of Foodborne Illness. We agree that all parties need to be clear on roles and responsibilities and will be working with relevant agencies within Wales and in the rest of the UK to ensure that the guidance fully reflects the needs of Wales while facilitating the effective management of cross-border outbreaks.

The Agency took over responsibility for foodborne disease policy from the UK health departments on its establishment. The Food Standards Act 1999 gives the Agency power to issue guidance to public authorities on foodborne disease outbreaks.

In line with the recommendation, a note on the Agency's role will be provided to the Minister.

Other comments

The Agency will also consider the recommendations addressed to the Outbreak Control Team, since it was a member of the Team, and is keen to be involved in discussions on the issues raised, where these fall within the Agency's remit.

We would also offer comments on the following matters raised, which although not addressed as recommendations to the Agency, do concern issues within the Agency's remit.

Recommendation 4.2.2

This recommendation concerns local authorities working with the FSA in the introduction of the new EU Food Hygiene Regulations. The Agency agrees that local authorities and the Agency need to work together on the implementation of the new regulations – in relation to all food premises, including butchers. This will be achieved through regular communication with all local authorities; specific training; and regular liaison meetings with nominated LA representatives. The Agency consults the Food Safety Technical Panel, The Communicable Disease Technical Panel, The Food and Agricultural Standards Group and the Port Health Technical Panel on local authority

training needs. This process has been agreed with the Directors of Public Protection, under whose auspices these groups operate, and ensures that training can be prioritised according to identified needs. The rationale for this recommendation includes a reference to a paper considered by the FSA Board in March 2005. (Paper and minutes available at www.food.gov.uk/aboutus/ourboard/boardmeetings)

The 30% figure referred to was the estimate of the proportion of all food businesses in Wales at that time with food safety management (HACCP) systems in place. Within that figure, 100% of butchers selling unwrapped raw meat and ready to eat foods from the same premises were required to be operating such systems. Action to increase uptake of food safety management in other premises has varied across the UK according to the availability of resources. Since 1 January 2006 all food businesses are required by law to operate food safety management procedures. Compliance is the responsibility of the food business operator. Welsh local authorities are working to increase compliance through their advisory work and through appropriate enforcement action when breaches of the law are found.

Application of the new Regulations to Catering Butchers

Annex D of the report suggests that the business in question might need to be registered after 1 January 2006 but would not need to be approved under the Food Hygiene Regulations. At the time of the outbreak the business operated as a catering butcher and was licensed as such. The business concerned could not, however, have been designated as a meat products establishment as the relevant legislation did not apply to those supplying the final consumer and the term “final consumer” was defined to include caterers. The definition of “final consumer” has now changed significantly and consequently many catering butchers will now require approval under the new regulations. The premises had already been identified by the local authority as one which (were the nature of its business to remain unchanged) would need to be approved as a cutting plant and transferred to MHS enforcement at the appropriate time.



**From the Chair,
Dame Deirdre Hutton CBE**

Dr Brian Gibbons AM
Minister for Health and Social Services
Welsh Assembly Government
Cardiff Bay
Cardiff
CF99 1NA

8 February 2006

When we met in November, I informed you that the Agency would be carrying out its own internal review of its handling of the E.coli O157 outbreak in South Wales. As I explained, it is standard procedure within the Agency to review all major food incidents to identify ways in which we can improve our internal procedures and improve our response. In these reviews we assess the management of the incident against the principles of an agreed protocol. I promised to notify you of the outcome of the review and to feed any lessons learned into the Assembly's inquiry.

The internal management of the incident was reviewed formally in line with the Agency's usual procedures and the findings considered by the Board in December.

I attach a table of the key lessons learned from the review. In common with other incidents, some of the main issues related to roles and responsibilities and communication. A need for greater clarity between the headquarters and devolved parts of the Agency over internal roles and responsibilities was identified. This will be reflected in a forthcoming revision of the Agency's internal protocol for incident handling. It was also noted that the protocol could reflect more clearly the fact that the Outbreak Control Team sets the 'rhythm' of the incident and that this must form part of the overall forward planning of how the Agency responds.

