

**26 January 2010**

**GUIDANCE ON THE IMPLEMENTATION OF ARTICLES 11, 12, 14, 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**

## **INTRODUCTION** **4**

### **I. ARTICLE 14** **6**

<b>I.1. RATIONALE</b>	<b>8</b>
<b>I.2. IMPLICATIONS</b>	<b>8</b>
<b>I.3. CONTRIBUTION/IMPACT</b>	<b>8</b>
I.3.1. ARTICLE 14 (1)	8
I.3.2. ARTICLE 14 (2)	8
I.3.3. ARTICLE 14 (3) – CONSIDERATIONS IN DETERMINING WHETHER FOOD IS UNSAFE	9
I.3.4. ARTICLE 14 (4) – CONSIDERATIONS IN DETERMINING WHETHER FOOD IS INJURIOUS TO HEALTH	9
I.3.5. ARTICLE 14 (5) – CONSIDERATIONS IN DETERMINING WHETHER FOOD IS UNFIT FOR HUMAN CONSUMPTION	10
I.3.6. ARTICLE 14(7) FOOD IN COMPLIANCE WITH FOOD SAFETY LEGISLATION	10

### **II. ARTICLE 17** **12**

<b>II.1. RATIONALE</b>	<b>13</b>
<b>II.2. IMPLICATIONS</b>	<b>13</b>
<b>II.3. CONTRIBUTION/IMPACT</b>	<b>13</b>
II.3.1. GENERAL COMPLIANCE AND VERIFICATION REQUIREMENT	14
II.3.2. ALLOCATION OF LIABILITY	14

### **III. ARTICLE 18** **15**

<b>III.1. RATIONALE</b>	<b>16</b>
<b>III.2. REQUIREMENTS</b>	<b>16</b>
<b>III.3. IMPACT ON FOOD BUSINESS OPERATORS</b>	<b>17</b>
III.3.1. SCOPE OF THE TRACEABILITY REQUIREMENT	17
i) Covered products.	17
ii) Covered operators	18
iii) Applicability to third country exporters (in connection with Article 11)	18
III.3.2. IMPLEMENTATION OF TRACEABILITY REQUIREMENTS	19
i) Identification of suppliers and customers by food business operators	19
ii) Internal traceability	19
iii) Traceability systems laid down by specific legislation	20
iv) Information to be kept	20
v) Time of reaction for traceability data availability	21
vi) Time for keeping Records	21

### **IV. ARTICLE 19** **23**

<b>IV.1. RATIONALE</b>	<b>23</b>
<b>IV.2. IMPLICATIONS</b>	<b>24</b>
<b>IV.3. CONTRIBUTION/ IMPACT</b>	<b>24</b>
IV.3.1. ARTICLE 19 (1)	24
i) Obligation to withdraw	24
ii) Notification of the withdrawal to the competent authorities	25
iii) Methods of the notification to competent authorities	25
iv) Recall and information to the consumers	26



# **INTRODUCTION**

Regulation (EC) N° 178/2002<sup>1</sup> (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.

Since then, the guidance document has therefore been reviewed and complemented. A new section has been developed on food safety requirements, and the sections on traceability, withdrawal/recall and export of food and feed, have been redrafted with a view to simplifying, clarifying and completing them. The Standing Committee on the Food Chain and Animal Health has approved the revised version of the guidance document at its meeting of 26 January 2010.

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,

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<sup>1</sup> 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.

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<sup>2</sup>.

The following issues will be addressed:

- Food safety requirements (Article 14);
- 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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<sup>2</sup> Written question E-2704/04 of W. Pieck on the implementation of traceability requirements to charities.

# **I. ARTICLE 14**

## **FOOD SAFETY REQUIREMENTS**

### **Recital 1**

The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

### **Recital 10**

Experience has shown that it is necessary to adopt measures aimed at guaranteeing that unsafe food is not placed on the market and at ensuring that systems exist to identify and respond to food safety problems in order to ensure the proper functioning of the internal market and to protect human health. Similar issues relating to feed safety should be addressed.

