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. This Guidance has been produced with the aim of providing informal, non-statutory advice and 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, as only the courts have this power. 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

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 will be that unlicensed medicinal products will be 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 Producers 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 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 all animals, 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 these Articles can be found in EC Guidance at the Annex to these Notes and is also available at:
http://europa.eu.int/comm/food/food/foodlaw/guidance/index_en.htm

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.

Notification

15. Businesses are required to notify **both** the Agency and the relevant enforcement authority. A form has been produced by the Agency for use by stakeholders (both food and feed business operators) and can be obtained from the Agency's website. Businesses should return the completed forms to the Agency's Food Incidents Branch (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.

Enforcement

16. 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.

17. 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.

18. 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

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

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Revisions:
Version 1.0 (23/12/2004)
- Original Release

Version 2.0 (9/3/2005)
- Guidance on Articles 14-20 of Regulation 178/2002 replaced by EC Guidance.

ANNEX

20 December 2004

GUIDANCE ON THE IMPLEMENTATION OF ARTICLES 11, 12, 16, 17, 18, 19 AND 20 OF REGULATION (EC) N°178/2002 ON GENERAL FOOD LAW

CONCLUSIONS OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH

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INTRODUCTION

Regulation (EC) N° 178/2002[1] (hereafter "the Regulation") was adopted on 28 January 2002. One of its objectives is to establish common definitions and to lay down overarching guiding principles and legitimate objectives for food law in order to ensure a high level of health protection and the effective functioning of the internal market.

Chapter II of the Regulation seeks to harmonise at Community level general food law principles (Articles 5 to 10) and requirements (Article 14 to 21), already existing in Member States' legal history, placing them in the European context and providing the basic framework of definitions, principles and requirements for future European food law.

Following an informal working practice, the Commission's Health and Consumer protection Directorate General has set up a Working Group with experts from Member States in order to examine and reach consensus on a series of issues concerning the implementation and interpretation of the Regulation.

In addition, in the interest of transparency, the Commission has encouraged all parties concerned to discuss the implementation and application of the Regulation openly and in forums where Member States can be consulted and where different socio-economic interests can express an opinion. To this end the Commission has organised a meeting with representatives from Member States, producers, industry, commerce and consumers to discuss general issues relating to the implementation of the Regulation (held on 19 April 2004). However, it should be noted that matters relating to the non-compliance of national legislation with the Regulation remain outside the scope of this exercise and will continue to be dealt with in accordance with established Commission procedures.

Finally, the Standing Committee on the Food Chain and Animal Health has approved the following conclusions at its meeting of 20 December 2004 and considers that this useful procedure should continue in the light of the experience gained by the full application of the Regulation from 1 January 2005. These conclusions shall be made widely available to interested parties.

The present document aims to assist all players in the food chain to better understand and to apply correctly and in a uniform way the Regulation. However, this document has no formal legal status and in the event of a dispute, ultimate responsibility for the interpretation of the law lies with the Court of Justice.

It is also mentioned that some issues, specific to a category of food business operators, have been subject to written position from the Commission[2].

[1] Regulation (EC) N°178/2002 of the European parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food safety Authority and laying down procedures in matters of food safety.

[2] Written question E-2704/04 of W. Pieck on the implementation of traceability requirements to charities.

The following issues will be addressed:

- Responsibilities (Article 17);
- Traceability (Article 18);
- Withdrawal, recall and notification for food and feed (Articles 19 and 20) in relation to food and feed safety requirements (Articles 14 and 15);
- Imports and exports (Articles 11 and 12).

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I. ARTICLE 17

RESPONSIBILITIES

Article 17

1. Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.

2. Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution.

For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.

I.1. 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 operator[3] 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 law[4] and in particular food safety.

I.2. 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.

- 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.

[3] For the understanding of the present document, the term "food business operator" covers both food and feed business operators.
[4] 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.

I.3. Contribution/Impact

I.3.1. 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.

I.3.2. 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.

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II. ARTICLE 18

TRACEABILITY

Recital 28
Experience has shown that the functioning of the internal market in food or feed can be jeopardised where it is impossible to trace food and feed. It is therefore necessary to establish a comprehensive system of traceability within food and feed businesses so that targeted and accurate withdrawals can be undertaken or information given to consumers or control officials, thereby avoiding the potential for unnecessary wider disruption in the event of food safety problems.

Recital 29
It is necessary to ensure that a food or feed business including an importer can identify at least the business from which the food, feed, animal or substance that may be incorporated into a food or feed has been supplied, to ensure that on investigation, traceability can be assured at all stages.

