

DRAFT

**EC General Food Law Regulation 178/2002:**

**Guidance Notes on the Food Safety Act 1990 (Amendment) Regulations 2004 and the General Food Regulations 2004**

**Important Note**

1. These Guidance Notes provide advice on compliance with legal requirements and on certain aspects of best practice. They should be read in conjunction with the Food Safety Act 1990 (Amendment) Regulations 2004 (No. 2990), and the General Food Regulations 2004 (No. 3279)
2. The notes and examples in this Guidance should not be taken as an authoritative statement or interpretation of the law. Only the courts can decide whether, in particular circumstances, an offence has been committed. It is the responsibility of individual organisations to ensure their compliance with the law. Organisations with specific queries may wish to seek further advice from their home Food Authority.

**Purpose of the legislation**

3. EC Regulation 178/2002 lays down the general principles and requirements of food law, establishes the European Food Safety Authority, and lays down procedures in matters of food safety. It came into force on 21 February 2002, although certain key provisions apply only from 1 January 2005. The principal aim of this Regulation is to protect human health and consumers' interests in relation to food.
4. It applies to all stages of production, processing and distribution of food and feed, but there is an exemption for primary production for private domestic use, and the domestic preparation, handling, or storage of food for private domestic consumption. Key definitions are in Articles 2 and 3 of the Regulation.
5. The draft Regulation was subject to an extensive and ongoing consultation process with stakeholders. It was published in the Official Journal No. L 31 on 1 February 2002, and can be accessed via the Commission's web site at:-  
  
[http://europa.eu.int/eur-lex/en/archive/2002/l\\_03120020201en.html](http://europa.eu.int/eur-lex/en/archive/2002/l_03120020201en.html)
6. Although as a Regulation it is directly applicable in Member States, there is a need to introduce new enforcement powers and penalties in relation

to the new obligations on food and feed businesses in Articles 14 – 20 of Regulation 178/2002, to apply from 1 January 2005. The necessary changes to domestic food law have been effected by means of Statutory Instruments under the Food Safety Act 1990 and the European Communities Act 1972.

### **Legislation in the devolved administrations**

7. Following the process of devolution, food legislation is now commonly made on a separate basis in England, Scotland, Wales and Northern Ireland. However, it was decided that it would be appropriate for the two Regulations to apply to Great Britain. Separate Regulations apply in Northern Ireland, which differ only in the powers under which they are made, and the food authorities given the responsibility for enforcement.

### **Food Safety Act 1990 (Amendment) Regulations 2004**

8. These Regulations are made under the European Communities Act 1972. The case law of the European Court of Justice makes clear that it is not open to Member States to retain provisions in national legislation in so far as they duplicate, gloss or conflict with the directly applicable provisions of EU Regulations. These Regulations therefore narrow the scope of the public consultation requirement in Sections 40 and 48 of the Food Safety Act 1990 so that it does not apply in cases where the public consultation requirements of Article 9 of Regulation 178/2002 apply.

9. The Regulations also align the definition of 'food' in the Food Safety Act 1990 with that in Regulation 178/2002 as they essentially cover the same ground. The key difference is that unlicensed medicinal products are excluded from the definition of 'food' if they are medicinal products within the meaning of the Medicines Directive 2001/83/EC. However, certain borderline 'medicinal' products which are not medicinal products within the meaning of Directive 2001/83/EC will now be included in the new definition. It will continue to fall to the Medicines and Healthcare Products Regulatory Agency (MHRA), on behalf of the UK licensing authority, to determine whether a product is a medicinal product within the meaning of the Medicines Directive on a case by case basis, having regard to the overall presentation and function of the product.

10. This new definition of 'food' automatically applies to other legislation in related areas that uses the Food Safety Act definition, for example the Food Standards Act 1999 and the Food and Environment Protection Act 1985, as well as to Regulations and Orders made under all these Acts.

11. The EU definition of food excludes live animals unless they are prepared for placing on the market for human consumption. The definition would therefore include any animal, including fish and molluscs, which may enter the food chain.

## **General Food Regulations 2004**

12. The main purpose of these Regulations is to provide new enforcement powers in respect of new obligations to apply from 1 January 2005 under Regulation 178/2002. These are Articles 14, 16 (in so far as it relates to food), 18 (in so far as it relates to food business operators), and 19. Guidance on Articles 16-20 can be found in EC Guidance at the Annex to these Notes and is also available at:

[http://europa.eu.int/comm/food/foodlaw/guidance/index\\_en.htm](http://europa.eu.int/comm/food/foodlaw/guidance/index_en.htm)

Guidance to Article 14 can be found below.

