

**FOOD STANDARDS AGENCY
GUIDANCE NOTES ON ARTICLES 14-16 and 18-20 OF
THE GENERAL FOOD LAW REGULATION (EC) 178/2002**

Introduction

1. These Guidance Notes have been produced with the aim of providing informal, non-statutory advice on compliance with the requirements of Articles 14-16 and 18-20 of Regulation (EC) 178/2002.
2. We have taken account of the previous Food Standards Agency Guidance Notes on this Regulation issued on 10 March 2005. These previous Guidance Notes included EC Guidance issued on 20 January 2005. We have also taken account of the responses to the public consultation on the EC Guidance in July 2005. The FSA view is that these new Guidance Notes are more appropriate for food businesses in the UK.
3. The notes should be read in conjunction with the Food Safety Act 1990 (Amendment) Regulations 2004 (No. 2990), the General Food Regulations 2004 (No. 3279)¹ or, as appropriate, the Feed (Hygiene and Enforcement) Regulations 2005 (see Annex). Food and feed businesses are required to comply with these articles, which are about safety of food and feed, traceability, notification of food and feed safety incidents and withdrawal and recall of unsafe food and feed.
4. These Notes and the examples in them should not be taken as an authoritative statement or interpretation of the law, as only the Courts can decide whether, in particular circumstances, an offence has been committed under the relevant Regulations. 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 or Feed Authority, i.e.
 - their local authority²;
 - for imported food but not feed, their port health authority³;
 - the Food Standards Agency; or
 - in relation to feed in Northern Ireland, the Department of Agriculture and Rural Development (DARD).

Purpose of Regulation (EC) 178/2002

¹ In Northern Ireland, the Food Safety (Northern Ireland) Order 1991 (Amendment) Regulations (Northern Ireland) 2004 (No. 482) and the General Food Regulations (Northern Ireland) 2004 (No. 505).

² In Northern Ireland district councils only.

³ Ibid.

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5. Regulation (EC) 178/2002 of the European Parliament and of the Council, 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 applied only from 1 January 2005. The principal aim of this Regulation is to protect human health and consumers' interests in relation to food.
6. 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.

Definitions

7. A number of terms are defined in Articles 2 and 3 of the Regulation and, since they are used in the Guidance, these are included here for ease of reference. For the purposes of Regulation (EC) 178/2002:
 - **'food'** or ('foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

- (a) feed;
- (b) live animals unless they are prepared for placing on the market for human consumption;
- (c) plants prior to harvesting;
- (d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;
- (e) cosmetics within the meaning of Council Directive 76/ 768/EEC;
- (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC;
- (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;

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- (h) residues and contaminants.
- **‘food law’** means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food producing animals;
 - **‘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;
 - **‘food business operator’** means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control;
 - **‘feed’** (or ‘feedingstuff’) means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals;
 - **‘feed business’** means any undertaking whether for profit or not, and whether public or private, carrying out any operation of production, manufacture, processing, storage, transport or distribution of feed including any producer producing or storing feed for feeding to animals on his own holding;
 - **‘feed business operator’** means the natural or legal person responsible for ensuring that the requirements of food law are met within the feed business under their control;
 - **‘retail’** means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets;
 - **‘placing on the market’** means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves;
 - **‘risk’** means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard;
 - **‘risk analysis’** means a process consisting of three interconnected components: risk assessment, risk management and risk communication;

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- **‘risk assessment’** means a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation;
- **‘risk management’** means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options;
- **‘risk communication’** means the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions;
- **‘hazard’** means a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect;
- **‘traceability’** means the ability to trace and follow a food, feed, food producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution.

Article 14 (Food safety requirements)

What the Article says

8. This Article prohibits food being placed on the market if it is unsafe. It is deemed to be unsafe if it is considered to be:
 - (a) injurious to health;
 - (b) unfit for human consumption.
9. Although these terms were used in Section 8 of the Food Safety Act 1990⁴, their meaning in the Regulation is not necessarily the same and will be determined by the European Court. The factors listed in Article 14 (3)-(5) were not part of Section 8 and are new to UK food law. These factors should be taken into account when determining whether food is injurious or unfit. Food that is considered to be either ‘injurious to health’ or ‘unfit’ is deemed to be unsafe under Article 14(2), and it follows that such food is subject to the withdrawal, recall and notification requirements of Article 19.

