



Guidance Notes for Food Business Operators on Food Safety, Traceability, Product Withdrawal and Recall

**A guide to compliance with Articles 14, 16, 18 and
19 of General Food Law Regulation (EC) 178/2002**

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Introduction

1. These Guidance Notes have been produced with the aim of providing informal, non-statutory advice on compliance with the requirements for food businesses of Articles 14, 16, 18 and 19 of Regulation (EC) 178/2002. Food businesses are required to comply with this legislation which relates to the safety of food, traceability, notification of food safety incidents and withdrawal and recall of unsafe food. The Guidance Notes should be read in conjunction with the Food Safety Act 1990 (Amendment) Regulations 2004 (No. 2990) and the General Food Regulations 2004 (No. 3279)¹ (see Annex 2). The Agency will produce separate guidance for feed businesses on the requirements for feed in the Regulation.
2. The Agency has taken account of the previous Food Standards Agency Guidance Notes on this Regulation issued on 10 March 2005. These earlier Guidance Notes included EC Guidance issued on 20 January 2005. Responses to the public consultation on the EC Guidance in July 2005 have also been taken into account. The Agency view is that these new FSA Guidance Notes are more appropriate for food businesses in the UK.
3. The EC Guidance classifies traceability information into two categories, the first to meet the legal requirements and the second to be followed as best practice. Responses from food businesses to the July 2005 consultation exercise indicated that following such best practice guidance could result in additional costs. The Notes are intended to address stakeholders' concerns from the consultation that following the EC Guidance resulted in disproportionate costs to the food industry.
4. The Agency has reviewed the results of the consultation on the EC Guidance; the FSA Guidance Notes now focus primarily on the legal requirements.
5. The principal changes are:
 - food businesses have a greater discretion regarding the period for which they are required to keep traceability records;
 - changing the need for immediate production of traceability records in certain cases to a need to produce these within 'a short timescale';
 - concentrating on the requirements of the legislation and providing minimal advice on good practice.
6. There is no new guidance on Articles 11, 12 and 17 of the Regulation so the EC Guidance on these Articles is reproduced at Annex 3.

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).

7. These Guidance 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 Authority, i.e.
- their local authority²; or
 - the port health authority³ if relevant

² In Northern Ireland district councils only.

³ Ibid.

Summary for Small Businesses

All food businesses are responsible for the safety of food

8. The principal aim of the Regulation is to protect human health and consumers interests in relation to food. The main requirements are:
- Food must not be unsafe, i.e. it must not be injurious to health or unfit for human consumption.
 - Labelling, advertising and presentation of food must not mislead consumers.
 - Food businesses must be able to identify the businesses from whom they have obtained food, ingredients or food-producing animals and the businesses they have supplied with products, and produce this information on demand.
 - Unsafe food must be withdrawn from sale or recalled from consumers if it has already been sold.

Overview

Purpose of Regulation (EC) 178/2002

9. 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. The Regulation also aims to promote free movement of food within the EU.

10. 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.

Article 14 (Food safety requirements)

What the Article says

11. 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.
12. Although these terms were used in Section 8 of the Food Safety Act 1990⁴, their meaning in the Regulation is not necessarily the same. The European Court may provide further clarification of their meaning through case law. 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. Unsafe food is subject to the withdrawal, recall and notification requirements of Article 19.
13. Regulation 4(b) of the General Food Regulations 2004⁵, (as amended) creates an offence of contravening or failing to comply with the food safety requirements of Article 14(1) (see Annex 2). This replaces the offence under Section 8 of the Food Safety Act 1990 of selling food which fails to comply with food safety requirements, which was removed by the General Food Regulations 2004.

How we believe businesses can comply

14. The food safety requirements in Article 14 apply to sales and supplies of food, including one-off sales and supplies free of charge.
15. The requirements of this Article are not limited to mainstream 'food business operators'. They include all others who supply food, including food produced by individuals for charitable and similar events, for example someone running a one-off food event such as a buffet at a dance. 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) of the Regulation.
16. The factors that need to be taken into account when determining whether food is unsafe, injurious to health or unfit are set out at paragraphs (3), (4) and (5) respectively of Article 14. 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

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

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

for consumers requiring a gluten-free diet could be considered to be injurious if it were found to contain gluten.