Article 3 Point 15
'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 18

1. The traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be, incorporated into a food or feed shall be established at all stages of production, processing and distribution.

2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a food-producing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand.

3. Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.

4. Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.

5. Provisions for the purpose of applying the requirements of this Article in respect of specific sectors may be adopted in accordance with the procedure laid down in Article 58(2).

II.1. Rationale

Recent food scares (BSE and dioxin crisis) have demonstrated that the identification of the origin of feed and food is of prime importance for the protection of consumers. In particular, traceability helps facilitate the withdrawal of food and enables consumers to be provided with targeted and accurate information concerning implicated products**.** Traceability does not itself make food safe. It is a risk management tool to be used in order to assist in containing a food safety problem.

- Traceability has different objectives such as food safety, fair trading between operators and reliability of the information provided to consumers. The Regulation introduces the traceability requirement with in particular the objective to ensure food safety and to assist in enabling unsafe food/feed to be removed from the market.

- Traceability is meant to ensure that targeted and accurate withdrawals or recalls can be undertaken, appropriate information can be given to consumers and food business operators, risk assessment can be performed by control authorities and unnecessary wider disruption of trade can be avoided.

II.2. Implications

- Article 18 requires food business operators:

  - to be able to identify from whom and to whom a product has been supplied;

  - to have systems and procedures in place that allow for this information to be made available to the competent Authorities upon their request.

The requirement relies on the "one step back"-"one step forward" approach which implies for food business operators that:

- They shall have in place a system enabling them to identify the immediate supplier(s) and immediate customer(s) of their products.
- A link "supplier-product" shall be established (which products supplied from which suppliers).
- A link "customer-product" shall be established (which products supplied to which customers). Nevertheless, food business operators do not have to identify the immediate customers when they are final consumers.

II.3. Contribution/impact

- Although traceability is not a new notion in the food chain, it is the first time that the obligation for all food business operators to identify the suppliers and direct recipients of their food/feed is stipulated explicitly in a horizontal community legal text. Consequently, Article 18 creates a new general obligation for food business operators.

- Article 18 is worded in terms of its goal and intended result, rather than in terms of prescribing how that result is to be achieved.

Without prejudice to specific requirements, this more general approach leaves industry with greater flexibility in the implementation of the requirement and is thus likely to reduce compliance costs. However, it requires both food businesses and the control authorities to take an active role in ensuring effective implementation. This may present some difficulties, although the elaboration of industry codes of practices could alleviate the problem.

II.3.1. Scope of the traceability requirement

i) Covered products.

- The wording of this Article and in particular the part *"any substance intended to be, or expected to be, incorporated into a food or feed"* should not be interpreted in the sense that veterinary medicinal products, plant protection products, fertilisers may fall into the scope of the requirement. It should be noted that some of these products are covered by specific Regulations or Directives that may even impose more stringent requirements on traceability.

- The covered substances are those intended or expected to be "*incorporated"*, as a part of a food or feed during its manufacture, preparation or treatment. This would cover for example all types of food and feed ingredients, included grain when incorporated in a feed or food. But it excludes grain when used as seed for cultivation.

- Similarly, packaging material does not make part of food as defined under Article 2 and does not fall into the scope of Article 18 despite the possible unvoluntary migration of its constituents into the food. The traceability of those food packaging materials has been covered by specific rules, adopted on 27 October 2004[5].

- Furthermore, the new food hygiene Regulation (EC) N° 852/2004 and the forthcoming feed hygiene Regulation should ensure, from the 1st of January 2006, a link between food/feed and veterinary medicinal and plant protection products, covering this gap as farmers will have to keep and retain records on these products.

ii) Covered operators

- Article 18 of the Regulation applies to food business operators at all stages of the food chain, from primary production (food producing animals, harvests), food/feed processing to distribution. This includes charities. However, Member States should take into consideration the particular situation of charities and donation activities in the context of enforcement and sanctions.

[5] Regulation (EC) N° 1935/2004 of 27 October 2004, OJ L 338, 13.11.2004, p.4.

- Article 3 Points 2 and 5 defines a food business operator as "any undertaking…carrying out any of the activities related to any stage of production, processing and distribution of food/feed". Transporters and storage operators, as undertakings involved in the distribution of food/feed, are covered by this definition and are required to comply with Article 18.

- Where transportation is integrated within a food business, the business as a whole must comply with the provision of Article 18. For the transport unit, maintaining records of products supplied to customers may be sufficient as other units within the business would maintain records of products received from suppliers.

- The manufacturers of veterinary medicinal products, agricultural production inputs (such as seeds) are not subject to the requirements of Article 18.

iii) Applicability to third country exporters (in connection with Article 11)

- The traceability provisions of the Regulation 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 business operators in third countries. It requires that food/feed imported into the Community complies with the relevant requirements of EU food law.