⁴ Article 7 of the Food Safety Order (Northern Ireland) Order 1991.

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10. There is no longer an offence under Section 8 of the Food Safety Act 1990 of selling food which fails to comply with the food safety requirements. Instead, an offence of failing to comply with the food safety requirements of Article 14(1) is created by Regulation 4(b) of the General Food Regulations 2004⁵, as amended (see Annex).

How we believe businesses can comply

11. 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, which is exempted by Article 1(3). It should be noted that this exemption does not extend to food produced by individuals for charitable and similar events.
12. Article 14(3) – 14(5) indicate what factors need to be taken into account when determining whether food is injurious to health or unfit. Article 14(3) requires that the normal conditions of use of the food, such as cooking, should be taken into account. Article 14(4) requires that the particular health sensitivities of specific categories of consumers be taken into account where the food is intended for that category of consumers. So, for example, food intended for consumers requiring a gluten-free diet could be considered to be injurious if it were found to contain gluten.
13. Conversely, the general requirement not to market unsafe food is not breached simply because a certain group of people are particularly susceptible to be injured by it. Food intended for general consumption is not injurious for the purposes of this Article because some people are allergic or intolerant and so liable to be injured by it.

Food that is injurious to health

14. Once a hazard is identified which might make food injurious to health, an assessment of the associated risk should be carried out, taking the factors in Article 14(3) and (4) into account. Not all hazards that might be found in food are controlled by specific regulations. Food could be injurious to health without exceeding a particular legal limit. For example, this could apply when glass, which is not a specifically banned substance, is found to be present in food, or if, for example, a hazardous chemical not specifically identified by legislation on contaminants in food is found to be present. The key point is that once a hazard of any kind has been identified, the need to assess the risk is paramount.
15. When there are concerns that a particular food may be injurious to health, food businesses then have to consider how serious the risk is. Risk assessment in this context means addressing two key questions:

- what is the harm that might be caused?

⁵ In Northern Ireland, the General Food Regulations (Northern Ireland) 2004 (No. 505).

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- how likely is it?

16. There is a range of reputable, expert organisations that are able to advise on particular cases.

Food that is unfit

17. The central concept of unfitness is unacceptability. Food can be rendered unfit by reason of contamination, by the presence of foreign objects, by unacceptable taste or odour as well as by more obvious detrimental deterioration such as putrefaction or decomposition.

Food not in compliance with food safety legislation

18. Where food is found to be in breach of specific legislation governing its safety, it will be presumed to be either injurious to health or unfit for human consumption and thus 'unsafe' for the purposes of Article 14. For example, a breach of a particular legal limit within legislation on contaminants in food would raise the presumption that the food was unfit for human consumption in the light of Article 14(5). In such a case, an assessment should still be carried out, considering the factors in Articles 14(3)-(5) in the light of the legislation on contaminants in food. If that assessment shows that the food is neither injurious to health nor unfit for human consumption it would not be regarded as unsafe for the purposes of Article 14. However, it would still be in breach of the legislation on contaminants in food.

Article 15 (Feed safety requirements)

What the Article says

19. This article prohibits feed being placed on the market if it is unsafe, i.e. if it either:

- (a) has an adverse effect on human or animal health;
- (b) makes the food derived from food-producing animals unsafe for human consumption.

20. The definition of unsafe (for human consumption) is that in Article 14(2).

21. Animal feed is deemed to be safe if it complies with specific Community provisions governing feed safety, where such Community provisions exist. The provisions include, for example, maximum permitted levels of undesirable substances (contaminants such as lead, arsenic or aflatoxin B1), conditions governing the authorisation, marketing and use of feed additives, and prohibitions on certain ingredients. However, enforcement authorities may also impose restrictions on, or require the withdrawal of,

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consignments of feed if they believe that the feed is unsafe even though it otherwise complies with feed law requirements. The decision to impose restrictions or require withdrawal will be a matter of judgement by the enforcement authority.

22. The feed safety requirements of this Article apply to all stages of the production, transport, storage, supply and sale of animal feed, including producers producing, processing or storing feed for feeding their own animals, one-off sales and supplies free of charge. The aim is the protection of both animal and human health, in the latter case by ensuring the safety of animal products (meat, dairy products and eggs) for human consumption.

