

ANNEX F

PARTIAL REGULATORY IMPACT ASSESSMENT: GUIDANCE ON THE EC GENERAL FOOD LAW REGULATION 178/2002

TITLE OF MEASURE

1. Agency Guidance on the General Food Law Regulation 178/2002, incorporating EC Guidance on Articles 11, 12, 16 - 20.
2. The Agency Guidance also includes additional text on Article 14 (food safety requirements) of Regulation 178/2002.

OBJECTIVE OF STAKEHOLDER INPUT INTO THIS RIA

3. **This RIA represents our assessment of the cost/benefit impact of the EC Guidance (Annex E) and the additional text in the Agency's Guidance (Annex D) on Article 14.**
4. Stakeholder comments will provide supporting evidence to inform our negotiating position when the **EC Guidance** is reviewed this year by the European Commission.
5. Responses refining our estimates of the costs/benefits of the EC Guidance or highlighting costs/benefits that do not feature in this RIA are particularly welcome.

PURPOSE AND INTENDED EFFECT

Objectives

6. **This RIA relates to a consultation that does not seek to change food or feed law or policy. It offers an opportunity to have clearer guidance on existing food and feed law (i.e. General Food Law Regulation 178/2002).**
7. The Guidance provides advice on compliance with legal requirements and on certain aspects of best practice. These obligations in particular cover food and feed safety requirements, traceability provisions; and the need to notify, withdraw and/or recall products not in conformity with the safety requirements that applied in the UK from 1 January 2005, under Regulation 178/2002.

Background

8. EC Regulation 178/2002, laying down the general principles and requirements of food law, establishing the European 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 at:-

http://europa.eu.int/eur-lex/en/archive/2002/l_03120020201en.html

9. Whilst the Regulation came into force on 21 February 2002, certain key provisions applied from 1 January 2005. These included new food and feed safety requirements, new traceability requirements and also measures to ensure effective product recall/withdrawals and notification to competent authorities.

10. Although as a Regulation, 178/2002 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 law¹.

11. Food Standards Agency Guidance Notes were subject to the same consultation as domestic legislation last autumn, and in Scotland, issued to Local Authorities on 24 December 2004 and to Industry on 18 January 2005. Subsequent to this, the European Commission produced more detailed Guidance which was published on 20 January. The UK then decided that the EC Guidance should replace domestic Guidance on Articles 11, 12 and 16-20, and therefore the Agency's Guidance Notes were revised accordingly and reissued in March 2005.

Rationale for Government Intervention

12. The Commission intends to revisit its Guidance in the light of experience gained, starting in September 2005.

13. The Agency needs feedback from stakeholders on the impact of this Guidance to inform its negotiating position in Brussels. The Agency would therefore encourage industry and other affected groups to comment on any

¹ The Food Safety Act 1990 (Amendment) Regulations 2004 came into force on 7 December 2004. They align the definition of 'food' in the Food Safety Act 1990 with the definition in the General Food Law Regulation (EC) 178/2002, and also make some minor amendments to the Food Safety Act 1990 in respect of public consultation requirements, to remove duplication with directly applicable provisions in EC 178/2002. The General Food Regulations 2004 provide enforcement powers in respect of new food safety requirements under EC 178/2002, designate competent authorities, specify enforcement authorities, make provision for offences and penalties, and introduce some consequential amendments to the Food Safety Act 1990, in particular Sections 7 and 8.

cost implications of practical application of the Guidance over and above those identified when the legislation was consulted on last year.

14. The overall aim is to have informative and accurate guidance on Regulation 178/2002, so that the public health protection offered by the Regulation is achieved without imposing unnecessary burdens on either business or enforcers.

CONSULTATION

Within Government

15. The Agency is consulting with the Scottish Executive Environment and Rural Affairs Department and the Improving Regulation in Scotland unit, as well as the Small Business Service.

Public Consultation

16. There was extensive public consultation during the negotiations on Regulation 178/2002 in 2001. This was followed by a public consultation on domestic 'implementing' legislation and Agency 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 Regulation 178/2002 would not be significant (as it reflected existing business practice).
17. Revised Agency Guidance Notes, incorporating the EC Guidance, were circulated to stakeholders, including industry groups, on 14 March 2005. In addition, they were placed on the Agency's website.
18. The further revised version of these Guidance Notes included in this Consultation includes guidance on the food safety requirements of Article 14 of Regulation 178/2002. No cost implications have been identified for this guidance as it reflects the legal requirements that were already in force prior to Regulation 178/2002, under the Food Safety Act 1990 and the relevant case law.
19. This consultation seeks further views on the cost impact of the EC Guidance to inform the Agency's negotiating position for when the Guidance is reviewed by the Commission later this year. **The Agency cannot amend it independently.**

OPTIONS

20. In view of the forthcoming Commission review of the EC Guidance, two options have been identified for consideration.

Option 1

Negotiate to maintain the *status quo*, i.e. to leave the EC Guidance unchanged, but with additional Agency guidance on Article 14 (food safety requirements).