- Exporters in trading partner countries are not legally required to fulfil the traceability requirement imposed within the EU (except in circumstances where there are special bilateral agreements for certain sensitive sectors or where there are specific Community legal requirements, for example in the veterinary sector).

- The objective of Article 18 is sufficiently fulfilled because the requirement extends to the importer. Since the EU importer shall be 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 practice 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 the food business's contractual arrangements and not of requirements established by the Regulation.

II.3.2. Implementation of traceability requirement

i) Identification of suppliers and customers by food business operators

- A food business operator should be able to identify any "person" from whom it received its food/raw materials. This person can be an individual (for example a hunter or a mushroom collector) or a legal person. Recital 29 stipulates that a food business

must identify at least the business from which the food/feed or substance that may be incorporated into a food/feed has been supplied.

It should be clarified that the term "supply" should not be interpreted as the mere physical delivery of the food/feed or food producing animal (e.g. truck driver who is an employer for a certain operator). Identifying the name of the person physically delivering is not the objective pursued by this rule and it would not be sufficient to guarantee the traceability along the food chain.

- A food business operator must identify only the other businesses (legal entity) to whom it provides its products (excluding final consumers). In case of trade between retailers, such as a distributor and a restaurant, the traceability requirement is also applicable.

ii) Internal traceability

- It is in the logic of Article 18 that a certain level of internal traceability would be put in place by food business operators. Article 18 has to be read in conjunction with Recital 28 which refers to a *"**comprehensive** system of traceability **within** food and feed businesses so that **targeted** and **accurate** withdrawals can be undertaken…, thereby avoiding the potential **for unnecessary disruption in the event of food safety problems***".

- An internal traceability system will benefit the operator by contributing to more targeted and accurate withdrawals. Food business operators would save costs in terms of time of a withdrawal and in avoiding unnecessary wider disruption.

- Without prejudice to more detailed rules, the Regulation does not compel operators to establish a link (so called internal traceability) between incoming and outgoing products. 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.

- In summary, food business operators should be encouraged to develop systems of internal traceability designed in relation to the nature of their activities (food processing, storage, distribution etc). The decision on the level of detail of the internal traceability should be left upon the business operator, commensurate with the nature and size of the food business.

iii) Traceability systems laid down by specific legislations

Apart from specific legislations establishing food safety traceability rules for certain sectors/products in line with the "spirit" of Article 18, there is a set of specific regulations laying down marketing and quality standards for certain products. These regulations that often have fair trade purposes contain provisions about the identification of the products, the transmission of the documents accompanying the transactions, the keeping of records, etc.

Any other system of identification of products existing within the framework of specific provisions may be used to satisfy the requirement established by Article 18, insofar as it

allows the identification of the suppliers and of the direct recipients of the products at all stages of production, processing and distribution.

However, the traceability requirements of the Regulation are general requirements and are therefore always applicable. The determination whether sectoral traceability provisions already meet Article 18 requirements would need a detailed analysis of those provisions.

iv) Types of information to be kept

Article 18 does not specify what types of information should be kept by the food and feed business operators. All relevant information for traceability purpose should be kept depending on each traceability system features.

However, to fulfil the objective of Article 18, the registration of the following information is considered necessary. This information can be classified in 2 categories according to its level of priority:

- The first category of information includes any information which shall be made available to the competent Authorities in all cases:

  - Name, address of supplier, nature of products which were supplied from him.
  - Name, address of customer, nature of products that were delivered to that customer.
  - Date of transaction / delivery.

The registration of date of transaction/delivery flows directly from the registration of the two other items. When a same type of products is provided several times to a food business operator, the sole registration of name of supplier and nature of products would not ensure the traceability requirement.

- The second category of information includes additional information which is highly recommended to be kept:

  - Volume or quantity
  - Batch number, if any.
  - More detailed description of the product (pre-packed or bulk product, variety of fruit/vegetable, raw or processed product).

The information to be registered has to be chosen in light of the food business activity (nature and size of business) and the characteristics of the traceability system.

Food crises in the past have shown that tracing the commercial flow of a product (by invoices at the level of a company) was not sufficient to follow the physical flow of the products. Therefore, it is essential that traceability system of each food / feed business operator is designed to follow the physical flow of the products: the use of delivery notes (or registration of the address of producing units) would ensure more efficient traceability.

v) Time of reaction for traceability data availability

- Article 18 requires food and feed operators to have in place systems and procedures to ensure the traceability of their products. Although the Article does not provide any details about these systems, the use of terms "systems" and "procedures" implies a structured mechanism able to deliver the needed information upon request from the competent Authorities.