How we believe businesses can comply

23. Where a potential hazard in feed has been identified, the feed business operator should carry out an assessment to ascertain if food derived from food-producing animals which have been given that feed is safe. This assessment should take into consideration all available information, including any maximum permitted levels for substances causing the potential hazard, where such limits exist.
24. It should be noted that in addition to this requirement under Regulation (EC) 178/2002, offences are committed by anyone who places on the market animal feed which does not meet the requirements of other feed legislation, e.g. feed that exceeds maximum permitted levels of undesirable substances.

Article 16 (Presentation)

What the Article says

25. This Article stipulates that the labelling, advertising, and presentation of food shall not mislead consumers. The Article applies to those involved in occasional events as well as to food businesses. The wording of Article 16 says that it is without prejudice to more specific provisions of Community law. Therefore, Article 16 is an additional measure. It does not overrule or otherwise affect other legal provisions, whether at Community or national level, and so applies additionally to the Trade Descriptions Act 1968 and Section 15 of the Food Safety Act 1990⁶. Section 15, which implements the requirements of Article 2 of the Food Labelling Directive 2000/13, continues in place. Unlike Section 15, Article 16 applies in case of a one-off supply free of charge, subject to the exemption in Article 1(3) for private domestic use.
26. Article 16 also applies to the labelling, advertising and presentation of feed. There are also other provisions on the labelling of feeds, which are set out in Schedule 3 of the Feeding Stuffs Regulations 2005.

⁶ Article 14 of the Food Safety (Northern Ireland) Order 1991.

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How we believe businesses can comply

27. This Article covers misleading labelling and advertising. It also covers cases where a consumer is misled as to the nature, substance or quality of the food by the setting in which food is displayed. This could apply, for example, if a synthetic cream cake was displayed in a chill cabinet in such a way as to give the impression that it contained fresh dairy cream.

Article 18 (Traceability)

What the Article says

28. Under this Article, food and feed businesses are required to

- identify their suppliers of food, feed, food-producing animals and any other substance for incorporation into food or feed,
- identify the businesses to which they have supplied products, and
- produce this information to the competent authorities on demand.

29. The requirements of Article 18 of the Regulation apply to food and feed business operators at all stages of the food chain. This includes primary producers, manufacturers, wholesalers, retailers, transporters, distributors, those dealing in the purchase and sale of bulk commodities, and caterers. A food or feed business would also include any business that trades in food or feed, even if they do not take physical possession (food/feed broker). Also included are charities where these meet the definition of food business, and businesses importing from third countries, even though their supplier is not within the EU. The requirements do not, however, extend to suppliers in third countries.

30. The products covered are ‘food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed.’ So, for example, seeds will be subject to the traceability requirements only if these go directly into a food product. Live animals supplied for eventual use in food would constitute “food producing animals” and would be subject to the traceability requirements. Veterinary medicines, pesticides and fertilisers do not fall within the scope of the Regulation as they are not within the definition of ‘food’ under Regulation (EC) 178/2002.

How we believe businesses can comply

31. Taken at face value, the only information Article 18 requires food and feed business operators to provide is the name of businesses who supply them and to whom they supply their products, i.e. one step back – one step forward. However, EC law should be interpreted according to its purpose, and account has to be taken of the relevant recitals and role of Article 18 in

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supporting the notification requirements of Articles 19 and 20. It follows that, as a minimum, traceability records should also include the address of the customer or supplier, nature and quantity of products, and the date of the transaction and delivery. It is expected that the provision and retention of this type of information is already standard practice in basic invoicing.

