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DRAFT

Guidance document on the implementation of certain provisions of Regulation (EC) No 852/2004 On the hygiene of foodstuffs

PURPOSE OF THIS DOCUMENT

This document is mainly directed at food businesses and competent authorities, and aims to give guidance on the implementation of the new food hygiene requirements and on related subjects.

NOTE

This document is an evolving document and will be updated to take account of experiences and information from the Member States, from competent authorities, food businesses and the Commission's Food and Veterinary Office.

1. INTRODUCTION

Regulation (EC) No 852/2004 on the hygiene of foodstuffs[1] (hereafter "the Regulation") was adopted on 29 April 2004. It lays down general hygiene requirements to be respected by food businesses at all stages of the food chain. Since the adoption of the Regulation, the Commission has been requested to clarify a number of aspects thereof. This document aims to follow-up these requests.

The Commission's Health and Consumer Protection Directorate General has held a series of meetings with experts from the Member States in order to examine and reach consensus on a number of issues concerning the implementation of the Regulation.

In the interest of transparency, the Commission has also promoted discussion with stakeholders so as to allow different socio-economic interests to express an opinion. To this end the Commission has organised a meeting with representatives from producers, industry, commerce and consumers to discuss issues related to the implementation of the Regulation.

It was considered that this is a useful procedure, which should continue in the light of the experience gained by the full application of the Regulation from 1 January 2006.

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.

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.

For a complete understanding of the different aspects of Regulation (EC) No 852/2004, it is essential to be also familiar with other parts of Community legislation, and in particular with the principles and definitions of :

- Regulation (EC) No 178/2002 of the European Parliament and of the Council 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].(also referred to as the General Food Law), and

[1] OJ No L 226, 25.6.2004, p. 3
[2] OJ No L 31, 1.2.2002, p. 1

- Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare[3].

A separate guidance document on Regulation (EC) No 178/2002 has been established.

(See http://europa.eu.int/comm/food/food/foodlaw/guidance/index_en.htm)

[3] OJ No L 191, 28.5.2004, p. 1

2. OBLIGATIONS OF FOOD BUSSINESS OPERATORS

The Regulation is addressed to, and must be implemented by, food businesses. They must ensure that all the requirements are properly implemented in order to ensure food safety.

All food businesses must implement Regulation (EC) No 852/2004.

Food businesses that handle food of animal origin must, in addition to Regulation (EC) No 852/2004, also implement the appropriate requirements of Regulation (EC) No 853/2004.

The role of the competent authority is to verify whether the food hygiene rules are properly implemented. This verification must be carried out in accordance with the general principles laid down in Regulation (EC) No 882/2004, and, with regard to food of animal origin, in accordance with Regulation (EC) No 854/2004.

3. SCOPE

3.1. Primary production

The Regulation covers primary production.

Primary production is defined in Article 3(17) of Regulation (EC) No 178/2002:

'*Primary production*' *means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products.*

In addition, Annex I, Part A, point I(1) of Regulation (EC) No 852/2004 lays down that primary production includes the following associated operations:

- The transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;
- The transport of live animals, where this is necessary to achieve the objectives of this Regulation; and
- In the case of products of plant origin, fishery products and wild game: transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.

Primary production is a term to describe activities at the farm or at a similar level and includes *inter alia*:

- Production, rearing or growing of plant products such as grains, fruits, vegetables and herbs as well as their transport within and storage and handling of products (without substantially changing their nature) at the farm and their further transport to an establishment.

- Production, rearing or growing of food producing animals at the farm and any activity linked therewith as well as the transport of meat producing animals to the slaughterhouse or the transport of animals between farms.

- Production, rearing and growing of snails at the farm and their possible transport to a processing establishment or to a market.

- Milking and the storage of milk at the farm.

- The production and collection of eggs at the producer's premises, but not egg packaging operations.

- Fishing, the handling of fishery products (without changing their nature substantially) on board vessels (except freezer and factory vessels) and their transport to the first establishment on land.

- Production, rearing, growing and harvesting of fish in aquaculture farms and their transport to an establishment.

- The production, rearing, growing and harvesting of live bivalve molluscs and their transport to an expedition centre.