- The most crucial point in having a good traceability system in place that would satisfy the objective pursued as described in Recital 28, is the time needed to deliver fast and accurate information. A delay in the delivery of this relevant information would undermine a prompt reaction in case of crisis.

- The minimal information which belongs to the first category defined above shall be immediately available to the competent authorities.

- The information belonging to the second category shall be available as soon as reasonably practicable, within deadlines appropriate to circumstances.

vi) Time of records keeping

Article 18 does not foresee a minimum period of time for keeping records. On a broad basis, it is considered that commercial documents are usually registered for a period of 5 years for taxation controls. This 5 year period, where applied from date of manufacturing or delivery to traceability records[6], would be likely to meet the objective of Article 18.

However, this common rule would need to be adapted in some cases:

- For products[7] without a specified shelf life, the general rule of 5 years applies;

- For products with a shelf life above 5 years, records should be kept for the period of the shelf-life plus 6 months;

- For highly perishable products, which have a "use by" date less than 3 months or without a specified date[8], destined directly to final consumer, records should be kept for the period of 6 months after date of manufacturing or delivery.

Finally, it should be taken into account that, apart from the traceability provisions of Article 18 of the Regulation, many food businesses are subject to more specific requirements in terms of record keeping (type of information to be kept and time). Competent authorities should ensure that they comply with these rules.

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[6] more particularly to records belonging to the first category of information foreseen in paragraph II. 3. 4.
[7] Products such as wine.
[8] Products such as fruits, vegetables and non pre-packed products.

III. ARTICLE 19

WITHDRAWAL, RECALL AND NOTIFICATION

BY FOOD BUSINESS OPERATORS

Article 19

1. If 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, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection.

2. A food business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the food shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the food-safety requirements and shall participate in contributing to the safety of the food by passing on relevant information necessary to trace a food, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food.

4. Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

III.1. Rationale

- The obligations of Article 19 aim at reducing or eliminating the risk due to the placing on the market of unsafe foodstuffs and at preventing, reducing or eliminating the risk due to the placing of the market of food that may be injurious to health.

- The extent of the obligations of operators in relation to withdrawal (or recall) and notification of an unsafe food is correlated to the general safety requirements provided for in Article 14 of Regulation 178/2002.

- To ensure the proportionality of the actions taken to reduce or eliminate a risk, it is important to make reference to relevant criteria for applying the concept of unsafe food, noting that withdrawal and recall are meant to be used when such an immediate action is necessary to eliminate a risk.

- The information of competent Authorities by the food business operators is an important element for market surveillance as it enables the competent authorities to monitor whether the business operators have taken the appropriate measures to address the risks posed by a food placed on the market and to order or take additional measures if necessary for avoiding the risks.

III.2. Implications

- Article 19 imposes specific obligations from 1st January 2005 on food business operators to withdraw from the market food that does not meet the food safety requirements and to notify this to competent authorities. Where the product may have reached the consumer, the operator shall inform the consumer and if necessary recall from consumers' products already supplied to them.

- Article 19 provides for the necessary cooperation between the food chain operators in order to ensure the withdrawal of unsafe food from the market.

- Article 19 imposes a specific obligation on the food business operator to inform the competent authorities should it considers or has reason to believe that a food which it has placed on the market may be injurious to health.

- It specifies a general obligation of cooperation of the food business operators with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

III.3. Contribution/ Impact

III.3.1. Article 19 (1)

i) Obligation to withdraw

Article 19 (1) imposes the specific obligation on food business operators to withdraw from the market a food that does not meet the food safety requirements and inform the competent authorities thereof.

Regarding a definition of withdrawal, reference can be made to the definition laid down in Directive 2001/95/EC on General Product Safety which states that "withdrawal means any measure aimed at preventing the distribution, display or offer of a product dangerous to the consumer".

It has to be underlined that in the context of Article 19:

- The withdrawal from the market may take place at any step along the food chain and not only at time of delivering to the end consumer;

- The obligation to notify a withdrawal to the competent Authorities is a consequence of the obligation to withdraw;

- The obligation to withdraw from the market applies when the following two cumulative criteria are met:

- **First criterion triggering a withdrawal: the food in question is considered by the operator as not being in compliance with the food safety requirements**

Article 14 of Regulation 178/2002 provides for the approach to follow in making this type of consideration.

Paragraphs 2, 3, 4 and 5 provide for general criteria that have to be taken into account to consider a food unsafe.