32. This requirement should not be taken as meaning that businesses necessarily need a dedicated traceability system. It is the need to produce information that is important, not the format in which it is kept.
33. Article 18 requires that the traceability records be made available on demand. As the purpose of the traceability provision is to assist with withdrawals and recalls of unsafe food, food and feed businesses should have their records sufficiently organised and available to be produced within the short timescale needed for them to be of use in any such withdrawal or recall.
34. The Regulation does not specify how long traceability records should be kept. Again, this article should be interpreted according to its purpose in supporting the notification requirements of Article 19. It is for businesses to decide how long they should keep their records, bearing in mind the nature of the food or feed, its product life, and the circumstances under which they might be required to produce records, should a notification under Articles 19 or 20, or assistance to enforcement authorities, be subsequently required. However, failure to produce such documentation constitutes an offence.
35. Food retailers are not required to keep records of sales to the final consumer (since consumers are not food businesses). Wholesalers supplying to retail outlets are required to keep records. Where a retailer knows that it is supplying to another food business, for example a catering outlet, traceability requirements should be adhered to. Caterers such as restaurants will need to keep traceability records of inputs, but will not be required to keep records of supplies to the final consumer.
36. The traceability requirements of Article 18 apply without prejudice to more detailed sector specific requirements. These include the mandatory labelling requirements at the point of sale for fresh and frozen beef; the mandatory cattle identification and registration scheme and the rules relating to consumer information for fish and fish products sold at retail, where commercial documentation (e.g. sales note, invoice) is the usual means of providing this information through the chain.
37. Article 18 does not require internal traceability, i.e. the matching up of all inputs to outputs. Nor is there any requirement for records to be kept identifying how batches are split and combined within a business to create particular products or new batches. For example, a cake manufacturer would not need to specify which batch of flour went into which cakes.

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38. Other EC feed legislation (Regulation (EC) Feed Hygiene 183/2005) specifies in more detail the information that must be recorded by different categories of feed business operators to ensure traceability. This requirement is set out in the record-keeping sections of Annexes I and II of Regulation 183/2005.

Article 19 (Withdrawal, recall, and notification of food)

What the Article says

39. This places obligations on food businesses to recall, and/or withdraw, food from the market if it is not in compliance with the food safety requirements of Article 14, to notify competent authorities (their Home Authorities and the Food Standards Agency), and to collaborate with these authorities on action taken to avoid or reduce risks posed by the food.
40. Article 19(1) requires that, where a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, and has left the immediate control of the initial food business, the food should be withdrawn from the market and notified to the competent authorities. (Article 19(3) identifies where there is an obligation to notify immediately.)
41. The obligation to withdraw/recall arises when a food business operator considers or has reason to believe that a food is unsafe. The test is an objective one. Where products may have reached the consumer, there is an obligation on food businesses to inform consumers effectively and accurately of the reason for the withdrawal of the product and where necessary recall products already supplied. The reason given should provide details as to why the product is unsafe.
42. Article 19(2) imposes a requirement on food business operators responsible for retail or distribution activities, which do not affect the packaging, labelling, safety or integrity of food. The purpose of this provision is to ensure that such food business operators also play their part in the withdrawal of food not in compliance with food safety requirements, and in passing on relevant information.
43. Article 19(3) imposes an obligation on food business operators to inform the competent authorities immediately if food that they have placed on the market may be injurious to human health (see Definitions section for clarification of 'placing on the market').
44. Article 19(4) requires that food business operators co-operate with the competent authorities on action taken to avoid or reduce risks posed by a food that they supply or have supplied.

How we believe businesses can comply

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Withdrawal/Recall

45. For the purposes of these Guidance Notes, the terms 'withdrawal' and 'recall' mean:

- **'Withdrawal'** means the process by which a food is removed from the market up to and including the retail stage, and including action by food producers, packers, distributors, wholesalers and retailers, as appropriate.
- **'Recall'** means the process by which consumers are advised, for example, by means of public notices and other publicity, to return food supplied to them.

46. Food Business Operators must as a minimum withdraw from the market food failing to meet the food safety requirements specified in Article 14. Where this is insufficient to provide the required level of health protection to consumers, they must recall the product.

47. The withdrawal of food from the market may take place at any step along the food chain and not only at time of delivery to the end consumer. The obligation to withdraw from the market applies when the following two cumulative criteria are met:

- When a food is considered by the operator (at any stage of the chain) as being unsafe (Article 14). In making this judgement, the operator will need to consider the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution.
- Where the food has left the immediate control of that food business operator.

48. The wording "has left the immediate control of that initial food business operator" stresses that the initial food business operator is no longer able to take action by itself to remedy the non-compliance, but needs to request/require co-operation from other operators it has supplied. The words "of the initial food business operator" are important. It means that the food has left, for example, the processing unit and is in the hands of another operator (change of step inside the food chain).

49. We consider that it is the responsibility of any ethical business to let suppliers know of any problems in order to protect human health. If an operator considers that a raw material or an ingredient is not compliant with food safety requirements, it should inform its supplier of this non-compliance. The supplier will then have reason to consider or to believe that a food not under its immediate control is non-compliant with the food safety requirements. This supplier should, therefore, withdraw the affected food from the market and notify this withdrawal to the competent authorities.

