

REPORT OF EU MEETING

Council Working Party: Veterinary Experts – Public Health, 13 September 2007

Proposal to amend Article 5 of Regulation 852/2004

Introduction

This update reports on the meeting of a Working Party to discuss a compromise text (copy attached) produced by the Portuguese Presidency regarding the proposal, issued by the Commission in March 2007, to exempt certain food businesses from the requirement in Article 5 of Regulation (EC) 852/2004 to operate HACCP-based food safety procedures.

The Presidency, following comments at the meeting from Member States, also produced a further compromise text (attached), on which Member States have been asked to comment by 20 September.

On this same issue, the Agency last reported on a meeting of 21 May 2007 to discuss a compromise text produced at that time by the German Presidency, which can be found elsewhere on the web site. The Agency has also held a stakeholder consultation on the proposal, the responses to which it will be publishing shortly.

Detail

The Presidency introduced its compromise text (the first two pages of which represent the proposal, the rest is explanatory material). This was intended to address the concerns previously expressed in discussions. It set out to clarify in the legislation (rather than in guidance) that for some types of food business, a process of hazard identification could show that hazards could be controlled by compliance with general food hygiene requirements such that procedures based on the HACCP principles would not be needed. The text included an Annex of example businesses to which the provision might apply.

Member states were invited to comment. Some questioned why the proposal was being brought forward now when the Commission review of the hygiene legislation had not been completed and whether there was evidence that problems were being encountered with the operation of the current requirements. The Commission reminded member states of the commitment given by Heads of Government to pursue the 10 fast-track proposals identified as better regulation initiatives.

Other Member States identified that the current regulation and accompanying guidance did provide for the type of flexibility that the proposal attempted to make explicit. Concerns therefore remained about the extent to which the proposal provided for anything new. For some member states this rendered it more likely to be acceptable, whereas for others it confirmed their view that it was unnecessary and should be resisted.

Comments on the text

- Scope of the proposal - Member States did not support the suggestion of an annex listing business types which might be covered by the proposal. Opposition

focussed on the principle of including a list of examples in legislation and on the inclusion of certain types of business (e.g. small restaurants) for which no evaluation of associated risks was offered.

- Reference to 'hazard identification' - a number of Member States queried whether this reference was correct or sufficient. It was generally held that all businesses had to undertake some form of evaluation of the hazards in their activities before being able to judge the means by which these could be appropriately controlled.

Further Presidency compromise text

Following the initial table round, the Presidency produced a further version of its compromise (also attached) and invited initial views. All member states reserved their position until they had been able to study/refer back to capitals. The Presidency asked for written comments by 20 September.

UK Position

The UK's position remains that the UK Government supports the Commission in looking to reduce administrative burdens on business, but we consider the current food hygiene legislation gives the necessary flexibility for businesses to meet their obligations to produce food safely.



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 7 September 2007

11542/07

LIMITE

AGRILEG 100

NOTE

from : The Presidency

to : Delegations

Subject : Proposal for a Regulation of the European Parliament and of the Council amending Regulation N° 11 concerning the abolition of discrimination in transport rates and conditions, in implementation of Article 79(3) of the Treaty establishing the European Economic Community and Regulation (EC) N° 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs

Delegations will find in Annex a Presidency document intended to be discussed during the meeting of the Working Party of Veterinary Experts (Public Health) to be held on Thursday 13 September 2007 at 10.00.

Draft Regulation of the EP and of the Council amending Regulation No 11 concerning the abolition of discrimination in transport rates and conditions, in implementation of Article 79(3) of the Treaty establishing the EEC and Regulation (EC) No 852/2004 of the EP and the Council on the hygiene of foodstuffs

New Art. 5 (3) of Reg. (EC) n° 852/2004

“3. a) No change:

Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I;

b) New:

Where individual or collective hazard identification, referred to in paragraph (2) a), applied to food business operators, in particular those included in Annex III, shows to the competent authority, that hazards can be controlled through the implementation of prerequisite requirements laid down in Article 4, no further implementation of the other HACCP principles mentioned in paragraph (2) is necessary.”