- Article 14 (2) provides that a food shall be deemed to be unsafe if it is considered to be injurious to health or unfit for human consumption.

- Article 14 (3) provides that in determining whether any food is unsafe, regard shall be had to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and to the information provided to the consumer.

- Article 14 (4) and 14 (5) provide that in determining whether any food is injurious to health or unfit for human consumption regard shall be had to certain criteria.

In more concrete terms, Article 14 (7) and Article 14 (9) specify that food compliant with the specific Community provisions (or in their absence, with national provisions) governing the safety of the food in question is deemed to be safe.

Finally the wording of Article 14 (8), even if it is explained in the framework of the actions of the competent authorities, confirms that despite the conformity of a food to applicable specific provisions, this food can be found unsafe.

- **Second criterion triggering a withdrawal: a food[9] is on the market and has left the immediate control of the initial food business**

This criterion derives from the wording used in Article 19 (1) "withdrawal from the market", which implies that the food was placed on the market. In addition, Article 19 (1) provides that a withdrawal shall be undertaken only when the food in question has left the immediate control of the initial operator.

Therefore, the scope of the withdrawal foreseen in the framework of Article 19 (1) does not concern actions of withdrawal undertaken before the placing on the market of a product. Furthermore, withdrawals of food that has not left the immediate control of the operator are not defined as withdrawal within the meaning of Article 19 (1).

The wording "has left the immediate control of the initial operator" stresses that when there is the possibility for the food business operators to remedy the non compliance by their own means, without a need to request/require cooperation from other operators, the obligations of Article 19 (1) do not apply. The additional words "of the initial operator" are important. It implies that the food has left for example the processing unit and is in the hands of an other operator (change of step inside the food chain).

The scope of the withdrawal defined in Article 19 (1) does not limit the scope of withdrawal that can be decided by competent authorities. Food business operators can be required to withdraw a food which is under their immediate control as directed by a competent authority whenever such measures are justified.

The scope of the withdrawal defined in Article 19 (1) is without prejudice to the legal obligation on food business operators to ensure, within the businesses under their control, that foods satisfy the requirements of food law (e.g. Article 17 (1) above).

ii) Practical approach

In the framework of the approach established in Article 14, two types of cases will need to be considered:

- **The food does not comply with the specific Community (or national) provisions governing its safety:**

A food compliant with the specific Community (or national) provisions governing its safety is deemed safe in accordance with Article 14 (7) and (9).

[9] As defined in Article 2 of Reg.178/2002

When the food does not comply with the specific Community (or in their absence, national) provisions governing its safety, it can be presumed that the food is unsafe and the general criteria set up in paragraphs 2, 3, 4 and 5 of Article 14 have to be taken into account.

These criteria are general and have to be considered on a case by case basis. In particular, these criteria have to be considered in the light of the specific legislation applicable to the food involved.

For example, Article 14 (3) provides that in determining whether any food is unsafe, regard shall be had to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution. This general criterion will need to be considered in the framework of the applicable legislation.

Specific legislative provisions provide for example for different levels of safety according to the destination of the food[10] (food intended for direct human consumption and food not for direct human consumption but intended for secondary treatment). These specific legislations usually provide for additional requirements ensuring that a food not intended for direct human consumption will not be provided to a final consumer or used as an ingredient before undertaking secondary treatment and these requirements must be respected.

Factual questions such as satisfactory representativeness of samples or the sensitivity of analytical methods might also need to be addressed.

National legislation or guidelines may also help for the determination of the unsafe character of a food (some national legislation includes in particular provisions on food injurious to health or unfit for human consumption). These national legislation or guidelines will have to be in conformity with Article 14 or EU sectoral legislation when this legislation provides for a definition of an unsafe food[11]. In particular, considering that the purpose of Article 14 is the setting up of food safety requirements, these provisions shall be limited to identifying cases where there is a direct or indirect risk for human health deriving from the food.

This section has been particularly identified as requiring further discussion and eventual revision in the light of the experience gained.

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[10] Article 4 (3) of Regulation N) 466/2001 setting up maximum levels for certain contaminants in foodstuff provides that "groundnuts, nuts and dried fruits not complying with the maximum level of aflatoxins laid down in point 2.1.1.1 of Annex 1 and cereals not complying with the maximum levels laid down in point 2.2.2.1 can be placed on the market provided that these products a) are not intended for direct human consumption or used as as an ingredient in foodstuffs; b) comply with the maximum levels laid down in point 2.1.1.2 of Annex 1 for groundnuts and point 2.1.1.3 of Annex 1 for nuts and dried fruits c) are subjected to a secondary treatment involving (…) c) are labelled clearly showing their destination and bearing the indication '*product must be subjected to sorting or other physical treatment to reduce aflatoxin contamination before human consumption or use as an ingredient in foodstuffs'* "