### **Recital 23**

The safety and confidence of consumers within the Community, and in third countries, is of paramount importance. The Community is a major global trader in food and feed and, in this context, it has entered into international trade agreements, it contributes to the development of international standards which underpin food law, and it supports the principles of free trade in safe feed and safe, wholesome food in a non-discriminatory manner, following fair and ethical trading practices.

### **Recital 26**

Some Member States have adopted horizontal legislation on food safety imposing, in particular, a general obligation on economic operators to market only food that is safe. However, these Member States apply different basic criteria for establishing whether a food is safe. Given these different approaches, and in the absence of horizontal legislation in other Member States, barriers to trade in foods are liable to arise. Similarly such barriers may arise to trade in feed.

### **Recital 27**

It is therefore necessary to establish general requirements for only safe food and feed to be placed on the market, to ensure that the internal market in such products functions effectively.

### **Article 14**

- 1. Food shall not be placed on the market if it is unsafe.*
- 2. Food shall be deemed to be unsafe if it is considered to be:*
  - (a) injurious to health;*
  - (b) unfit for human consumption.*

*3. In determining whether any food is unsafe, regard shall be had:*

- (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and*
- (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.*

*4. In determining whether any food is injurious to health, regard shall be had:*

- (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;*
- (b) to the probable cumulative toxic effects;*
- (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.*

*5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.*

*6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.*

*7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.*

*8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.*

*9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.*

## **I.1. Rationale**

- The safety and acceptability of food is of critical importance. Consumers must have confidence and assurance that the food they buy will be what they expect and will do them no harm or have an adverse effect. The aim of Article 14 is to protect the consumer from food that is either a health risk or unacceptable.
- Article 14 defines the general food safety requirements which are used with the risk management requirements covered by Article 19 to reduce or eliminate any risk due to the placing of unsafe foods on the market.

## **I.2. Implications**

- The objective of this Article is to protect public health. It establishes therefore the factors that need to be taken into consideration when deciding whether food, as defined in Article 2 of the Regulation, is injurious to health or unfit for human consumption.
- The requirements of Article 14 apply to food that is 'placed on the market'. The definition of 'placing on the market'<sup>3</sup> is quite wide and it includes all sales and supplies, including one-off sales, one-off supplies free of charge, and holding food for the purpose of sale. The Article does not, however, cover primary production for private domestic use, or the use of food for private domestic consumption, which are exempted by Article 1(3) of the Regulation.

## **I.3. Contribution/impact**

### **I.3.1. Article 14 (1)**

This Article prohibits food being placed on the market if it is unsafe. 'Unsafe' is defined below.

### **I.3.2. Article 14 (2)**

Food is considered to be 'unsafe' if it is either:

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

### **Food that is injurious to health**

Once a hazard is identified which may 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,

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<sup>3</sup> Placing on the market' is defined in Article 3 Point 8 of Regulation (EC) No 178/2002, as 'the holding of food [...] for the purpose of sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves'.



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 it may pose to health.

When there are concerns that a particular food may be injurious to health, food businesses must then consider how serious the risk is in this context. This will enable them to take decisions on appropriate action. The responsibility for the risk assessment lies with the food business operators, under the control of national competent authorities once informed, as stated in Article 17.

### **Food that is unfit for human consumption**

The central concept of unfitness is unacceptability. Food can be rendered unfit by reason of contamination, such as that caused by a high level of non-pathogenic microbiological contamination (see Article 14(3) and (5) of the Regulation), by the presence of foreign objects, by unacceptable taste or odour as well as by more obvious detrimental deterioration such as putrefaction or decomposition.

