

REGULATORY IMPACT ASSESSMENT: FOOD STANDARDS AGENCY GUIDANCE ON GENERAL FOOD LAW REGULATION (EC) 178/2002

TITLE OF PROPOSAL

1. Food Standards Agency (FSA) Guidance Notes on Articles 14, 16, 18 and 19 of the General Food Law Regulation (EC) 178/2002 (subsequently referred to as 'the Regulation'.)

PURPOSE AND INTENDED EFFECT OF MEASURE

Objective

2. This Regulatory Impact Assessment (RIA) represents our analysis of the impact of introducing national guidance. The Agency view is that these new Guidance Notes are the most appropriate guidance for food businesses in the UK.
3. These new FSA Guidance Notes provide advice on compliance with legal requirements covering food safety, traceability provisions and the need to notify, withdraw and/or recall products not conforming with the food safety requirements applying under the Regulation.
4. Stakeholder comments have been used to determine whether the guidance in these Notes is proportionate.

Background

5. Regulation (EC) 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, came into force on 21 February 2002. The draft Regulation was subject to an extensive consultation process with stakeholders in 2001. It was published in the Official Journal No. L 31 on 1 February 2002, and can be accessed via the European Commission's web site <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002R0178:EN:HTML>
6. Whilst the Regulation came into force on 21 February 2002, certain key provisions applied only as from 1 January 2005. These included new food safety requirements, new traceability requirements and measures to ensure effective product recall/withdrawals and notification to competent authorities.
7. Although the Regulation was directly applicable in Member States, there was still a need to make changes to domestic legislation, to introduce new enforcement provisions and to ensure conformity with EU law.

8. FSA Guidance Notes on the new food requirements were originally issued on 31 December 2004. EC Guidance was issued on 20 January 2005, which replaced the Food Standards Agency guidance on Articles 11, 12 and 16-20. An amended version of the FSA Guidance Notes on this Regulation was issued on 10 March 2005, which referred to and included a copy of the EC Guidance. The current FSA Guidance Notes have taken account of all this previous guidance.
9. In July 2005 the Agency consulted on how the EC Guidance had been working in practice. In view of the responses to this consultation exercise and the extra costs the food industry said it was incurring due to following the EC Guidance, the Agency has decided to issue its own guidance, which it believes is the most appropriate guidance for food businesses in the UK.

Rationale for Government Intervention

10. In the responses to the consultation in July 2005, some stakeholders commented that following the best practice recommendations in the EC Guidance would incur substantial costs due to the length of time records should be kept and unnecessary burdens resulting from the need to produce traceability records immediately on demand. These recommendations are not specified in the legislation itself.
11. The new FSA Guidance Notes address these concerns and include

greater discretion to food businesses over time requirements for keeping traceability records;

changing the need for immediate production of traceability records in certain cases to a need to produce these within “a short timescale” and

concentrating on the requirements of the legislation and providing minimal advice on good practice, including clarification that internal traceability is not necessary under the Regulation.
12. The overall aim is to have informative and accurate guidance on the Regulation, so that the public health protection offered by the Regulation is achieved without imposing disproportionate burdens on either business or enforcers.

CONSULTATION

Within Government

13. The Agency has consulted the Cabinet Office, the Small Business Service, the Department for Environment, Food and Rural Affairs and the Department of Trade and Industry and all relevant stakeholders. The Agency has also consulted the European Commission on the status of the EC Guidance.