[11] For example Article 5 of Regulation N° 2377/90 on maximum residues limits of veterinary medicinal products in foodstuffs of animal origin provides that the substances included in Annex IV are substances for which no residues limits are possible because residues of the substances concerned **at whatever limit, constitute a hazard to the health of consumer**. In addition, the current discussion on the establishment of EU microbiological criteria contemplates two sets of food safety criteria. One of this criteria, " a "food safety criterion" , is defined as a criterion defining the safety and acceptability of a product or a batch of foodstuff applicable to products ready to be placed on the market or which are already on the market. It sets a limit value above which a product or a batch of foodstuffs is considered "unsafe".

- **The food complies with the specific Community (or in their absence, national) provisions governing its safety but there are reasons to consider that it is unsafe**

When an operator considers or has reason to believe that a food is unsafe, despite its conformity with the specific Community (or in their absence, national) provisions governing its safety, it shall also withdraw the food in question from the market.

This type of case might happen because of accidental (or intentional) contamination not foreseen in legislation, For example when an operator has reason to believe, because of information in its possession, that the consumption of a food that if has placed on the market is causing food poisoning or otherwise injuring the health of consumers, it shall withdraw the food in question.

The presence in a food of foreign material with the potential to cause injury (e.g. glass, metal) would fall in this category. It is not a case always explicitly foreseen in existing legislation but the food is considered unsafe.

This type of case can also arise when new scientific information is available on a substance authorised in legislation. In this type of case, the percentage of uncertainty is in some cases high and it will fall in practice in the situation covered by Article 19 (3).

iii) Notification of the withdrawal to the competent authorities

When a food business operator withdraws a food in accordance with Article 19 (1), it shall notify this withdrawal to the competent authorities which supervises his establishment. It is up to the national authority to trigger the RASFF according to point III.3.5 if relevant.

It is useful to emphasise that when a food business operator takes out of the food chain a food that does not meet the food safety requirements but that is under its immediate control, there is no obligation to notify the competent authorities under the provisions of Article 19 (1).

Agreed guidelines between national competent authorities and food business operators may provide for this information.

iv) Modalities of the notification to the competent authorities

Modalities of the notification procedure to the competent authorities should be left to subsidiarity (up to national or regional competent Authorities).

v) Recall and information to the consumers

When the same circumstances as the ones mentioned for withdrawal are met and when in addition, the product may have reached the consumer, Article 19 (1) requires the food business operators:

- To inform the consumer of the reason for withdrawal

and,

- If necessary to recall from consumers products already supplied to them - i.e. to take "any measure aimed at achieving the return of a unsafe product that has already been supplied or made available to consumers by a food business operator". The recall is necessary when other measures are not sufficient to achieve a high level of health protection.

vi) Responsibility for the application of Article 19 (1)

All food business operators (who have imported, produced, processed, manufactured or distributed a food) are covered by the provisions of Article 19 (1) (withdrawal and/or recall and notification) and shall apply them within the limits of the activities under their control and in proportion to their responsibilities.

Retailers shall also apply Article 19 (1) since they distribute food to the final consumers. Some of their activities might affect the packaging, labelling safety or integrity of the food. In addition, it can be noted that in some cases, production or processing activities (for example bakery) are undertaken in shops.

As explained in relation to Article 17, Regulation 178/2002 has no incidence on the legal national systems regulating the liability of the operators (civil, criminal liability).

It should be emphasised that when an operator withdraws a raw material or an ingredient under its immediate control because it is non compliant with the food safety requirements, it will normally inform its supplier of this non compliance.

The supplier thus informed, will be in possession of information, giving him reason to consider or to believe that a food not under its immediate control, is non compliant with the food safety requirements. This supplier shall therefore apply the obligations of withdrawal and subsequent notification of this withdrawal to the competent authorities.

If this operator considers that the information in its possession is such that the food may be injurious to health, the obligations provided for by Article 19 (3) will be applicable. This reasoning also applies to similar cases such as when the internal controls of a distributor lead to a withdrawal of a food supplied by a producer or processor.

Cooperation between each level of the food chain will be necessary to achieve the objectives of Article 19 (1).

III.3.2. Article 19 (2)

Article 19 (2) constitutes a requirement on food business operators responsible for retail[12] 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 withdrawal of food not in compliance with food safety requirements, and in passing on relevant information. For example, when a producer withdraws/recalls a food for which it is responsible, the distributor and/or the retailer is/are required to participate as necessary.