Staff Training on the management of incidents, which is already planned, will address issues arising from recent internal incident reviews.

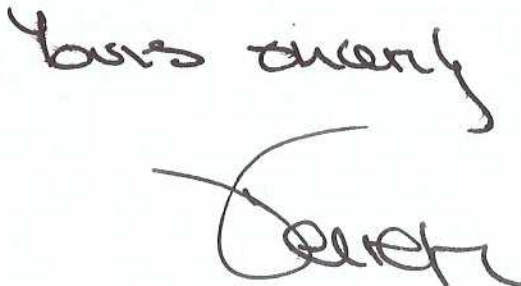


It was noted that in this and other outbreaks there needs to be a clear understanding of the Agency's particular role and obligations in relation to external communication. In this case the Agency did discuss this in the Outbreak Control Team at an early stage, and media handling, co-ordinated for the team by the National Public Health Service, appears to have worked well. However, in this and other outbreaks, there were occasions where the Agency needed to explore different approaches, and it may be beneficial for this to be discussed with local authorities and the NPHS outside of an outbreak situation, to strengthen a shared understanding of respective roles and responsibilities in such situations.

Complex incidents do have a substantial impact on the ability of the Agency to make progress in other areas. This is a strategic issue for the Agency and we are considering how to take this forward.

It is clear that this outbreak put considerable demands on the already-stretched resources within FSA Wales. (Completion of audit reports on local authorities was an additional pressure on the Agency's enforcement branch in Wales, where capacity was already identified as a concern). The resourcing issues both in Wales and in relation to the investigation of major incidents do need further consideration, and I know that my officials have been in discussion with yours on these issues.

In summary, the review concluded that the Agency was able to fulfil its role as an active member of the Outbreak Control Team as soon as a food hazard was identified, and no serious shortcomings in the Agency's response were found. I can assure you that the lessons learned will be acted on, and that, should other issues be identified in the course of the Inquiry, these will be addressed.

A handwritten signature in black ink, appearing to read 'DAME DEIRDRE HUTTON', written in a cursive style.

DAME DEIRDRE HUTTON

TABLE 1: LESSONS LEARNED FROM INTERNAL REVIEW

LESSONS LEARNED	ACTIONS TAKEN
1. <u>Roles and Responsibilities</u>	
<ul style="list-style-type: none"> • Need forward planning on how the the Agency works with Outbreak Control Teams (OCT) and handles joint or separate communications with the media and stakeholders 	<p>Revisions to Incident Protocol to reflect need to establish clarity of roles and communication priorities with OCT at early stage of engagement</p>
<ul style="list-style-type: none"> • HQ needs to maintain a strategic overview of the incident leaving incident Manager in Wales (or Scotland/NI) to lead on operational matters 	<p>Establish single point of contact in HQ for all daily communications and updates for senior management, Board and Ministers, in line with arrangements for Sudan I</p>
	<p>Training in management of incidents to be rolled out in first half of 2006 to get better clarity of roles.</p>
2. <u>Resources</u>	
<ul style="list-style-type: none"> • Need flexible contingency plans to enable staff resources to be re-allocated quickly to support incident response, especially if incident is in Wales, Scotland or NI 	<p>Staff from HQ were sent to Wales at an early stage to to assist with the investigation</p>
	<p>Further consideration needed on how to resource the investigation of major incidents, especially when they occur in Scotland, Wales or NI</p>
<ul style="list-style-type: none"> • Completion of the audit reports of local authorities in Wales at the same time as responding effectively to the incident put demands on the already stretched resources in FSA Wales 	<p>Need further discussions with Welsh Assembly to secure adequate funding for FSAW</p>
	<p>Questions about the LA audit issues in Wales were dealt with by staff working long hours and audits were completed but this put the FSAW team under significant strain as they were dealing with the incident at the same time</p>