17. 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. For example, there is no prohibition on selling peanuts (when correctly labelled) even though some people are allergic to them.
18. It should be noted that Article 14(6) provides that if part of a batch is unsafe, then the whole batch must also be considered unsafe unless a detailed assessment shows there is no evidence for this.

Food that is injurious to health

19. 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 paramount need is to assess the risk.
20. 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?
 - how likely is it?
21. There is a range of reputable, expert organisations that are able to advise on particular cases, for example the Food Research Associations or firms carrying out public analyst work.

Food that is unfit

22. 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 (see Article 14(3) and (5)).

Food not in compliance with food safety legislation

Where food is found to be in breach of specific legislation governing its safety, it can 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 mean that it was likely that the food was injurious to health in the light of Article 14(4) or 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 and therefore cause an offence subject to possible prosecution by enforcement authorities.

Article 16 (Presentation)

What the Article says

23. 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.

How we believe businesses can comply

24. This Article covers misleading labelling and advertising. Businesses should seek to ensure that food is labelled accurately and that the way the product is advertised is not misleading. The Article 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 cake containing synthetic cream was displayed in a chill cabinet in such a way as to give the impression that it contained fresh dairy cream.

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

Article 18 (Traceability)

What the Article says

25. Under this Article, food businesses are required to:

- identify their suppliers of food, food-producing animals and any other substance intended or expected to be incorporated into food;
- identify the businesses to which they have supplied products; and
- produce this information to the competent authorities on demand.

26. The purpose of the traceability provisions is to assist in targeted and accurate withdrawals and to give information to control officials in the event of food safety problems, thereby avoiding the potential for wider disruption. The requirements apply to any business that trades in food 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, caterers and food brokers. Also included are charities where these meet the definition of a 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.

27. Live animals supplied for eventual use in food constitute 'food producing animals' and are subject to the traceability requirements. Other items such as seeds will be subject to the traceability requirements only if these go directly into a food product. Veterinary medicines, pesticides and fertilisers are not within the scope of the Regulation as they are not regarded as 'food' under Regulation (EC) 178/2002.

How we believe businesses can comply

28. Taken at face value, the only information Article 18 requires food 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 (7, 28 and 29) and role of Article 18 in supporting the notification requirements of Articles 19 and 20. It follows that, as a minimum, traceability records should 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 accounting. It can also be helpful to record the batch number or durability indication (where applicable).

29. This requirement does not mean 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.
30. Article 18 requires that the traceability records be made available to the competent authorities on demand. As the purpose of the traceability provision is to assist with withdrawals and recalls of unsafe food, food 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.
31. The Regulation does not specify how long traceability records should be kept, although this may be required by sector specific legislation. 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. Businesses should bear in mind the nature of the food, its product life, and the circumstances under which they might be required to produce records, should a notification under Article 19, or assistance to enforcement authorities, be subsequently required. However, failure to produce such documentation constitutes an offence.
32. 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.
33. Although all food businesses must comply with the traceability requirements of Article 18, there are more detailed requirements in separate legislation specific to particular food sectors. These include, for example, 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.
34. 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. However, internal traceability may be required by commodity specific legislation, for example beef labelling.

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

What the Article says

35. This places obligations on food businesses to withdraw, and/or recall, food from the market if it is not in compliance with the food safety requirements of Article 14. Food business operators must also notify the competent authorities (their local Authority and the Food Standards Agency), and collaborate with these authorities on action they should take to avoid or reduce the risks posed by the food.
36. Article 19(1) requires a food business operator to withdraw food from the market where it considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed does not comply with the food safety requirements, and the food has left the immediate control of the initial food business. The operator should also notify the competent authorities. (Article 19(3) identifies where there is an obligation to notify immediately.)
37. Where the unsafe food may have reached the final consumer, the food business operator must inform consumers effectively and accurately of the reason for the withdrawal of the product. The food business operator must also recall the food from consumers where other measures are insufficient to protect their health. The reason for the recall should provide details as to why the product is unsafe.
38. 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.
39. 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 Annex 1 for clarification of 'placing on the market').
40. Article 19(4) requires that food business operators co-operate with the competent authorities on action they have taken or propose to take to avoid or reduce risks posed by a food that they supply or have supplied.