[12] Retail is defined in Article 3 Point 7

Article 19 (2) provides for an important section of the cooperation between the different operators of the food chain. It does not cover all situations where cooperation might be needed and it will be essential that the food business operators investigate how to promote an efficient cooperation between them to ensure the application of Article 19.

III.3.3. Article 19 (3)

Article 19 (3) places an information requirement on food business operators when they consider or have reasons to believe that a food that they have 'placed on the market' may be 'injurious to health. In this case, they shall immediately inform the competent authorities and detail the action taken to prevent the risk.

Article 19 (3) does not impose systematically a withdrawal but provides for immediate information of the competent authorities of a potential risk and the action taken to prevent it.

The following conditions need to be met to trigger the application of Article 19 (3):

- The food in question is placed on the market[13]. The 'placing on the market' also covers food products which have already been produced by food business operators or imported and are being held with a view to sale or supply free of charge. It does not include food products which are still under processing, or raw materials provided by suppliers.

and

- The food in question may be injurious to health.

The objective of this Article is to ensure that the competent authorities are informed in case of a potential risk for health.

Article 19 (3) can be applied in different types of cases such as:

- New information in possession of the operator leading to consider the food as injurious to health but this information diverges from other information. For example, when an operator withdraws internally an unsafe food and informs thereof the supplier of this food, the supplier might consider that the information sent contradicts other information in its possession.

- Information that the product is injurious to health, but this information is not yet completely confirmed

- Information on an emerging risk.

It should facilitate a global prevention of risks by enabling the competent authorities to receive early warnings or to identify potential (possibly emerging) risks in order to ensure the most efficient and proportionate ways to manage it.

In some cases, for example when further or more validated information confirms that the product is injurious to heath, the obligations set up in Article 19 (1) will apply.

[13] 'Placing on the market' is defined in Article 3.8 as 'the holding of food (or feed) for the purposes of sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves'

The operator responsible for providing the information to the competent authorities is the operator that has placed the product on the market.

The second part of Article 19 (3) is designed to prevent food business operators from discouraging their employees from cooperating with competent authorities where this may prevent, reduce or eliminate a risk arising from food.

III.3.4. Article 19 (4)

It requires that the food business operators will cooperate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.
For example, food business operators should contact the competent authorities when they need help in determining how to fulfil their obligations.
In accordance with the general objective of prevention set up in Article 19 (3), operators, in particular small operators should be encouraged to contact the competent authorities in case of uncertainty on the risk at stake.
Assistance should be given by the competent authorities when operators contact them in the framework of Article 19.

III.3.5. Notification to the Rapid Alert System for Food and Feed (RASFF)

A clear distinction should be made between the RASFF and the obligation of notification provided by Articles 19 and 20. The RASFF involves only competent Authorities (Commission, Member States and EFSA). Food operators have an obligation, under certain circumstances (see part III on notification), to notify only the competent authorities (at appropriate level depending on Member States rules) and not the RASFF.

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IV. ARTICLE 20

WITHDRAWAL, RECALL AND NOTIFICATION

BY FEED BUSINESS OPERATORS

Article 20

1. If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof. In these circumstances or, in the case of Article 15(3), where the batch, lot or consignment does not satisfy the feed safety requirement, that feed shall be destroyed, unless the competent authority is satisfied otherwise. The operator shall effectively and accurately inform users of the feed of the reason for its withdrawal, and if necessary, recall from them products already supplied when other measures are not sufficient to achieve a high level of health protection.

2. A feed business operator responsible for retail or distribution activities which do not affect the packaging, labelling, safety or integrity of the feed shall, within the limits of its respective activities, initiate procedures to withdraw from the market products not in compliance with the feed-safety requirements and shall participate in contributing to the safety of food by passing on relevant information necessary to trace a feed, cooperating in the action taken by producers, processors, manufacturers and/or the competent authorities.

3. A feed business operator shall immediately inform the competent authorities if it considers or has reason to believe that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a feed.

4. Feed business operators shall collaborate with the competent authorities on action taken in order to avoid risks posed by a feed which they supply or have supplied.

IV.1. Rationale

- The objectives of this Article are the same as those of Article 19, applied to feed mutatis mutandis.
- However, some of the wordings used in 20 (1) are specific to the feed sector and need to be explained.
- In the context of feed, it is important to take into account that some type of feed in some of its raw state prior to processing is not fit for animal consumption.

IV.2. Implications

- Mostly similar to those of Article 19, except that Article 20 (1) provides in particular for the destruction of the feed or batch of feed considered as non compliant with the feed safety requirements, unless the competent authority is satisfied otherwise.
- In the context of feed, the information on withdrawal will concern the users (farmers) of the feed and not consumers.