#### **I.3.3. Article 14 (3) – Considerations in determining whether food is unsafe**

Food can be unsafe because of an intrinsic property of the food, such as contamination from pathogenic bacteria. However, food should not be considered unsafe if the normal conditions of use would render it safe (see Article 14(3)(a)). For example it is generally accepted that most meat needs to be cooked correctly in order for it to be safely consumed.

On the other hand where, in certain cases, essential information on the use of food is not supplied or is incorrect, this could render the food unsafe. Article 14(3)(b) states that regard shall be had to the information provided to the consumer including information on the label or other available information about avoidance of specific adverse health effects from a particular category of foods. An example of this would be where a food or a food ingredient may pose a risk to the health of a specific group of consumers in the case where mandatory information about that food or one of its ingredients was not effectively communicated.

#### **I.3.4. Article 14 (4) – Considerations in determining whether food is injurious to health**

The concept of 'injurious to health' relates to the potential to harm human health. An example might be *botulinum* toxin in a manufactured food. Food could be injurious even if the harm was cumulative or only became apparent over a long period of time, such as contamination with dioxins, methyl mercury, or genotoxic carcinogens that could affect subsequent generations.

Article 14 (4) (c) requires that if food is produced for a group of consumers with particular health sensitivities (e.g. intolerant or allergic), then these sensitivities should be taken into account when determining whether a food is injurious to health. An example would be food that is unintentionally cross contaminated with nuts, which would be injurious to health if it was designed for those who needed a nut-free diet. However, when a product is not making a claim that it is intended for a group with particular health sensitivities, the fact that it may be harmful for that group does not automatically mean it is injurious within the meaning described in this Regulation (except where the mandatory information is not appropriately communicated).

### **I.3.5. Article 14 (5) – Considerations in determining whether food is unfit for human consumption**

The concept of 'unfit' relates to unacceptability. Some food may not pose a risk to health at all, but will still qualify as unfit because it would be reasonably considered to be unacceptable for human consumption. Examples could be:

- Decomposing fish with a strong smell; or
- A fingernail in a sausage roll.

Food can also be unfit where it may also pose a risk to health – depending on the level of contamination. For example:

- Certain types of mouldy food. This could include food that contains mould that is not immediately apparent (e.g. in a fruit filling) and is not a normal characteristic of the product;
- Fish containing parasites or
- Food carrying an abnormally high level of non-pathogenic micro-organisms.

### **I.3.6. Article 14(7) Food in compliance with food safety legislation**

This paragraph states that food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned. It means, therefore, that food that does not comply with specific safety Community provisions shall be deemed to be unsafe, unless a risk assessment proves otherwise.

In particular, food businesses should apply Article 14(7) in a proportionate way when meeting their obligation under Article 17 and taking decisions under Article 19.

For example, a breach of a particular legal limit with the Community legislation on residues would mean that it is likely that the food is injurious to health in the light of Article 14(4) or unfit for human consumption in the light of Article 14(5).

In that context, an assessment should be carried out, considering the factors in Articles 14(3)-(5) in the light of the legislation concerned. If, however, 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 19 of the Regulation. This could be the case, for example, because a tolerance level has been built into legislation for pesticide residues in food and whilst a food was in breach of the legal limit, it would not be considered to be unsafe for the purposes of Article 19 of the Regulation, because the maximum residue level for pesticides takes account of good agricultural practice. However, it would still be in breach of the relevant legislation on pesticide residues and should not be placed on the market.

In instances, however, where the food is found not to comply with sector-specific Community legislation and is also subsequently assessed to be in breach of the food safety requirements of Article 14, the requirements of Article 19 of the Regulation would be, nevertheless,

applicable. Therefore, each incident needs to be dealt with on a case by case basis for the purposes of Article 19 requirements.

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## **II. ARTICLE 17**

### **RESPONSIBILITIES**

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#### **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.*

## **II.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<sup>4</sup> 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<sup>5</sup> and in particular food safety.

## **II.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.

## **II.3. Contribution/Impact**

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<sup>4</sup> For the understanding of the present document, the term “food business operator” covers both food and feed business operators.