How we believe businesses can comply

Withdrawal/Recall

41. For the purposes of these Guidance Notes

- **'Withdrawal'** is the process by which a product is removed from the supply chain, with the exception of product that is in the possession of consumers.
 - **'Recall'** means the process by which a product is removed from the supply chain and where consumers are advised to take appropriate action, for example to return or destroy food.
42. The withdrawal of food from the market and notification of the competent authorities may take place at any step along the food chain, not only at time of delivery to the end consumer. The obligation to withdraw from the market applies when both of the following two criteria are met:
- 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; and
 - the food has left the immediate control of that initial food business operator.
43. The decision whether to withdraw/recall should be made objectively. Food business operators should consider whether the food is likely to injure the health of those who will consume it and whether it is otherwise unfit for human consumption. Where the unsafe food may have reached the final consumer and/or withdrawal is insufficient to protect their health, the food business operator must recall the product and inform the consumer effectively and accurately of the reason for the recall.
44. 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).
45. Food would not be considered to have left the control of the initial food business operator if it was being held, for example, on behalf of the operator in a cold store operated by a third party and the owner retained control over that food.
46. If food that does not meet food safety requirements has not left the immediate control of the initial food business operator, removal of the food from the food chain does not constitute a withdrawal and there is therefore no requirement to notify the competent authorities. However, if the food is injurious to health then see paragraph 52.

47. While this is not a stated obligation in the Regulation, the Agency considers that it is the responsibility of any ethical business to let suppliers know of any problems with the products they have supplied 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.
48. Where retailers sell a branded product that does not meet the food safety requirements, the manufacturer/importer (or brand owner if they have responsibility for the management of the product) will be responsible for notification and withdrawal/recall, but the retailer is required to co-operate as necessary.
49. 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

50. When a food business operator withdraws a food in accordance with Article 19(1), it should notify this withdrawal to the competent authorities.
51. **Important:** 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. 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 an unsafe food.
52. Businesses should submit the required information about withdrawals of unsafe food to the Agency's Incidents Branch (fax: 020 7276 8446). They should also notify the local authority where the food business operator is based, and, the port health authority if relevant. Food business operators can obtain a form to notify the Food Standards Agency at <http://www.food.gov.uk/foodindustry/regulation/foodfeedform> if they wish, but the required information can be submitted in another format if businesses would find it easier. A form for local authorities is at <http://www.food.gov.uk/multimedia/worddocs/lafoodincidentreportform.doc>.
54. More detailed Agency advice on withdrawal, recall and notification is available in the document 'Principles for preventing and responding to food incidents', which is at <http://www.food.gov.uk/foodindustry/guidancenotes/incidentguidance/principlesdoc> .

Enforcement

55. 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.
56. The General Food Regulations 2004 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 1990⁸ for food law offences.

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

⁸ In Northern Ireland, the Food Safety (Northern Ireland) Order 1991.

Annex 1: Definitions

A number of terms are defined in Articles 2 and 3 of the Regulation and, since they are used in the Guidance Notes, 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;
- (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;

'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;

'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.

Although not defined in the Regulation, a 'home authority' is the local authority where the relevant decision making base of a food business is located. For a business with multiple branches etc, the home authority will generally be the local authority where the head office is located.

Annex 2: Legislation relevant to Regulation (EC) 178/2002

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

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 1990⁹, the Agriculture Act 1970 and the European Communities Act 1972.

Food Safety Act 1990 (Amendment) Regulations 2004¹⁰

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.

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.

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)¹¹

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.

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

¹⁰ Ibid.

¹¹ 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.

'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.