Option 2

Negotiate for changes to the EC Guidance where it goes beyond the legal requirements, and also provide additional Agency guidance on Article 14 (food safety requirements).

21. Areas where the EC Guidance goes beyond the legal requirements are;

- Internal traceability;
- Time for keeping traceability records;
- Reaction time to provide traceability information; and
- Notification criteria where food is not in compliance with the food safety requirements.

22. In the following sections, each of the areas where the EC Guidance goes further than the legal requirements is being explored from the perspective of both Option 1 and Option 2. We would therefore be interested in hearing from you if you can identify cost implications from maintaining the *status quo*, or if you can suggest changes to the Guidance and associated costs.

Sectors and Groups Affected

23. All food and feed businesses (including small businesses); voluntary organisations and charities that fall under the definition of a 'food' or 'feed business' in Article 2 of Regulation 178/2002; and local authorities.

Benefits

24. The Guidance should help to clarify the requirements of Regulation 178/2002, and contribute towards common interpretation of the General Food Law Regulation 178/2002 across Europe. This benefits food or feed businesses in the UK who supply or purchase from other businesses in Europe, and also larger UK food businesses that have operations in other Member States, as they have greater certainty with regards to compliance with the legal requirements of Regulation 178/2002.

25. This contributes towards the wider social benefit of this i.e. increased public health protection through reduced food safety incidents – as was detailed in the RIA on EC Regulation 178/2002
26. Negotiation provides an opportunity to clarify **further** the requirements of Regulation 178/2002, and to revise the Guidance so that it **more helpful** to stakeholders and further reduce the likelihood of business incurring unnecessary costs out of fear of non-compliance with the law.
27. The additional Guidance on Article 14 will further clarify the law, so providing greater certainty for businesses.

Costs

28. Exploring how the EC Guidance can be further clarified and made more helpful to stakeholders is not expected to place any costs on business. **If you can identify aspects of the EC Guidance that incur additional costs for your business, please could you specify, and provide examples where possible. Please do not include costs that result from complying with the legal requirements of Regulation 178/2002.** Development of the UK negotiating stance regarding possible revisions to the Guidance will take into account your views and any estimates of costs.
27. The new Guidance on Article 14 will not lead to any new burdens as it mirrors the effect of existing law.

Issues on which there might be negotiation

Guidance on Internal Traceability (pg 14 of the EC Guidance)

28. **Internal traceability – i.e., the matching up of all inputs to outputs – is not a legal requirement under the General Food Law Regulation 178/2002.**
29. **The Commission has publicly announced, and stated in the EC Guidance, that internal traceability is not required by Regulation 178/2002.** However, the Guidance concludes that Food Business Operators should be encouraged to develop internal traceability systems in relation to the nature of their activities. We see this as best practice guidance, as it indicates the types of systems that businesses might choose to put in place to minimise the business risks to them, should it become necessary for them to withdraw and recall their products from the market.
30. It would be helpful to have answers to the following questions.

- *Could the distinction between compliance and best practice be made clearer in the Guidance?*
- *Do you already have an internal traceability system in place? If so, what was the cost to your business of introducing a system that links goods bought in to goods sold or supplied?*
- *Can you provide an evaluation of the benefits for your business?*
- *Could you achieve internal traceability with a paper-based system?*

Guidance on time for keeping traceability records (pg 16 of the EC Guidance)

31. **Regulation 178/2002 does not specify the time period for keeping traceability records.** The Commission's best practice guidance suggests that for most products records should be kept for a minimum of five years.

- *How long do you already keep records for other purposes (e.g. for tax purposes)?*
- *Are there any additional costs to your business in following this suggestion?*
- *Are there any benefits, for example in being able to accurately identify the lots and batches that might be affected should a withdrawal or recall be necessary, and thereby minimise your business costs?*
- *Can you estimate any likely additional costs and benefits for your business for the following options for a shorter period for keeping records?*
 - one year and under*
 - two years*
 - three years*
 - four years*

Guidance on reaction time to provide traceability information (pg 16 of the EC Guidance) (As noted above this does **not** refer to internal traceability)

32. **Article 18(2) and 18(3) of Regulation 178/2002 require food and feed business operators to have in place systems and procedures which allow for traceability information to be made available to the competent authorities 'on demand'.**

33. The Agency has previously consulted on a Guidance Note recommending that, as a minimum, the records to be kept for traceability purposes under Article 18 should include;

- name and address of customer or supplier,
- nature of products, and
- the date of transaction delivery.