<sup>5</sup> 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.

### II.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.

### II.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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## **III. ARTICLE 18**

### **TRACEABILITY**

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#### **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 3**

‘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.

#### **Article 3 Point 6**

‘Feed business operator’ means the natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control.

#### **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).*

### **III.1. Rationale**

Past food incidents have demonstrated that being able to trace food and feed throughout the food chain is of prime importance for the protection of public health and consumers' interests. In particular, traceability records help to:-

- Facilitate targeted withdrawal and recall of food, thereby avoiding unnecessary disruption of trade;
- Enable consumers to be provided with accurate information concerning implicated products, thereby helping to maintain consumer confidence; -
- Facilitate risk assessment by control authorities.

Traceability does not itself make food safe. It is a way of assisting in containing a food safety problem.

The focus of Regulation 178/2002 is on food safety and the removal of unsafe food from the market. However, apart from their food safety role, traceability requirements also help to ensure:-

- Fair trading amongst operators;
- The reliability of information supplied to consumers in terms of substantiating claims made by manufacturers.

### **III.2. Requirements**

- 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 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.

### **III.3. Impact on Food Business Operators**

- 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 created 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 allows industry 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.

#### **III.3.1. Scope of the traceability requirement**

##### **i) Covered products.**

- Article 18 refers to “*any substance intended to be, or expected to be, incorporated into a food or feed*”. However, this provision does not apply to veterinary medicinal products, plant protection products and fertilisers. It should be noted that some of these products are covered by specific Community 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, including grain when incorporated in a feed or food. But, it would exclude grain when used as seed for cultivation.
- Similarly, packaging material does not meet the definition of 'food' laid down in Article 2 of the Regulation and therefore, it does not fall within the scope of Article 18. The traceability of those food packaging materials has been covered by Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/950/EEC and 89/109/EEC.

- Furthermore, the Food Hygiene Package<sup>6</sup> and the Feed Hygiene Regulation<sup>7</sup> ensure a link between food/feed and veterinary medicinal and plant protection products, covering this gap as farmers 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/feed chain, from primary production (food producing animals, harvests), food/feed processing to distribution and supply, including brokers, regardless of whether they take physical possession of the food/feed in question. This may also include charities; however, Member States should take into account the degree of organisation and continuity of their activities for the purposes of the application of Article 18
- Article 3 Points 2 and 5 define a food/feed business as “any undertaking...carrying out any of the activities related to any stage of production, processing and distribution of food/feed”. Independent transporters and storage businesses, as undertakings involved in the distribution of food/feed, are covered by this definition and are required to comply with Article 18.
- Where transportation/storage is integrated within a food/feed 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 and 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 apply outside the EU. This requirement covers all stages of production, processing and distribution in the EU, namely from the EU importer up to retail level, excluding, however, supply to the final consumer.
- 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 cannot be legally required to fulfil the traceability requirement imposed within the EU (unless there are special bilateral

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<sup>6</sup> Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs; Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin; and, Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

<sup>7</sup> Regulation (EC) No 1831/2003 of the European Parliament and of the Council laying down requirements for feed hygiene, OJ L 35, 8.2.2005, p. 1.

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 in cases of food/feed imports because the requirement extends to the EU importer. The EU importer must be able to identify from whom the product was exported in the third country
- It is common practice among some EU food business operators to request trading partners to meet the traceability requirements 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 are not required by the Regulation.

### **III.3.2. Implementation of traceability requirements**

#### **i) Identification of suppliers and customers by food business operators**

A food business operator should be able to identify any “person” from whom food/raw materials are received. This person can be an individual (for example a hunter or a mushroom collector) or a legal person (such as a business or company).

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. This term refers more to the transfer of ownership of the food/feed or food producing animal. However, brokers must be considered as a form of supplier for the purposes of this Article, whether or not they take physical possession of the goods. 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 also identify the other food/feed businesses to whom it provides its products (excluding final consumers). In the case of trade between a retailer such as a supermarket and a restaurant, the traceability requirement still applies.