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 your Home Authority for further advice.

Legislation in the devolved administrations

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 Regulations enforcing food aspects of Regulation (EC) 178/2002 to apply to Great Britain. Details of the separate Regulations applying in 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.

Copies of the UK legislation mentioned above are obtainable from the Office of Public Sector Information. You can access these from the website at <http://www.opsi.gov.uk>.

Annex 3: Guidance on Articles 11, 12 and 17

The guidance below is reproduced from that issued by the European Commission on 20 Jan 2005. It contains references to feed as well as food.

Article 11

Import of Food and Feed

The traceability provisions of the General Food Law do not have an extra-territorial effect outside the EU. This requirement covers all stages of production, processing and distribution in the EU, namely from the importer up to the retail level.

Article 11 should not be construed as extending the traceability requirement to food/feed business operators in third countries. It requires that food/feed imported into the Community complies with the relevant requirements of EU food/feed law.

Exporters in trading partner countries are not legally required to fulfil the traceability requirement imposed on operators within the EU by Article 18 of Reg. 178/2002. However, there may be circumstances where there are special bilateral legal requirements for certain sectors or where there are specific Community legal requirements, for example in the veterinary sector, where certification rules require information concerning the origin of the good. These requirements are not affected by the traceability provisions of the general food law.

The objective of Article 18 is sufficiently fulfilled because the requirement extends to the importer. Where the EU importer is able to identify from whom the product was exported in the third country, the requirement of Article 18 and its objective is deemed to be satisfied.

It is common practice¹² among some EU food business operators to request trading partners to meet the traceability requirements and even beyond the 'one step back-one step forward' principle. However, it should be noted that such requests are part of food business' contractual arrangements and not of requirements established by the Regulation.

Article 12

Export of Food and Feed

Rationale and objective

As it is clearly stated in recital 24, it is necessary to ensure that food and feed exported or re-exported from the Community complies with Community law or the requirements set up by the importing country. In other circumstances, food and

¹² of explanations in Chapter II. 3. 1. iii of EC Guidance

feed can only be exported or re-exported if the importing country has expressly agreed. However, it is necessary to ensure that even where there is agreement of the importing country, food injurious to health or unsafe feed is not exported or re-exported.

The objective was to take into account the level of protection established by importing countries.

It was also considered essential to prevent the 'exportation' of crisis. When a new risk arises, all countries are likely not to have set up relevant safety requirements to prevent this risk. Therefore, it is essential to ensure that in such circumstances, food and feed can only be exported or re-exported with the agreement of the competent authorities of the country of destination and only after these authorities have been fully informed of the reasons for which the food or feed concerned could not be placed on the Community market. In addition, when in such a case foods are injurious to health or feeds are unsafe, they cannot be exported or re-exported even with the agreement of the importing countries.

The scope of this Article is limited to food/feed produced within the EU (exported) or food/feed that has been put on the EU-market after having been imported (re-exported). This Article is not applicable for feed and food rejected at the external border of the EU.

Article 12 (1)

This first subparagraph of Article 12 (1) provides for a general rule: 'food and feed intended for export or re-export must comply with the relevant requirements of food law, unless otherwise required by the authorities, legislation or administrative procedures of the importing country'. The situation referred to is the most usual one: third countries have set their own level of protection for a particular food or feed and exporting operators must then comply with the requirements set up by importing countries.

Where no requirements are set up by the authorities of the importing countries (legislation or administrative procedures), the food and feed intended for export or re-export must comply with the relevant requirements of Community food law.

The second subparagraph of Article 12 (1) provides for the approach to be taken in cases other than the ones covered in the first paragraph of Article 12 (1).

In these other cases, i.e. if there is no relevant Community food law requirement and the third country has not set any specific requirements applicable to imports, food and feed can only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons why the food or feed could not be placed or remain on the market within the EU. However in such circumstances, where food is injurious to health or feed is unsafe, the food or feed cannot be exported or re-exported and a safe disposal must be ensured.

