

EU FOOD HYGIENE REGULATIONS

Executive Summary

1. The Board is asked to:

- **note** the outcome of the public consultation on the draft national legislation, guidance to industry and Regulatory Impact Assessments (RIAs) to apply the EU food hygiene regulations.
- **agree** that the conclusions officials have reached on the responses to the consultation are the right way forward on the issues where some degree of flexibility is allowed.
- **note** that officials are working in parallel on various pieces of statutory guidance and other instructions to enforcement authorities and will conduct public written consultation on these from April 2005.
- **note** that officials will report back to the Board on the outcome of the ongoing work on industry and enforcement guidance in the Autumn.
- **agree** the approach proposed as the basis for seeking Ministerial agreement to the national regulations.

FOOD HYGIENE IMPLEMENTATION DIVISION

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EU FOOD HYGIENE REGULATIONS

Issue

1. To apply the new legislative framework so that it protects consumers and is practicable and proportionate and can be equitably and consistently enforced.

Strategic Aims

2. Appropriate application of the new legislation in the UK is expected to contribute to the FSA strategic plan objective of further reducing foodborne illness. These measures will help promote best practice within the food industry and increase consumer confidence.

Background

3. New EU food hygiene regulations¹ entered into force on 20 May 2004 and will apply directly from 1 January 2006. The new legislation represents a major streamlining and modernising of food safety controls. It replaces the existing sector-specific prescriptive controls of the current general food hygiene directive and 16 vertical directives covering various products of animal origin with a more risk based approach. The responsibility for producing food safely will rest more clearly with the food business operator. The new legislation applies throughout the food chain, including in most areas of primary production for the first time. The Board has been kept informed on the progress of the negotiation of the new legislation. The Board was last updated by an information paper at its September 2004 meeting (INFO 04/09/01).
4. One of the most notable changes from existing legislation will be a requirement on all food businesses (other than primary production) to operate food safety management procedures based on HACCP principles. In negotiating the legislation the main aim for the FSA in representing the UK was the achievement

¹ Regulation EC No. 852/2004 - applying general food hygiene rules to all food businesses. Regulation EC No. 853/2004 – applying specific food hygiene rules on food businesses for certain products of animal origin.

Regulation EC No. 854/2004 – applying official controls on the products of animal origin covered by 853/2004.

Directive EC No. 2004/41 – repealing or otherwise amending certain existing directives.

of effective, proportionate and risk-based controls. The focus was on high-level objectives with a view to securing less prescription and a more proportionate approach, particularly in relation to the application of HACCP-based procedures. The Board has received a progress report (FSA 04/03/03) on planned action to promote implementation of these new procedures and will receive a further update at this meeting (FSA [DN ref to "Implementation of Food Safety Management Paper]).

Outcome of the consultation

5. Officials consulted on the basis described in the September 2004 Board paper and consultation ended on 31 January 2005. Full details of the consultations are available on the Agency's website. A summary of the main issues on which stakeholder views were sought and the views received is at Annex A , together with the approach officials propose to take in respect of these issues. The main issues to arise are discussed further at paragraphs 7 to 20 below.
6. In order to give the Board a fuller picture of the issues impacting on application of the legislation, Annex B contains a table detailing the provisions in the EU Regulations where national policy decisions are required in order to apply the legislation or where additional options are available to Member States. The table sets out the approach we propose to take to secure an application of the legislation in line with the high-level aims of proportionate, risk-based effective controls. Unless otherwise stated, the approach will be to maintain current arrangements in line with these aims. The table also indicates areas where we need to develop instructions/guidance to enforcers. As mentioned in paragraph 21 below this will be the subject of further public consultation.

Particular issues for Board attention

Raw Drinking Milk and Raw Cream

7. The EU Regulations allow us to introduce or maintain national rules restricting the placing on the market of raw milk or raw cream for direct human consumption. There are existing, but different, approaches in the countries of the UK, and there has been extensive consultation on policies in this area, including on the policy options to apply the hygiene legislation in the EU, as well as in this most recent consultation.

8. In England it is proposed to maintain the current controls whereby raw cows' drinking milk may be sold only under strict marketing conditions and providing it carries a health warning label. Existing labelling requirements, together with information on the FSA's website, are considered to represent a proportionate and balanced approach to protecting consumers, bearing in mind drinking patterns. Relatively few people drink raw cows' milk, and they choose to do so regardless of the label warnings. The FSA in England makes it clear in its advice, that despite being popular with some consumers, raw milk and cream are, nevertheless, high risk products.
9. In Northern Ireland there are no retail sales of raw cows' milk for drinking and it is proposed to maintain existing controls.
10. In Scotland, the sale of raw cows' drinking milk and cream was banned in the 1980s following a number of milk related illnesses over a number of years. The ban resulted in a marked decline in milk-related illness that has subsequently been maintained. Scottish Ministers have recently reaffirmed that the ban should be retained, and decided that it should be extended to raw milk and cream from other species. This view has been endorsed by the vast majority of stakeholders in Scotland in the latest round of consultation.
11. In Wales, the proposal is to maintain existing marketing controls for raw cows' drinking milk, but to strengthen labelling requirements. This reflects a decision by the Minister for Health and Social Services at the Welsh Assembly Government in 2002 following an FSA stakeholder consultation.
12. In summary, in England the proposal is to maintain existing controls for raw cows' drinking milk comprising strict marketing conditions and labelling requirements. In Northern Ireland where there are no retail sales of raw cows' milk for drinking existing controls are also to be maintained. In Scotland the proposal is to maintain the ban on raw cows' drinking milk and cream and to extend it to other species, e.g. ewes, goats and buffaloes. In Wales, the proposal is to maintain existing marketing controls, but to introduce enhanced labelling requirements for consumers. These approaches are contained in the draft Statutory Instruments for each country.