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50. Where retailers sell a branded product that does not meet the food safety requirements, the brand owners will be responsible for notification and withdrawal/recall, but the retailer is required to co-operate as necessary under Article 19(2).
51. In addition to the requirements of Article 19(1), competent authorities can advise food business operators to withdraw a food which is under their immediate control whenever such measures are justified.

Notifying competent authorities

52. When a food business operator withdraws a food in accordance with Article 19(1), it should notify this withdrawal to the competent authorities. Where products may have reached the consumer, a food business must also inform consumers of the reason for the withdrawal of the product and, if necessary, recall from consumers products already supplied to them.
53. If food that does not meet food safety requirements has not left the immediate control of the food business operator, removal of the food from the food chain does not constitute a withdrawal and there is therefore no obligation to notify the competent authority.
54. **Important:** Article 19 (3) states that if an operator at any stage of the food distribution chain considers that food which it has placed on the market may be injurious to health, they shall immediately notify the competent authorities and detail the action taken to prevent the risk. The assessment as to whether the food might be injurious to health should be objective (see paragraph 13). Under Article 19(3), operators are also required not to prevent or discourage anyone from co-operating with the competent authorities to prevent, reduce or eliminate the risk arising from a food.
55. Businesses should submit the necessary information under Article 19(1) or 19(3) to the Agency's Incidents Branch (<http://www.food.gov.uk/foodindustry/foodfeedform> or fax: 020 7276 8446), to the local authority where the food business operator is based, and in the case of imports, the relevant port health authority.

Article 20 (Withdrawal, recall, and notification of feed)

What the Article says

56. This places obligations on feed business operators to recall and/or withdraw feed from the market if it is not in compliance with feed safety requirements (see paragraph 17 above), and to notify competent authorities.

How we believe businesses can comply

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57. A feed business operator which considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not comply with feed safety requirements should withdraw it from the market and notify the competent authorities. Operators responsible only for feed retail and distribution activities should still initiate recall action of affected product that it has in its possession or has distributed.
58. All feed business operators must immediately inform the competent authorities (the enforcement authority and the Food Standards Agency) if it has reason to believe that a feed placed on the market may not satisfy feed safety requirements and indicate the action being taken to prevent the risk arising from the use of the feed. All feed business operators are required to co-operate with the action being taken by other feed business operators and competent authorities. This will include passing on information to enable affected products to be traced.
59. The notification procedure for feed incidents⁷ is the same as for food incidents (see paragraph 54.)

Enforcement

60. Regulation 3 of the General Food Regulations 2004 designates food authorities, port health authorities, and the Food Standards Agency as the competent authorities in relation to food⁷. 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 (EC) 178/2002. The Agency is specified as an additional enforcement authority in relation to Articles 14 and 19 to allow, for example, for the flexibility of the Meat Hygiene Service enforcing Regulation 178/2002 requirements in meat plants, where this would be more effective.
61. This means that port health authorities or local authorities⁸ 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.
62. 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 1990⁹ for food law offences.

⁷ Regulation 3 of the General Food Regulations (Northern Ireland) 2004 designates district councils only.

⁸ Ibid.

⁹ In Northern Ireland, the Food Safety (Northern Ireland) Order 1991.

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63. In Great Britain, local authorities (mainly trading standards departments) are responsible for enforcing the feed provisions of Regulation (EC) 178/2002. In Northern Ireland, the enforcement authority is the Department of Agriculture and Rural Development. This duty to enforce the provisions is set out in the Feed (Hygiene and Enforcement) Regulations 2005. There are separate Regulations for England, Scotland, Wales and Northern Ireland. These Regulations also specify offences for contravention of the feed provisions of Regulation (EC) 178/2002 and related penalties.