Public Consultation

14. There was extensive public consultation during the negotiations on the Regulation in 2001. This was followed by a public consultation on domestic enforcing legislation and FSA Guidance Notes, which took place in August 2004. Regulatory Impact Assessments were produced for both of these consultation exercises, which concluded that the cost implications of complying with the Regulation would not be significant (as it reflected existing business practice).
15. Revised FSA Guidance Notes, incorporating the EC Guidance on Articles 11, 12 and 16-20 of the Regulation, were widely circulated to stakeholders, including industry groups, on 10 March 2005. In addition, they were placed on the Agency's website.
16. In July 2005 a public consultation was carried out on the EC Guidance to Articles 11, 12 and 16-20 of the Regulation to inform the Agency's negotiating position on an EC review of the Guidance. Replies to the consultation indicated that there were significant costs to food business operators arising from the EC Guidance, primarily owing to suggested best practice on traceability, not legally required under Article 18 of the Regulation.
17. The draft FSA Guidance Notes were sent out to stakeholders. 25 responses were received, of which two offered no comment. Three commented on the potential cost implications for industry. Two disagreed or doubted that any manager could read the document in 30 minutes, and one said that time taken to see an adviser should be added. One said that they had carried out two surveys which had shown the cost of compliance to businesses would be around £800 million. The other said that additional administrative costs for their company would be minimal, as they already had systems in place to comply with legislative requirements. Details of all comments are available on the Food Standards Agency website.
18. We consider it would be possible for a manager to read the guidance in 30 minutes and that there should be no need to contact advisers except in exceptional cases. The Food Standards Agency has previously addressed the issue raised with regard to the costs identified in the surveys: the results of the surveys indicated that what these costs included was measures taken by businesses which were over and above that needed by the Regulation.

OPTIONS

19. Two options have been considered:

Option 1

20. Do nothing. Do not introduce new FSA Guidance Notes on the Regulation. The current EC Guidance would remain as the primary advice on compliance with legal requirements.

Option 2

21. Introduce new FSA Guidance Notes on the Regulation as the most appropriate guidance for food businesses in the UK on Articles 14-16 and 18-20.

COSTS AND BENEFITS

Sectors and groups affected

22. All food businesses (including small businesses); voluntary organisations and charities that fall under the definition of a “food business” in Article 2 of the Regulation; and local authorities. The Administrative Burdens Measurement exercise carried out by PricewaterhouseCoopers’ study for the Food Standards Agency Administrative Burdens exercise in 2006 indicated that there are approximately 346,000 food businesses in the UK, all of which are affected by this Regulation.
23. The British Retail Consortium estimated in 2006 that complying with the EC Guidance would require major retailers to develop new IT systems, generating a one-off cost of £37m, as well as maintenance costs of £19m over five years. Those estimates relate to the 15 largest food retailers, which account for more than 85% of all food sales in the UK.
24. The cross-Government Administrative Burden Measurement Exercise conducted in 2006 estimated the administrative burden for all food businesses to comply with the EC Guidance to be £16 million annually. This does not include the burden incurred by business in complying with the legal requirements of the Regulation.

Benefits

25. Option 1: Food businesses would not have to change practices adopted in order to follow the EC guidance.
26. Option 2: The new FSA Guidance Notes remove the additional burdens resulting from the recommendations of the EC guidance, which will lead to a decrease in the administrative burden borne by food businesses. The results of previous consultations on the Regulation and the associated domestic General Food Regulations 2004 suggest that the new FSA Guidance Notes would not impose costs on businesses in excess of what they incur during their normal course of operation. It is therefore estimated that the introduction of the new FSA Guidance Notes would remove the

majority of the administrative burden created by following the EC Guidance, identified as £16 million annually in the Administrative Burden Measurement Exercise.

27. In addition, the new FSA Guidance Notes are more concise than the EC Guidance and help to clarify the requirements of the Regulation. They should be easier for food business operators and others who work with food to follow.
28. The new FSA Guidance Notes ask businesses to judge for themselves how long it is necessary to keep traceability records (to ensure they can comply with Article 19 should action be necessary), rather than the 5 years in most cases recommended in the EC Guidance. For large retailers, these savings are likely to be negligible as the records are kept electronically, but for the majority of food businesses that keep paper records, the benefit could be substantial. Evidence received in response to last year's consultation on the EC Guidance suggests that the benefit from having to store records for periods of less than five years could be £14,000 per year for a typical food manufacturer. Another food company with 300 workers reported that the requirement to keep records for three years would force them to build suitable storage facilities at a cost of £15-20,000.
29. The removal of the need to supply traceability information immediately, where the severity of the incident does not justify it, will mean that the requirement becomes more proportionate in these cases.