Cold store operators and transporters are food businesses and they should also keep traceability records.

#### **ii) Internal traceability**

- Without prejudice to sector specific rules, the Regulation does not expressly 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.
- Nevertheless an internal traceability system would contribute to more targeted and accurate withdrawals. Food business operators are likely to save costs in terms of time of a withdrawal and in avoiding unnecessary wider disruption. This in turn would help maintain consumer confidence. Traceability systems also provide information within food businesses to assist in process control and stock management. The decision on

whether to adopt an internal traceability system and the level of detail should be left to the Food Business Operator, commensurate with the size and nature of the food business.

### **iii) Traceability systems laid down by specific legislation**

Apart from specific legislation establishing food safety traceability rules for certain sectors/products, such as Beef Labelling,<sup>8</sup> Fish Labelling<sup>9</sup> and GMOs<sup>10</sup>, there are specific regulations laying down marketing and quality standards for certain products. These regulations often have fair trade purposes and 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. Food Business Operators should determine whether sectoral traceability provisions already meet Article 18 requirements.

### **iv) Information to be kept**

Article 18 does not specify what type of information should be kept by the food and feed business operators. However, to fulfil the objective of Article 18, the following information should be kept at least.

- Name, address of supplier, and identification of products supplied;
- Name, address of customer, and identification of products delivered;
- Date and, where necessary, time of transaction / delivery;
- Volume, where appropriate, or quantity:

It may be that if printed traceability records are kept, these will already have on them the date and time of delivery as well as the name and address of the supplier and customer. If not, the date should be specifically recorded, and the time if there is more than one supply/ delivery in

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<sup>8</sup> Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97, *OJ L 204, 11.8.2000, p. 1*

<sup>9</sup> Regulation (EC) No 2065/2001 of 22 October 2001 laying down detailed rules for the application of Council Regulation (EC) No 104/2000 as regards informing consumers about fishery and aquaculture products, *OJ L 278, 23.10.2001 p.6*

<sup>10</sup> Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed, *OJ L 268, 18.10.2003, p. 1*; Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, *OJ L 268, 18.10.2003, p. 24*.

a particular day. Whilst not compulsory, it would also be very helpful if details are kept of any reference or batch number enabling the product to be identified.

Food crises in the past have shown that tracing the commercial flow of a product by keeping invoices was not sufficient to follow the physical flow of the products, as food/feed could be, for example, sent for storage. Therefore, it is essential that the traceability system of each food / feed business operator is designed to follow the physical flow of the products.

**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.
- When developing a traceability system, it does not necessarily mean that Food and Feed Business Operators need to have a dedicated system. It is the need to provide information that is important, not the format in which it is kept. The traceability records should be sufficiently organised to enable availability ‘on demand’, without unduly delaying the requirements imposed by Article 19.
- A traceability system is good when it delivers accurate information in a fast manner; this would help to satisfy the objective pursued as described in Recital 28 of the Regulation. A delay in the delivery of this relevant information would undermine a prompt reaction in case of crisis.

**vi) Time for keeping Records**

Article 18 does not specify a minimum period of time for keeping records, and therefore it is for the businesses to decide, bearing in mind that failure to produce adequate records would constitute an offence. On a broad basis, it is considered that commercial documents are usually registered for a period of 5 years for taxation controls. It is suggested that this 5 year period, where applied from date of manufacturing or delivery to traceability records<sup>11</sup>, would be likely to meet the objective of Article 18.

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

- For highly perishable products, which have a “use by” date less than 3 months or without a specified date<sup>12</sup>, destined directly to final consumer, records could be kept for the period of 6 months after date of manufacturing or delivery.
- For other products with a “best before” date, records could be kept for the period of the shelf-life plus 6 months;

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<sup>11</sup> more particularly to records belonging to the first category of information foreseen in paragraph II. 3. 4.