- Hunting, killing and evisceration on-the-spot of wild game, and the transport of wild game to a game handling establishment.

- The harvesting of mushrooms, berries, snails etc. in the wild and their transport to an establishment.

Remarks on primary production:

- **Egg packaging centres**: in accordance with the definitions and requirements of the new food hygiene rules, egg packaging centres (even when situated at the farm of production) are not considered primary production. However, the impact of the new food hygiene rules on egg packaging centres is limited since the approval of egg packaging centres and the application of an identification mark to the eggs is regulated in the egg marketing regulations.

- **Milk collection centres**: once raw milk has been collected from the farm, the product has left the level of primary production. Milk collection centres where raw milk is stored after collection from a farm and before dispatch to a milk processing establishment must therefore be approved by the competent authority.

- **Honey**: all the beekeeping activities must be considered as primary production. This includes beekeeping, the collection of honey and the wrapping and/or packaging at the beekeeper's premises. Other operations outside the beekeeper's premises (e.g. the wrapping/packaging of honey) cannot be considered as primary production.

- **Wild game**: primary production ceases when wild game [apart from wild game that falls under national rules pursuant to Article 1(2)(c) of the Regulation] arrives in the game handling establishment. This means that game collection centres (where hunted game is gathered and kept prior to being transported to a game handling establishment) fall under the term "primary production".

- **Freezer and factory vessels**: the handling, storage and transport of fishery products on board freezer and factory vessels are not covered by the term "primary production".

3.2. Primary products

Primary products are defined in Article 2, paragraph 1, point (b) of Regulation (EC) No 852/2004 as follows:

'*primary products*' means products of primary production including products of the soil, of stock farming, of hunting and fishing.

Primary products include *inter alia*:

- Products of plant origin: grains, fruits, vegetables, herbs, mushrooms.
- Products of animal origin, e.g. eggs, raw milk, honey.
- Fish (the nature of which has not been changed substantially) caught wild.
- Fish from an aquaculture farm.
- Wild game after shooting and possible evisceration on the spot.
- Products harvested wild: mushrooms, berries, snails etc.

Remarks on primary products:

- **Fresh meat** is not a primary product since obtained after slaughter.

- **Wild game** in fur or feather, and possibly eviscerated, is a primary product but wild game meat obtained in a game handling establishment is not a primary product.

3.3. "Small quantities" of primary products as referred to in article 1, paragraph 2(c) of the Regulation

The Regulation does not apply to small quantities of primary products supplied directly by the producer to the final consumer or to local retail establishments directly supplying the final consumer.

In general terms, the notion "small quantities" should be broad enough to allow *inter alia*:

- Farmers to sell primary products (vegetables, fruits, eggs, raw milk etc.) directly to the final consumer e.g. farm gate sales or sales at local markets, to local retail shops for being sold directly to the final consumer and to local restaurants.

- Individuals who collect products in the wild such as mushrooms and berries to deliver their yield directly to the final consumer or to local retail shops for being sold directly to the final consumer and to local restaurants.

- Hunters to deliver wild game directly to the final consumer or to retail establishments supplying the final consumer.

Pursuant to Article 13 of Regulation (EC) No 852/2004, it is up to Member States to further refine the notion of small quantities depending on the local situation, and to lay down under national law the rules necessary to ensure that the safety of the food is guaranteed (risk based approach).

In general, the rules under national law established by the Member States in respect of small quantities as referred to in Article 1, paragraph 2(c) should allow current practices to continue to apply, provided they ensure the achievements of the objectives of the Regulation.

3.4. Cross-border trade of small quantities of primary products

Article 1, paragraph 3 of the Regulation requires Member States to establish under national law the rules governing the supply by the producer of small quantities of primary products to the final consumer or to local retail establishments. Such national rules shall ensure the achievement of the objectives of the Regulation, these objectives being:

- The pursuit of a high level of protection of human health, and

- The aim of achieving free movement of food within the Community.

There should therefore be no impediment to the cross border supply of small quantities of primary products by the producer in a Member State to a final consumer or a local retail establishments directly supplying the final consumer in a neighbouring Member State.