34. The EC Guidance also identifies the essential information as being:

- the name and address of customer or supplier,
- nature of products, and
- the date of transaction delivery

This information should be available ‘*on demand*’ to competent authorities. This is guidance on compliance – this is the EU view of the information that businesses must be able to provide in order to comply with the law.

35. The EC Guidance also recommends that information including:

- volume or quantity,
- batch number (if any), and
- a more detailed description of the product, where this is relevant to the food business activity, the nature and size of the business, and the characteristics of the traceability system

should be available as soon as reasonably practicable, within deadlines appropriate to circumstances. It is information which, if it were made available to the competent authorities, would allow them to specify which lots or batches should be withdrawn or recalled in the event of a food incident, and might minimise loss to business. It is our expectation that businesses would provide to the competent authorities whatever relevant information that they held.

36. **Guidance does not supersede the law**, but the EC Guidance makes a distinction between the timescales for information that should be ‘immediately available’ and that which should be made available ‘as soon as reasonably practicable’.

Do you already have any or all of the above information available for the food you produce? Would there be any additional costs to you in making the traceability information specified by the EC Guidance available on demand? Would this be likely to save your business money in the event of a food incident, as a result of being able to identify the specific lots that would need to be withdrawn?

Guidance on notification criteria

37. Articles 19 and 20 of Regulation 178/2002 sets out a range of requirements for businesses to notify competent authorities where product is not in compliance with food and feed requirements under Article 14 and 15.

- Articles 19(1) and 20 (1) are primarily aimed at food and feed businesses responsible for allowing unsafe food/feed to enter the food chain, and impose obligations in respect of notification, withdrawal and recall of

unsafe food/feed. For food, this applies only where such food has left the 'immediate control' of the initial food business operator.

- Articles 19(2) and 20(2) are primarily aimed at those further down the food chain and require such businesses to co-operate by passing on relevant information.
- Articles 19(3) and 20(3) impose a requirement on food and feed business operators to immediately inform competent authorities if food/feed may be injurious to health. This applies for food regardless of whether food has left the 'immediate control' of the initial food business operator.

38. The EC Guidance suggests criteria (**see EC Guidance pgs 18 - 29**) for the initiation of withdrawal, recall and notification procedures.

- *Do you currently have procedures in place for withdrawal and recall?*
- *Does the EC Guidance suggest to you that you should do more?*
- *Would there be an additional cost if you were to follow the suggestions in the EC Guidance?*
- *What financial impact will these procedures have on your business?*

CONSULTATION WITH SMALL BUSINESS: THE SMALL FIRMS IMPACT TEST

39. The Agency is conscious of the effect any Guidance Notes or Regulation may have on small businesses. The Small Business Service has been involved in previous consultations on legislation relating to this area. The Agency will be consulting further with the Small Business Service and intends to set up focus groups around the country to look at specific cases. If your business can identify immediate costs or concerns, please provide them as a response to this consultation.

COMPETITION ASSESSMENT

40. The Agency has considered the competition assessment, and does not anticipate that the Guidance will lead to competition issues. The recommendations apply equally to all food businesses throughout the EU. Information provided as a result of this consultation will enable the Agency to review the competition filter.

IMPLEMENTATION AND DELIVERY PLAN POST-IMPLEMENTATION REVIEW SUMMARY AND RECOMMENDATION

41. These three sections will be completed following the consultation process. In addition to details about cost, the Agency will provide information to stakeholders on the negotiating line that it will take to the Commission as a result of this consultation.

ENFORCEMENT, SANCTIONS AND MONITORING

42. The EC Guidance seeks to promote compliance with EC Regulation 178/2002. This may be referred to by enforcing bodies namely, the Port Health Authorities, Local Authorities, and the Food Standards Agency. Sanctions reflect those already in place relating to non-compliance with the provisions of EC Regulation 178/2002. There are no additional sanctions specifically relating to the EC Guidance. The best practice elements of the EC Guidance are not enforced.

43. This consultation is a result of the Commission's intention to review its Guidance later in the year, and, dependent on the results of this consultation, the Agency may recommend further reviews.

SUMMARY COSTS AND BENEFITS TABLE

44. To be added following consultation.

SUMMARY AND RECOMMENDATION

45. To be added following consultation.

MINISTERIAL DECLARATION

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

Signed

Date

Minister
Department

CONTACT POINT

Name: Jennifer Howie
Branch: Strategy and Co-ordination, Food Standards Agency Scotland
Address: 6th floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ
Telephone: 01224 285142