<sup>12</sup> Products such as fruits, vegetables and non pre-packed products.

- For products<sup>13</sup> without a specified durability date, the general rule of 5 years could apply).

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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<sup>13</sup> Products, such as wine.

## **IV. ARTICLE 19**

### **WITHDRAWAL, RECALL AND NOTIFICATION**

#### **BY FOOD BUSINESS OPERATORS**

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##### **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.*

##### **IV.1. Rationale**

- Article 19 aims at mitigating the problems caused when foodstuffs that do not meet the food safety requirements have left a food business's control and at preventing, reducing or eliminating the risk, when a business has placed on the market food which may be injurious to health.
- The obligation to withdraw, recall or notify unsafe food under Article 19 arises when the food is or may be unsafe under Article 14 of Regulation 178/2002.

- Food business operators must apply the criteria in Article 14 for determining whether food is unsafe and action should be taken under Article 19.
- The notification of competent Authorities by food business operators enables those 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.

## **IV.2. Implications**

- Article 19 imposes specific obligations from 1<sup>st</sup> 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 consumer products already supplied to them.
- Article 19 provides for the necessary cooperation between operators in different parts of the food distribution chain, so as to ensure the withdrawal of unsafe food from the market.
- Article 19 also imposes an additional obligation on the food business operator to inform the competent Authorities should they consider or have reason to believe that a food which it has placed on the market may be injurious to health.
- It provides a general obligation on food business operators to co-operate with competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied.

## **IV.3. Contribution/ Impact**

### **IV.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 which has left their immediate control and that does not meet the food safety requirements, and inform the competent authorities thereof.

Withdrawal is not defined in Regulation (EC) 178/2002, but is commonly understood to be the process by which a product is removed from the supply chain, with the exception of a product that is in the possession of consumers. The definition in Directive 2001/95/EC on General Product Safety is useful, as it indicates that withdrawal is aimed at preventing the distribution, display or offer of a product



It should be emphasised that under 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:
  - **i. the food in question is considered unsafe by the operator as not being in compliance with the food safety requirements**

Article 14 of Regulation 178/2002 specifies the food safety requirements to be used in deciding whether the food is unsafe.

- **ii. a food<sup>14</sup> is on the market and has left the immediate control of the initial food business.**

So Article 19(1) does not apply where a food business operator has placed the food on the market (and thus is considered as the initial food business) but it is still in their immediate control.

A food is considered to have left the immediate control of a food business operator when it has been sold or supplied free of charge or otherwise transferred so that the initial operator no longer has the legal right to the food, for example when they have sent it to a wholesaler or it is with any other operators later in the distribution chain.

## **ii) 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 authority, which has enforcement responsibility for the operator's establishment, and the national authority.

It is up to the national authority to issue the RASFF as in point III.3.5 if necessary.

If the product is removed before being placed on the market or if it is under the immediate control of a particular food business operator, there are no notification obligations under Article 19 (1).

## **iii) Methods of the notification to competent authorities**

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<sup>14</sup> As defined in Article 2 of Reg.178/2002

It is for competent authorities in individual Member States to decide what methods of notification are appropriate.

#### **iv) Recall and information to the consumers**

When a withdrawal is necessary and the product may have reached the consumer, Article 19 (1) requires the food business operators:

- to inform the consumer accurately and effectively 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 an unsafe product that has already been supplied or made available to consumers by a food business operator”. A recall will mean asking consumers to take the product back to the place of purchase or to destroy it. The recall is necessary when other measures are not sufficient to achieve a high level of health protection.

#### **v) Responsibility for 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). This may include retailers, when they have sent the product on to another retailer or have recall obligations because they have sold or supplied the product to consumers.

Cooperation between each level of the food chain will be necessary to achieve the objectives of Article 19 (1) – please see the obligations in Article 19(2).