IV.3. Contribution / Impact

IV.3.1. Article 20 (1)

i) Withdrawal and notification to the competent authorities

The first sentence of Article 20 (1) "*If a feed business operator considers or has reason to believe that a feed which it has imported, produced, processed, manufactured or distributed does not satisfy the feed safety requirements, it shall immediately initiate procedures to withdraw the feed in question from the market and inform the competent authorities thereof*" contains a similar wording to the one used in Article 19 (1).

Therefore, the same approach as the one explained for Article 19 (1) can be followed with the following differences:

- The first cumulative criterion to be met for the application of Article 19 (1) is worded slightly differently in Article 20 (1). The withdrawal of the feed is a withdrawal from the market, which implies that the product is on the market. However, the further condition "which has left the immediate control" is not included in Article 20 (1). This will mean that the feed operators will have to withdraw and notify unsafe feed that is placed on the market but that might still be under their immediate control. In practice, this will concern the holding of feed for the purpose of sale (e.g. definition of "placing on the market" in Article 3.8). The holding for sale takes place once all internal processes making a product ready for sale have been applied. Therefore, actions, including taking the product out of the food chain, undertaken before the product is ready for sale are not meant to be withdrawals in the meaning of Article 19 (1) and do not have to be notified.

- The second cumulative criterion "the feed is considered by the operator as not meeting the feed safety requirements" is similar to the one used in Article 19 (1). Therefore, the feed safety requirements mentioned in Article 15 will need to be taken into consideration. In particular, Article 15.2 specifies the intended use of a feed has to be taken into

consideration to consider it unsafe. For example, it is notable that for certain contaminants, processing that results in the removal of the contaminant could be allowed under certain conditions, laid down by the relevant specific legislation.

- In addition, since Article 15 provides that feed shall be deemed to be unsafe for its intended use if it is considered a) to have an adverse effect on human or animal health, b) to make the food derived from food-producing animals unsafe for human consumption, the requirements of Article 14 in relation to the determination of an unsafe food have to be taken into account to implement Article 15.

ii) Destruction

The second sentence of Article 20 (1) is specific to the feed sector. Its provides that in addition to the withdrawal and the information of the competent authorities, the feed considered as not meeting the feed safety requirement and any related batch, lot or consignment which is considered not to meet the feed safety requirement as provided for in Article 15 (3), shall be destroyed, unless the competent authority is satisfied otherwise. It is the case, for example, where another measure, specified by the relevant legislation, could be used.

Destruction shall be therefore the rule unless the competent authority is satisfied otherwise. In addition, in accordance with Article 15 (3) any related batch, lot or consignment shall be presumed unsafe and destroyed, unless following a detailed assessment there is no evidence that it fails to satisfy the feed safety requirement.

Therefore, when informing the competent authority of the withdrawal of an unsafe feed (and any related batch, lot or consignment) the feed operator shall specify if the destruction is planned or propose alternative measures ensuring that no unsafe feed shall be placed on the market or fed to any food-producing animal. An agreement of the competent authority on the alternative measures proposed is necessary in order for the operator to apply such measures, under the conditions laid down by the specific legislation.

iii) Information of users and recall

The comments made under Article 19 (1) in relation to information and recalls are applicable mutadis mutandis. However, as this provision applies in the context of feed, the information on withdrawal will usually concern the users of the feed, usually farmers, and not consumers.

IV.3.2. Article 20 (2), (3) and (4)

The comments made for the application of paragraphs 2, 3 and 4 of Article 19 are valid mutadis mutandis for the application of paragraphs 2, 3 and 4 of Article 20.

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V. ARTICLE 11

IMPORT OF FOOD AND FEED

Article 11

Food and feed imported into the Community

Food and feed imported into the Community for placing on the market within the Community shall comply with the relevant requirements of food law or conditions recognised by the community to be at least equivalent thereto or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

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 practice[14] 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.

[14] cf explanations in chapter II. 3. 1. iii).

VI. ARTICLE 12

EXPORT OF FOOD AND FEED

Article 12

1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

In other circumstances, except in the case where foods are injurious to health or feeds are unsafe, 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 for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.

2. When the provisions of a bilateral agreement concluded between the Community or one of its Member States and a third country are applicable, food and feed exported from the Community or that Member State to that third country shall comply with the said provisions.

VI.1. 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 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 food are injurious to health or feed 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.

VI.2. 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[15] applies from 1 January 2006.

VI.3. 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.

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[15] OJ L 165, 30.04.2004, p.1. Corrigendum published on OJ L191, 28.5.2004, p. 1