Temperature control requirements

13. The temperature controls at the level of retail and catering may be an area where eventually the Commission proposes harmonising legislation. Until then member states can retain national requirements. The proposal is to retain current national requirements (with a minor adjustment in Scotland), thereby maintaining the level of protection to consumers while avoiding the possibility of subjecting industry to further legislative change before harmonised measures are adopted.
14. In England, Wales and Northern Ireland a maximum holding temperature for chilled foods of 8°C and a minimum holding temperature for hot foods of 63°C would therefore be retained. In Scotland, the general temperature control provisions would also be retained (i.e. the maximum temperature of 8°C for chilling foods is not specified, but businesses are still required to chill foods as necessary) whilst it is proposed that the specific requirements for gelatine, which are currently unique to Scotland, would be dropped. It is considered that the risk based controls introduced by the EU regulations for all food businesses, in tandem with the general temperature control provisions which are being retained, would provide sufficient public health controls for this sector in Scotland. In light of the comments offered by respondents across all UK countries, we will review the proposed text to ensure it provides equivalent effect (as appropriate) to the Regulations it replaces.

Use of plant staff in certain slaughterhouses

15. The new Regulations allow the continued use of slaughterhouse staff to undertake official controls under the direct supervision of the official veterinarian in poultry and rabbit slaughterhouses. The UK is one of the Member States which currently allows such use. Inspection arrangements involving plant staff in the UK and in other Member States have always been found satisfactory by Commission auditors. There are no public health grounds for discontinuing their use. However, the new rules contain more extensive training requirements and further restrict the use of plant staff to slaughterhouses where operators have demonstrated an ability to take responsibility for the safe production of meat.
16. Under the new regulations plant staff must be trained in the same way and pass the same examination as meat hygiene inspectors before being allowed to carry out the same tasks. Although under the new rules plant staff could undertake all

the tasks carried out by meat hygiene inspectors, it is expected that in practice they will only assist in carrying out post-mortem inspection. We propose to apply the legislation to require plant staff, where they only assist in carrying out post-mortem inspection, to undertake only the relevant parts of the training and pass only the relevant parts of the examination. UNISON, the meat hygiene inspectors' union, has challenged the legality of this proposal, arguing that plant staff should be required to pass all the parts of the examination taken by meat hygiene inspectors. Our legal advice is that our approach is allowable under the legislation.

Guidance material issues

17. Stakeholders were invited to comment on the format of the guidance material as well as on specific points of interpretation. This latter had also been the subject of consultation in the previous policy options exercise.
18. We are reflecting on the format of the guidance in the light of comments received.
19. The major issues with regard to the content of the guidance continue to be the way in which terms are used without definition in the EU legislation. The interpretation of these terms including “small”, “marginal”, “local” and “restricted” will have an impact on which requirements of the legislation are to apply in particular cases. As with the previous consultation stakeholders have highlighted a wish for clarity, precision and consistency of treatment, but there is very little agreement on how this is to be achieved within the constraints of the legislation and our room for manoeuvre. A further complication is that the Commission intends to bring forward guidance on the interpretation of these (and other requirements). Although this would have no significance in law, it will be influential as a statement of intention.
20. Under the circumstances and given that no new arguments have been brought forward to counter the broad approach we are taking, officials propose to work further on the guidance material for industry, in the light of the comments received and the development of Commission guidance.
21. A review of the **Enforcement Code of Practice** and **Enforcement Practice Guidance** is also underway to ensure they address changes introduced by the new legislation. These, together with the equivalent material for the Meat Hygiene

Service, Dairy Hygiene Inspectorate and Egg Marketing Inspectorate (and equivalent bodies in each devolved administration), will be subject to public written consultation from April 2005. As it will be necessary to cover the same ground in the instructions/guidance to enforcers as it will in the industry guidance, there will be further opportunity to refine our proposals and seek input from those affected by them. We will report back to the Board on the outcome of this ongoing work in the Autumn.

22. The legislation reinforces the role of voluntary **Industry Guides to Good Hygiene Practice** in supporting industry compliance with the hygiene requirements. A consultation is currently underway on the future form of the guides.

Impact

23. Delivery of the necessary national legislation, guidance material for industry and instructions/guidance to enforcers will enable the FSA to fulfil its obligations to apply the EU Regulations properly and effectively. It is expected to contribute to the FSA strategic plan objective of further reducing foodborne illness.

24. The EU legislation will apply to all food businesses in the UK, from primary production to retail. Enforcement will fall to food authorities, the Meat Hygiene Service and the Agency. Application of the provisions of the legislation will support with other activities (e.g. the food hygiene campaign) efforts to reduce the incidence of foodborne illness. The application of food safety management procedures based on HACCP principles will allow food businesses and enforcers to focus controls and the auditing of food safety management more fully on risk than applies under current regulatory controls.

Conclusion

25. Officials will take forward the actions or outcomes described in paragraphs 7-20 and Annexes A and B and will reflect them as appropriate in the **draft legislation** and **industry guidance material**. It will also be reflected in the **statutory enforcement code and guidance**. Taken together the legislation and guidance to industry and enforcement should ensure an informed, balanced and proportionate application of the new legislation.

Board Action Required

26 The Board is asked to:

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