#### **IV.3.2. Article 19 (2)**

Article 19 (2) places a requirement on food business operators responsible for retail<sup>15</sup> or distribution activities, which do not affect the packaging, labelling, safety or integrity of food (i.e. retailers and distributors of branded food). The purpose of this provision is to ensure that these 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. It also compels them to let the manufacturer know if there is a safety problem, so that the manufacturer can co-ordinate the withdrawal.

#### **IV.3.3. Article 19 (3)**

Article 19 (3) places a specific, stronger requirement on food business operators when they consider or have reason to believe that a food that they have ‘placed on the market’ may be ‘injurious to health. In this case, they must immediately inform the competent Authorities and detail the action taken to prevent the risk.

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<sup>15</sup> Retail is defined in Article 3 Point 7

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**<sup>16</sup>. ‘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 for a product which is placed on the market, even if the product is under the immediate control of the operator.

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

- the operator definitely knows that the food is injurious to health and it is still in his/her possession.

- 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 likely to be injurious to health, but this information is not yet completely confirmed; this could originate from consumer complaints or batches placed on the market where sampling had proved satisfactory where other batches had not.

- Information of an emerging risk.

The aim of this provision is to enable the competent Authorities not only to be aware of definitely unsafe food, but 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 health and the product has left the immediate control of the initial food business operator, the withdrawal and recall obligations set up in Article 19 (1) will also apply.

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

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<sup>16</sup> ‘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 second part of Article 19 (3) is designed to prevent food business operators from discouraging their employees and others from cooperating with competent Authorities where this may prevent, reduce or eliminate a risk arising from food.

#### **IV.3.4. Article 19 (4)**

This paragraph requires that the food business cooperates 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.

#### **IV.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 Public 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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## **V. ARTICLE 20**

### **WITHDRAWAL, RECALL AND NOTIFICATION**

#### **BY FEED BUSINESS OPERATORS**

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##### **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.*

##### **V.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.

## **V.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.

## **V.3. Contribution / Impact**

### **V.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. It 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.

### **V.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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## **VI. ARTICLE 11**

### **IMPORT OF FOOD AND FEED**

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#### **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<sup>17</sup> 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.

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<sup>17</sup> cf explanations in chapter II. 3. 1. iii).



## **VII. 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.*

#### **VII.1. Rationale and objective**

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 the latter case, the objective is to take into account the level of protection established by importing countries.

In all other circumstances, food and feed can only be exported or re-exported, if the importing country has expressly agreed. The *rationale* of this provision is to prevent the “exportation” of crisis. When a new risk arises, not all countries are likely to have set up relevant safety requirements to prevent this risk. As such, (re)exportation of food and feed must be subject to the express 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. However, even where there is express agreement of the importing country, food that is considered injurious to health or feed that is considered unsafe may in no event be exported or re-exported.<sup>18</sup>

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<sup>18</sup> See Recital 24.

## **VII.2. Scope of Article 12**

The scope of Article 12 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) including food/feed that has been allowed to enter the Community, pending the results of sample border screening. However, this Article does not apply to feed and food rejected at the external border of the EU.

## **VII.3. Article 12 (1)**

This first subparagraph of Article 12 (1) provides for a general rule that food and/or feed exported or re-exported from the Community for placing on the market of a third country (i.e. a country not in the EU) shall comply with either Community law, or with the law of that third country. The latter 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 business 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 cases not covered by the first paragraph. In such circumstances, food may only be exported or re-exported if the competent authorities of the country of destination have expressly agreed, preferably in writing and only 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, this procedure does not apply in cases where the competent authority of the exporting EU Member State considers food to be injurious to health or feed to be unsafe. In such cases, the food or feed concerned may not be exported or re-exported and must be disposed of safely.

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 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare<sup>19</sup> rules applies.

## **VII.4. 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 those laid down in that agreement.

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<sup>19</sup> OJ L 191, 28.5.2004, p. 1.