3.5. Processing of primary products at the farm

Primary products are often processed at the farm, e.g. raw milk is processed into cheese, juice is extracted from fruit. These operations fall outside the activities described as primary production and are therefore the subject of the food hygiene requirements of Annex II of the Regulation and, ***with regard to food of animal origin***, also of the appropriate requirements in Regulation (EC) No 853/2004.

Examples:

- The preparation of fruit juice at the farm

  If a farm uses its harvest or part of its harvest (e.g. apples) to produce fruit juice at its premises, such farm exceeds the level of primary production. The activity of producing fruit juice is to be considered as an activity after primary production and it is therefore subject to the appropriate requirements of Regulation (EC) No 852/2004.

- The production of cheese at the farm

  Cheese is the result of processing raw or heat treated milk. Cheese is not, therefore, a primary product, even when made at the farm.

  As a consequence, cheese production at the farm must comply with the appropriate requirements of food hygiene laid down in Regulation (EC) No 852/2004 and of Regulation (EC) No 853/2004 (unless manufactured and sold at a retail premise at the farm).

  Remarks:

  Regulation (EC) No 853/2004 excludes retail (i.e. the handling and/or processing of food and its storage at the point of sale) from its scope. This means that where cheese is manufactured and sold at the farm to final consumers, these activities can be carried in compliance with the appropriate requirements laid down in Regulation (EC) No 852/2004, in particular in its Annex II, while not having to comply with the requirements of Regulation (EC) No 853/2004.

  In order to accommodate processing at the farm or in order to preserve traditional methods of production, Member States may introduce national measures adapting the relevant infrastructural requirements in accordance with the procedure laid down for that purpose in Article 13 of Regulation (EC) No 852/2004 and in Article 10 of Regulation (EC) No 853/2004, where the traditional methods cannot be accommodated within the requirements the Regulations lay down.

3.6. Eggs and primary production

Taking into account the definition of primary production in Article 3(17) of Regulation 178/2002, and Annex I, Part A, point I(1) of Regulation 852/2004, primary production of eggs includes the handling of eggs, i.e. the collection and transport between buildings, and storage of eggs at the production site, provided that this does not substantially alter their nature. The packaging of eggs, either at the site of production or at a packaging establishment, falls outside the activities of primary production and must therefore comply with the relevant requirements of Annex II to Regulation (EC) No 852/2004.

3.7. At the level of primary production, primary products may be transported, stored and handled <u>provided that does not substantially alter their nature</u> [see Annex I, Part A, point I.1(a) of the Regulation].

At the level of primary production, primary products are often subject to operations so as to ensure a better presentation, such as:

- Washing of vegetables, removing leaves from vegetables, the sorting of fruit etc.
- The slaughter, bleeding, gutting, removing fins, refrigeration and wrapping of fish on board fishing vessels,
- The removal of intestines of wild game.

Such operations must be considered as normal routine operations at the level of primary production and must not lead to the need to satisfy food safety requirements in addition to the ones already applying to primary production.

It must be borne in mind that certain other operations carried out on the farm are likely to alter the products and/or to introduce new hazards to food e.g. the bagging of salads and the application of preservation gases. These operations cannot be considered as normal routine operations at the level of primary production nor as operations associated to primary production.

3.8. The occasional handling, preparation, storage and serving of food by private persons

Operations such as the occasional handling, preparation, storage and serving of food by private persons at events such as church, school or village fairs are not covered by the scope of the Regulation. This is made clear in recital 9 of Regulation (EC) No 852/2004. The second sentence states that:

"Community rules should only apply to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organisation".

The term “undertaking” is integrated in the definition of a “food business” (in accordance with Article 3(2) of the General Food Law (Regulation (EC) No 178/2002), a “food business” must be an “undertaking”). Somebody who handles, prepares, stores or serves food occasionally and on a small scale (e.g. a

church, school or village fair and other situations such as organised charities comprising individual volunteers where the food is prepared occasionally and where the person preparing the food does not keep the proceeds of its sale) cannot be considered as an "undertaking" and is therefore not subject to the requirements of Community hygiene legislation.