New Annex III of Reg. (CE) n.º 852/2004

“ANNEX III

Food Business Operators referred in Article 5 (3), b)

- marquees;
- market stalls;
- mobile sales vehicles;
- bars, coffee shops and restaurants;
- small retail shops such as grocery and bakery shops;
- transport and storage of pre-packed food or non perishable food. ”

Proposal for a Regulation of the EP and of the Council amending Regulation No 11 concerning the abolition of discrimination in transport rates and conditions, in implementation of Article 79(3) of the Treaty establishing the EEC and Regulation (EC) No 852/2004 of the EP and the Council on the hygiene of foodstuffs

1. Objective: Ensure that the current flexibility provisions are applied in a uniform way, providing less administrative burden, fair competition for FBO and the same level of consumer protection in the EU.

There is still uncertainty as regards whether FBOs benefit of the Regulation 852 and guidance documents, concerning the way the application of the existing guidelines takes place across the EU. A non uniform application could lead to an unequal treatment of FBOs and to different levels of risk exposure of consumers.

In order to simplify the application of these hygiene requirements and reduce administrative burden in the food sector, there is a need to clarify to what extent they may be applied, providing that identified hazards are under control and that the high level of EU consumer protection is maintained.

2. Key points on which the proposal should be based:

- Risk analysis based controls and “low level” of risk (no need to establish CCP);
- Proportionate, aiming at increasing competitiveness, as regards:
 - cost-benefit (reduction of costly non justifiable requirements);
 - administrative burden to be reduced;
- Clear and transparent framework (exemptions and flexibility provisions currently available to be applicable in a clear way);
- Ensuring the respect of HACCP principles, since:
 - they are necessary for restricting hygiene risks because SMEs may be at the origin of the highest frequency of hygiene offences;
 - targeted training in HACCP is a necessary tool for its current application.

Elements expressed by MSs in previous discussions and contributions

Positive Elements	VS	Negative Elements
Reduction of administrative burden		Disproportionate or ambiguous measures, Administrative burden shifted to CA
Identified FBO		FBOs which only fulfil economic criteria
Flexibility, collective hazard identification		FBO for which exemptions could lead to diminish the high level of consumer protection
First HACCP principle (hazard identification) Prerequisite requirements Guides to Good Hygiene Practices		“Blind” full implementation of a HACCP plan
Direct sale to consumer “low risk” level operations		Any processing, preparation or treatment of the foodstuff released and depending on a cold chain after
Restaurants; Storage, wrapping and sale of non-perishable foodstuffs; Storage and sale of pre-packed foodstuffs which do not require temperature control conditions		Catering; Supermarket chains