Costs

30. Option 1: There would still be the estimated cost of £16 million annually to food businesses from following the best practice recommendations in the EC Guidance.
31. Option 2: The new Agency Guidance Notes are less stringent than the EC Guidance, and any costs should be "business as usual" costs only. Previous RIAs support that view, indicating that the costs of compliance with the requirements of the Regulation would not be significant.
32. There will, however, be a one-off additional cost of reading and understanding the new FSA Guidance Notes. Assuming that it takes 30 minutes for a manager to complete that task, and relying on the wage rates and overheads used in the Administrative Burden Measurement Exercise, that cost is estimated to be worth £3.65 million. One-off costs are not, however, included in the administrative burden baseline. However, business start-up costs, which include reading guidance are. There are estimated to be 34,600 food business start-ups per year and the estimated administrative burden of this would be £365,000 per year.

Administrative burden of keeping traceability records

33. The Regulation does not specify the time period for keeping traceability records. The Commission's best practice guidance suggested that for most products records should be kept for a minimum of five years. Responses to the consultation exercise on the EC Guidance indicated that this was unnecessary and would result in disproportionate cost for food businesses. This was confirmed by the Administrative Burdens Measurement Exercise. The new FSA Guidance Notes say that it is for businesses to decide how long they should keep their records, bearing in mind the business risks that would be posed by the unavailability of records that would be required should a withdrawal/recall notification of unsafe food be necessary.
34. The EC Guidance classifies traceability information in two categories, the first to meet the legal requirements and the second to be followed as best practice. Responses from food businesses to the consultation exercise on the EC Guidance indicated that following such best practice guidance could result in additional costs. The new FSA Guidance Notes therefore focus primarily on the legal requirements. The results of the consultation show that the only administrative burden of the new FSA Guidance Notes would be for new business start-ups, estimated at £365,000 per year. There would be no other administrative costs to business that they do not already incur through the normal course of business.

CONSULTATION WITH SMALL BUSINESSES: THE SMALL FIRMS IMPACT TEST

35. Small businesses may find it less of a burden not to have to produce traceability records immediately, and are likely to find the more concise nature of the Guidance Notes helpful in understanding the requirements. Conversely, it is possible that modification of record-keeping systems to accommodate the FSA Guidance Notes would impose a one-off cost that would be easier to bear by larger businesses. However, given that the requirements of the Guidance Notes are not as stringent as those of the EC Guidance, we consider it likely that companies could keep their existing record-keeping systems and there is therefore no reason to believe that the Guidance Notes might put small businesses at a disadvantage.

COMPETITION ASSESSMENT

36. The introduction of the new FSA Guidance Notes is not anticipated to have any significant impact on competition in the food sector.

ENFORCEMENT, SANCTIONS AND MONITORING

37. The FSA Guidance Notes are not legally enforceable. However, any person who contravenes or fails to comply with any of Articles 14(1), 16 in so far as it relates to food, 18(2) and 18(3) in so far as they relate to food business operators and Article 19 of the Regulation is guilty of an offence under the General Food Regulations 2004 (as amended), and the Guidance Notes might be used by courts in their interpretation of the Regulation. Local authorities will use the provisions of the Agency Guidance Notes when inspecting premises.

IMPLEMENTATION AND DELIVERY PLAN

38. The Food Standards Agency is sending the guidance to all major stakeholders within the Food Businesses and published on the Food Standards Agency website. It is also sending the guidance to LACORS with instructions that ask Local Authority enforcement officers to recommend to food businesses that they follow its provisions.

POST-IMPLEMENTATION REVIEW

39. A review of the impact of the new FSA Guidance Notes will be conducted within 2 years of publication.

SUMMARY AND RECOMMENDATION

Option	Cost	Summary
Do not implement FSA Guidance Notes on Regulation (EC) 178/2002	£16 million	Food businesses follow proposals on length of time for keeping traceability records in EC Guidance on Regulation (EC) 178/2002 Food businesses implement best practice recommendations on internal traceability in EC Guidance on Regulation (EC) 178/2002.
Implement FSA Guidance Notes on Regulation (EC) 178/2002	£365,000	Cost for new food businesses of reading Guidance Notes.

CHAIR'S DECLARATION

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by Dame Deirdre Hutton, Chair of the Food Standards Agency, on 13 July 2007

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