4. THE TERMS "WHERE NECESSARY", "WHERE APPROPRIATE", "ADEQUATE" AND "SUFFICIENT".

Where the Annexes to the Regulation use the terminology "where necessary", "where appropriate", "adequate" or "sufficient", it is up to the food business operator to decide whether a requirement is necessary, appropriate, adequate or sufficient to achieve the objectives of Regulation (EC) 852/2004. It is not for the competent authorities to require systematically the most stringent interpretation.

In determining whether a requirement is necessary, appropriate, adequate or sufficient to achieve the objectives of the Regulation, account should be taken of the nature of the food and of its intended use.

The operator could justify his choice under the procedures based on the HACCP principles or under the operational procedures of his business. Also the guides to good practice referred to in Article 7 of the Regulation may offer useful guidance and indicate what is best practice in cases where the words "where necessary", "where appropriate" , "adequate" and "sufficient" are used.

5. FLEXIBILITY

5.1. General background

The Regulation lays down principles to be applied by all food businesses. In order to ensure that solutions for specific situations are available without compromising food safety, the Regulation provides for flexibility. For that purpose, Member States may take national measures adapting the requirements of certain Annexes of the Regulation. National measures shall:

- Have the aim of enabling the continued use of traditional methods of production, processing and distribution of food, or
- Have the aim of accommodating the needs of food businesses situated in regions that are subject to geographical constraints.
- In other cases, they shall apply only to the construction, lay out and equipment of establishments.

Member States wishing to adopt national measures shall, for reasons of transparency, notify the Commission and the other Member States thereabout. The Commission and the other Member States have the right to make comments. Where these comments lead to diverging views, the matter shall be

brought to the Standing Committee and a decision may be taken (see Article 13, paragraph 5 of Regulation 852/2004).

5.2. Traditional methods of production

In the Member States, food may be manufactured in accordance with longstanding traditions that have proven their safety although not always fully in line with certain technical requirements of the Regulation. The Regulation recognises the need for maintaining these traditional methods of production which are proof of the cultural diversity of Europe, and provides therefore for the flexibility needed by food businesses.

There is no intention in the context of this document to proceed to making an inventory of the traditional methods of production in the Member States. It is up to the competent authorities to take the necessary initiatives or act on possible requests from food businesses for flexibility.

5.3. HACCP and flexibility

The HACCP methodology is flexible by its very nature, being based on a limited set of principles and procedures supporting the objective of food safety, without compelling food businesses to comply with rules or to implement procedures which are not relevant or adapted to the specific context for their activity.

Guides to good practice developed by the food business sectors themselves, either at national or at Community level, should help businesses to implement HACCP-based procedures tailored to the characteristics of their production.

The Commission will issue documentation explaining the main possibilities for flexibility with regard to the implementation of HACCP-based procedures.

6. THE REGISTRATION OF FOOD BUSINESSES

What does registration of food businesses mean in practice?

The purpose of registration is to allow the competent authorities in the Member States to know where food businesses are situated and what their activities are so as to enable official controls to be carried out whenever judged necessary by the national competent authority and in accordance with the general principles laid down in Article 31 of Regulation (EC) No 882/2004 which requires competent authorities in the Member States to establish procedures for feed and food business operators to follow when applying for registration.

Registration should be a simple procedure whereby the competent authority is informed about the address of the establishment and the activity carried out. Where this information is already available from other sources e.g. registration for environmental or animal health purposes, that information may also be used for food hygiene purposes.

Certain businesses are specialised in trading food (brokers). While they may arrange for the movement of food between suppliers or to retailers, they do not necessarily handle the food or even store it on their premises (which may effectively be an office). Provided they meet the definition of "food business" and "food business operator", then the registration requirement applies.

7. GUIDES TO GOOD PRACTICE FOR HYGIENE AND FOR THE APPLICATION OF THE HACCP PRINCIPLES

Articles 7-9 of the Regulation provide for the development of guides to good practice for hygiene and for the application of the HACCP principles.

Such guides enable food business sectors (**at the level of primary production and after primary production**) to describe in more detail how operators can comply with the legal requirements which are expressed in more general terms in the Regulation.