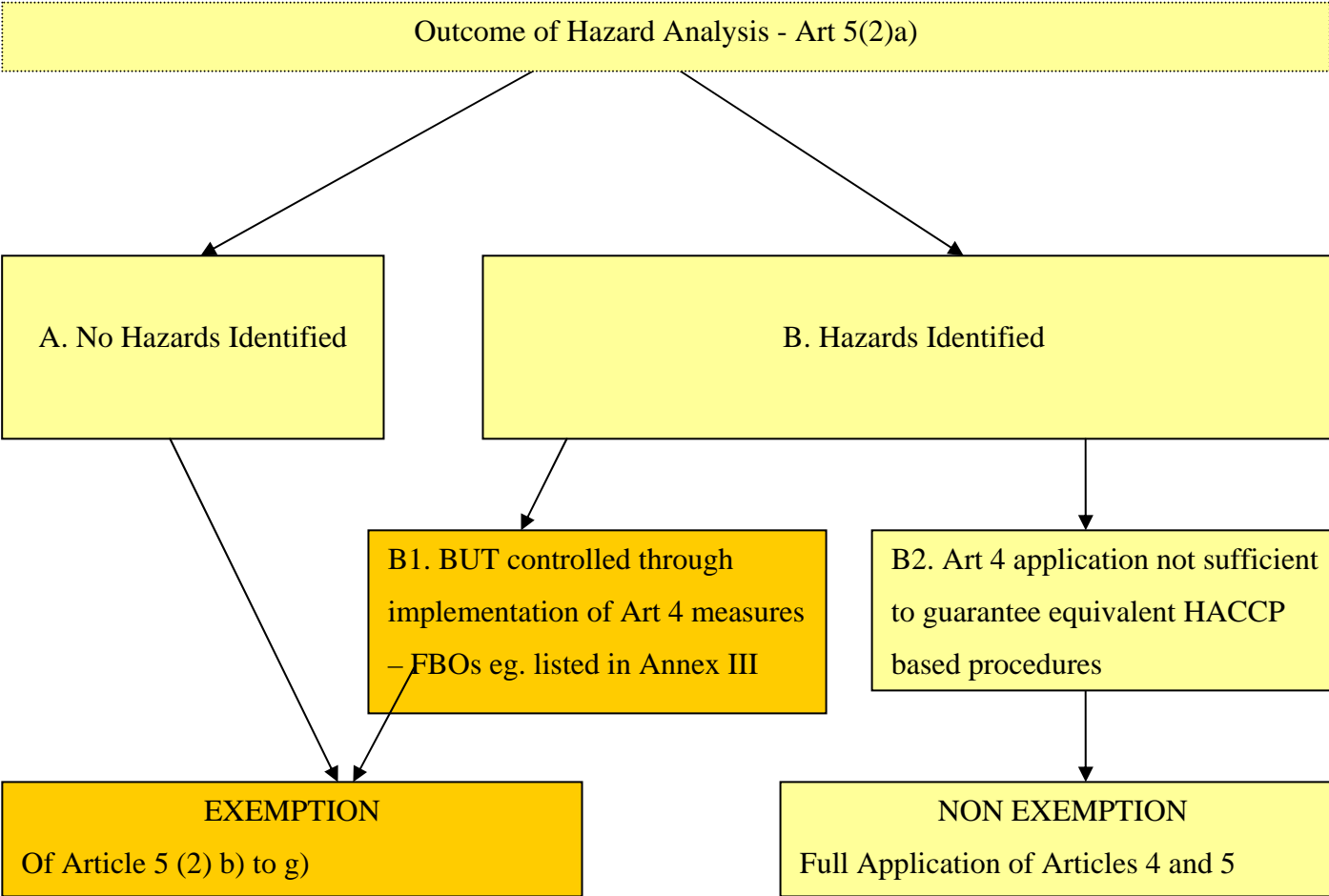
3. Current relevant Legal Framework (see annex):

- a) Reg. (CE) n° 178/2002, 28/01 and Guidance Document:
 - Whereas 2, 3, 4, 5, 9, 16, 17 and 18; Articles 5, 6, 17 and 18;
 - Guidance document parts I and II.

 - b) Reg. (CE) n° 852/2004, 29/04 and Guidance Document:
 - Whereas 12,13,15 and 16; Articles 1, d) and e), 4 and 5;
 - Guidance document N° 5.3 and 8.

 - c) Guidance document on the application and simplification of HACCP principles:
 - Annex II

 - d) CODEX - Recommended International Code of Practice General Principles of Food Hygiene - CAC/RCP 1-1969, Rev. 4-20031
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Requirements

Legal Framework

Reg. (EC) n° 178/2002 and Guidance Document on the implementation of Art. 11, 12, 16, 17, 18, 19 and 20

Whereas 2 and Art.° 5°:

“A high level of protection of human life and health should be assured in the pursuit of Community policies.”

“Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests [...]”.

Key point: Objective must be respected.

Whereas 3, 4 and 5:

“The free movement of food [...] within the Community can be achieved only if food [...] safety requirements do not differ significantly from Member State to Member State.”