Further information about these Guidance Notes

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

Bill Drennan
Room 115C
Food Law Policy Branch
Food Standards Agency
Aviation House
125 Kingsway
London WC2B 6NH

Tel: 020 7276 8138
Fax: 020 7276 8193
E-mail: guidance@foodstandards.gsi.gov.uk

65. Any queries specific to feed should be addressed to:

Joseph Nicholas
Room 415B
Animal Feed Unit
Food Standards Agency
Aviation House
125 Kingsway
London WC2B 6NH

Tel: 020 7276 8462
Fax: 020 7276 8478
E-mail: joseph.nicholas@foodstandards.gsi.gov.uk

66. In Northern Ireland, for general queries please contact:

Trevor Williamson
General Food Hygiene and Incidents Unit
Food Standards Agency Northern Ireland
10c Clarendon Road
Belfast BT1 3BG

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Tel: 028 9041 7713
Fax: 028 9041 7728
e-mail: trevor.williamson@foodstandards.gsi.gov.uk

67. In Scotland, for general queries please contact:

Jacqui Bunyan
Local Authority Food Law Enforcement Branch
Food Standards Agency Scotland
6th Floor, St Magnus House
25 Guild Street
Aberdeen
AB11 6NJ

Tel: 01224 285175
Mobile: 07876 131648
e-mail: jackie.bunyan@foodstandards.gsi.gov.uk

68. In Wales, for general queries please contact:

Phil Morgan
Food Standards Agency Wales
11th Floor
Southgate House
Wood Street
Cardiff CF10 1EW

Tel: 029 2067 8913
e-mail: phil.morgan@foodstandards.gsi.gov.uk

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Legislation relevant to Regulation (EC) 178/2002

1. The draft Regulation was subject to an extensive 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

2. Although as a Regulation it is directly applicable in Member States, there was 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 (EC) 178/2002, which have applied from 1 January 2005. The necessary changes to domestic food and feed law have been effected by means of Statutory Instruments under the Food Safety Act 1990¹⁰, the Agriculture Act 1970 and the European Communities Act 1972.

Food Safety Act 1990 (Amendment) Regulations 2004¹¹

3. 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 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 1990¹² so that it does not apply in cases where the public consultation requirements of Article 9 of Regulation (EC) 178/2002 apply.
4. The Food Safety Act 1990 (Amendment) Regulations 2004 bring in the new definition of 'food' contained in Regulation (EC) 178/2002 (see Definitions). This new definition excludes medicinal products within the meaning of Directive 2001/83/EC. This meaning is based on the presentation of a product as treating or preventing disease in humans, or its use with a view to correcting, restoring or modifying physiological function. However, certain borderline products for medicinal use which are not medicinal products within the meaning of Directive 2001/83/EC are now 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.
5. The new definition of food automatically applies to other legislation that uses the previous definition in the Food Safety Act 1990, 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.

¹⁰ In Northern Ireland, the Food Safety (Northern Ireland) Order 1991.

¹¹ Ibid.

¹² Articles 39 and 47 of the Food Safety (Northern Ireland) Order 1991.

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6. The revised definition of food excludes live animals unless they are prepared for placing on the market for human consumption, oysters for example.

General Food Regulations 2004 (as amended by the Official Feed and Food Controls (England) Regulations 2005)¹³

7. The main purpose of these Regulations is to create offences under UK law and provide enforcement powers in respect of obligations applying from 1 January 2005 under Regulation (EC) 178/2002. These are Articles 12, 14, 16 (in so far as it relates to food), 18 (in so far as it relates to food business operators), and 19.
8. 'Food business' and 'food business operator' are defined in Article 3.2 and 3.3 of Regulation (EC) 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'. 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 caterers are covered.
9. The extent to which home-producers or charities 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. If you have any doubt as to whether you operate a food business or not, then you might wish to consult their Home Authority for further advice.

Feed (Hygiene and Enforcement) Regulations 2005

10. These Regulations create offences and penalties in relation to the feed provisions of Regulation (EC) 178/2002. These are Articles 12, 16 and 18 (in so far as it relates to feed or feed business operators) and Articles 15 and 19. The Regulations also designate the authorities responsible for enforcing the provisions and provide those authorities with enforcement powers (e.g. powers of entry, seizure and detention of suspect feed).

Legislation in the devolved administrations

11. Following the process of devolution, food and feed 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 Regulations enforcing food aspects of Regulation (EC) 178/2002 to apply to Great Britain. Details of the separate Regulations applying in

¹³ In Northern Ireland, the General Food Regulations (Northern Ireland) 2004 (No. 505) as amended by the Official Feed and Food Controls Regulations (Northern Ireland) 2006.

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Northern Ireland, which differ only in the powers under which they are made, and the food authorities given the responsibility for enforcement, can be found in the footnotes. There are separate Regulations enforcing feed aspects of Regulation (EC) 178/2002 for England, Northern Ireland, Scotland and Wales.