In the new food hygiene rules, a number of requirements are laid down that:

- Leave room for judgement to the food business operator: for that purpose, the terms "where necessary", "where appropriate", "adequate" and "sufficient" are introduced into the Regulation (e.g. "*an adequate number of washbasins is to be available", or, "cleaning and disinfection of equipment are to take place at a frequency sufficient to avoid any risk of contamination"*), or

- Are formulated as an objective to be reached, but where the food business operator must develop the means to reach the objective (e.g. with regard to the heat treatment in hermetically sealed containers, "*any treatment is to prevent the product from becoming contaminated during the process*.")

Guides to good practice are a useful tool to assist food business operators in:

- Making a judgement on the necessity, appropriateness, adequacy or sufficiency of a particular requirement, e.g. to indicate what an adequate number of washbasins is, and

- Defining the means to reach the objectives that are defined in the Regulation e.g. to indicate what the frequency of cleaning and disinfection of equipment should be.

Guides may also usefully include procedures that must ensure a proper implementation of the Regulation, such as:

- Procedures to prevent the introduction of hazards at the level primary production,

- A procedure for the cleaning and disinfection of food businesses,

- A procedure for pest control, and

- A procedure to ensure that the requirement to develop HACCP-based procedures is fulfilled.

8. DOCUMENTATION

8.1. The Regulation creates the need for food businesses to establish, under the HACCP-based procedures, documentation **commensurate with the nature and the size of the business**.

8.2. It may be useful for food business to establish also other documentation. In establishing such documentation, food business operators may wish to take account of the following:

Documentation on structural requirements

Documentation may relate to structural requirements in order to clarify a number of requirements of a general nature contained in the Regulation, such as:

- Annex II, Chapter II, point 1, (a) and (b), where the surfaces of floors and wall are required to be "of impervious, non-absorbent, washable and non-toxic materials unless food business operators can satisfy the competent authority that other materials used are appropriate", and (f), where the surfaces in general are to be of "smooth, washable, corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate".

- Annex II, Chapter III, point 2(b), where the surfaces in contact with food are required to be of "smooth, washable, corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate".

Documentation of operational requirements

Documentation may relate to operational requirements such as:

- Annex II, Chapter IX, point 4: "Adequate procedures are to be in place to control pests".

- The need to justify choices with regard to the terms "where necessary", "where appropriate", "adequate" and "sufficient".

- The procedures and records based on HACCP principles.

8.3. Together, this documentation will constitute operational procedures that are an important element in ensuring food safety.

There are different possibilities for establishing that documentation:

- Guides to good practice may contain part or all of the documentation that is needed.

- Food businesses may decide to establish ad hoc documentation appropriate for their situation.

- Under the HACCP-based procedures (taking into account the flexibility needed for food businesses, in particular for small businesses).

Documentation could be provided in the form of results of laboratory tests, pest control reports, temperature measurements, and in the form of literature citations, documentation provided by the supplier of the construction materials etc.

9. TECHNICAL ISSUES (ANNEXES)

9.1. Heat treatment (Annex II, Chapter XI)

In the case of a heat treatment of food placed on the market in a hermetically sealed container, the Regulation requires food business operators to apply a heat treatment process conform to an internationally recognised standard. Such standards have for example been developed by Codex Alimentarius, e.g.:

- Code of Hygienic practice for Milk and milk products (CAC/RCP 57-2004).

- Recommended International Code of Hygienic Practice for Low and Acidified Acid Canned Foods (CAC/RCP 23-1979, rev. 2 (1993)).

- Code of Hygienic Practice for Aseptically Processed and Packaged Low-Acid foods (CAC/RCP 40-1993).

- Recommended International Code of Hygienic Practice for Canned Fish (CAC/RCP 10-1976).

9.2. Training (Annex II, Chapter XII)

Training as referred to in Annex II, Chapter XII of the Regulation should be commensurate to the tasks of staff in a particular food business and be appropriate for the work to be carried out.

Appropriate training does not necessarily involve participation in training courses. Training can also be achieved through information campaigns from professional organisations or from the competent authorities, guides to good practice etc.

With regard to HACCP training for staff in small businesses, it must be kept in mind that such training should be proportionate to the size and the nature of the business. If it is admitted that in certain food business where food safety can be achieved by implementing prerequisite requirements, training should be adapted to that situation.