For food and feed rejected at the external border of the EU and which can be re-dispatched, Article 21 of the Regulation (EC) No 882/2004 of the European

Parliament and of the Council of 29 April on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules applies from 1 January 2006.

Article 12 (2)

Article 12 (2) refers to the situation where a Member State or the Community have concluded a bilateral agreement with a third country. In such a case, the rules to comply with are the rules laid down in that agreement.

Article 17

Responsibilities

Rationale

This Article lies within the objective that was set in the White Paper on Food Safety to define the roles of competent Member States authorities and all categories of stakeholders in the food and feed chains – indicated thereafter by the term ‘food chain’ (i.e. farmers, feed and food manufacturers, importers, brokers, distributors, public and private catering businesses).

Given that a food business operator¹³ is best placed to devise a safe system for supplying food/feed and ensuring that the food/feed it supplies is safe, it holds **primary legal responsibility** for ensuring compliance with food law¹⁴ and in particular food safety.

Implications

Article 17 (1) imposes on food business operators an obligation according to which they must actively participate in implementing food law requirements by verifying that such requirements are met. This general requirement is closely linked to other mandatory requirements laid down by specific legislation (i.e. HACCP implementation in the field of food hygiene).

Thus Article 17 (1) implies a responsibility of the operators for the activities under their control pursuant to the classical liability rules according to which any person should be held liable for things and acts under his control. It consolidates this requirement in the Community legal order applicable in the field of food law (not only food safety legislation but also other food legislation), and thus prohibits Member States from maintaining or adopting nationally legal provisions which would exonerate any food business operator from this obligation.

¹³ For the understanding of the present document, the term ‘food business operator’ covers both food and feed business operators.

¹⁴ For the understanding of the present document, the term ‘food law’ covers both food and feed law and the term ‘food safety’ covers both food and feed safety.

Though the requirement laid down in Article 17 (1) is directly applicable from 1 January 2005, the liability of food business operators should flow in practice from the breach of a specific food law requirement (and from the rules for civil or criminal liability which can be found in the national legal order of each Member state). The liability proceedings will not be based on Article 17 but on a legal basis to be found in the national legal order and in the specific infringed legislation.

Article 17 (2) establishes a general duty for the competent Authorities in the Member States to monitor and control that food law requirements have comprehensively and effectively been enforced at all stages of the food chain.

Contribution/Impact

General Compliance and verification requirement

From 1 January 2005 this rule becomes a general requirement applicable in all Member States and all areas of food law.

The consolidation of this requirement should eliminate disparities resulting in barriers to trade and competitive distortion between food business operators.

It takes full account of the fundamental role of food businesses to the **farm to table policy** - covering all sectors of the food chain, in particular in ensuring food safety.

Allocation of liability

Article 17 aims at:

Defining responsibilities of food business operators and differentiating them from those of Member States and,

Extending to all areas of food law, the principle according to which primary responsibility for ensuring compliance with food law, and in particular the safety of the food, remains with the food business.

The Article does not have the effect of introducing a Community regime regulating the allocation of liability among the different links of the food chain. Determining the facts and circumstances which may render an operator liable to criminal penalties and/or civil liability is a complex matter which depends very much on the structure of the different national legal systems.

It should be noted that any discussion related to matters of responsibility should take into account the fact that interactions between producers, manufacturers and distributors are becoming increasingly complex. Thus for example, in many cases primary producers have contractual obligations to manufacturers or distributors to meet specifications which cover quality and/or safety. Distributors increasingly have products produced under their own brand-name and play a key role in product conception and design.

This new situation should then result in greater joint responsibility throughout the food chain, rather than dispersed individual responsibilities. However, each link in the food chain should take the measures necessary to ensure compliance with food law requirements within the context of its own specific activities, applying HACCP-type principles and other similar instruments.

Where a product is found failing food law requirements, the liability of each link in the chain should be reviewed according to whether or not it has properly fulfilled its own specific responsibilities.

Annex 4: Contact details for further queries on Guidance Notes

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

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In Northern Ireland, for general queries please contact:

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In Scotland, for general queries please contact:

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