13. 'Food business operator' and 'food business' are defined in Article 3.3 and 3.2 of Regulation 178/2002. In particular, 'food business' means 'any undertaking, whether for profit or not, and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food'. This would include seasonal and sporadic businesses. The expression 'stages of production, processing and distribution' is defined in Article 3.16 and covers all stages from and including primary production (as defined in Article 3.17) up to and including sale or supply to the final consumer. For example, the activities of farmers, importers, manufacturers, wholesalers, distributors, transporters, retailers and catering outlets are covered.

14. The extent to which home-producers fall within the definition of 'food business' will need to be decided on a case-by-case basis. The definition uses the expression 'an undertaking', which implies a certain continuity of activities and a certain degree of organisation.

### **Article 14 (Food Safety Requirements)**

15. This prohibits food being placed on the market if it is unsafe, i.e. if it is either:

- injurious to health, or
- unfit for human consumption.

The concept of 'injurious to health' relates to safety, but the concept of 'unfit' relates to unacceptability. Unfit food is not necessarily unsafe in the ordinary sense of the word. For instance, mouldy food may be unfit for human consumption even if it is not injurious to health. Also, food that is contaminated with a prohibited chemical but where the chemical is not present at a harmful concentration may be considered unfit for human consumption although there is no risk to human health. The requirements of Article 14 are considered to be broadly analogous to those previously in Section 8 of the Food Safety Act 1990, which no longer apply because of the new food safety provisions in Article 14. Case law on Section 8 clearly established that the prosecution did not need to prove that a food was injurious to health when establishing that it was unfit.

16. In determining whether food is unsafe, the way the food is used and the information given to or generally available to the consumer is relevant (Article 14(3)).

17. Article 14(4)(c) requires that if you are producing a food for a group of consumers with particular health sensitivities (e.g. intolerant or allergic), when determining whether a food is injurious to health you have to take these sensitivities into account. However, where the product is not intended for a group with particular health sensitivities, the fact that it may be harmful for that group does not automatically mean that it is unsafe.

18. The food safety requirements in Article 14 apply to sales and supplies, including one-off sales and supplies free of charge. The requirements of this Article are not limited to 'food business operators'. The aim is to protect public health by covering all eventualities, with the exception of private domestic consumption.

Q1: Is this sufficiently clear in describing food that is injurious to health or is unfit?

### **Notification of food not in compliance with the food safety requirements**

19. Under Article 19, food businesses are required to notify the competent authorities of food that is not in compliance with the food safety requirements, which means both the Agency and the relevant local authority or port health authority. A form has been produced by the Agency for use by food and feed business operators and can be found on the Agency's website at [www.food.gov.uk/foodindustry/foodfeedform](http://www.food.gov.uk/foodindustry/foodfeedform). Businesses should submit the form online to the Agency's Incidents Branch and also inform the Local Authority where the food business operator is based or, in the case of imports, the relevant port health authority, by fax or other appropriate means.

Q2: Is this notification procedure sufficiently clear?

### **Enforcement and Sanctions**

20. Regulation 3 of the General Food Regulations designates food authorities, port health authorities, and the Food Standards Agency as the competent authorities. Enforcement authorities are specified in Regulation 6 as food authorities or port health authorities in relation to Articles 14, 16, 18 and 19 of Regulation 178/2002, but the Agency is specified as an additional enforcement authority in relation to Articles 14 and 19 in certain circumstances.

21. This means that port health authorities or local authorities are responsible for enforcing all provisions. However, the Agency is an additional enforcement authority in relation to the enforcement of the food safety requirements, and also recall, withdrawal and notification requirements under

Article 19 under certain circumstances. This is to allow, for example, for the flexibility of the Meat Hygiene Service enforcing these requirements in meat plants, where this would be more effective.

22. The Regulations also specify offences in relation to the above requirements and impose penalties for these offences. These penalties are consistent with those currently in operation under the Food Safety Act 1990 for food law offences.

### **Further information about these Guidance Notes**

23. Enquiries about, and further copies of these Guidance Notes may be obtained from:

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Guidance on Articles 14-20 of Regulation 178/2002 replaced by EC Guidance