Key point: Harmonize procedures without undermining food safety requirements for foodstuffs.

Whereas 9:

“It is necessary to ensure that consumers, other stakeholders and trading partners have confidence in the decision-making processes underpinning food law, its scientific basis and the structures and independence of the institutions protecting health and other interests.”

Key point: Maintain the level of consumer confidence.

Whereas 16, 17 and 18 and Art.° 6°:

“Measures adopted by the Member States and the Community governing food [...] should generally be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure. Recourse to a risk analysis prior to the adoption of such measures should facilitate the avoidance of unjustified barriers to the free movement of foodstuffs.”

“[...], the three interconnected components of risk analysis - risk assessment, risk management, and risk communication - provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health.”

“In order for there to be confidence in the scientific basis for food law, risk assessments should be undertaken in an independent, objective and transparent manner, on the basis of the available scientific information and data.”

Key point: Risk based analysis, proportionate and targeted

Art.° 17° and Guidance Document Part I: FBOs and MS responsibilities

FBOs are legally responsible for food law compliance

Art. 17°, n° 1: Civil responsibility

Art. 17°, n° 2: Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled.

Key point: The application of harmonized flexibility criteria should be used uniformly

Art.° 18° and Guidance Document Part II: Traceability

Concerned FBOs: FBOs in all stages of the food chain

“Food business” definition (Art. 3°, n° 2): *“means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food”*.

Requirement application: always for suppliers, clients (except for final consumer).

Key point: No derogation concerning traceability.

Reg. (EC) n° 852/2004 and Guidance Document on the implementation of certain provisions of Reg. (EC) No 852/2004

Whereas 12, 13,15 e 16:

“Food safety is a result of several factors: [...] and food business operators should establish and operate food safety programmes and procedures based on the HACCP principles.”

“Successful implementation of the procedures based on the HACCP principles will require the full cooperation and commitment of food business employees. [...] The HACCP system is an instrument to help food business operators attain a higher standard of food safety. The HACCP system should not be regarded as a method of self-regulation and should not replace official controls.”

“The HACCP requirements should take account of the principles contained in the Codex Alimentarius. They should provide sufficient flexibility to be applicable in all situations, including in small businesses. In particular, it is necessary to recognize that, in certain food businesses, it is not possible to identify critical control points and that, in some cases, good hygienic practices can replace the monitoring of critical control points. [...] In addition, the requirement of retaining documents needs to be flexible in order to avoid undue burdens for very small businesses.”

“[...] however, flexibility should not compromise food hygiene objectives. Moreover, since all food produced in accordance with the hygiene rules will be in free circulation throughout the Community, the procedure allowing Member States to exercise flexibility should be fully transparent. [...]”

Key point: Legal reference to the application of guides to GHP and precise for which FBOs these guides may be enough (e.g. retail selling directly to final consumer, foodstuffs non-perishable, without processing)

Art.° 1°, d) and e):

“general implementation of procedures based on the HACCP principles, together with the application of good hygiene practice, should reinforce food business operators' responsibility;”

“guides to good practice are a valuable instrument to aid food business operators at all levels of the food chain with compliance with food hygiene rules and with the application of the HACCP principles;”

Key point: Legal reference to the application of guides to GHP and FBOs are legally responsible for food law compliance

Art.° 4°:

FBOs carrying out any stage of production, processing and distribution of food shall comply with the general hygiene requirements (Annex II + 853/2004).

FBOs shall, as appropriate, adopt specific hygiene measures (Comitology).

FBOs may use the guides provided as an aid to compliance with their obligations.

Key point: Ensure the respect of the general hygiene requirements and adopt relevant measures.

Art.º 5º:

“1. Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

2. The HACCP principles referred to in paragraph 1 consist of the following:

(a) identifying any hazards that must be prevented, eliminated or reduced to acceptable levels;

(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels;

(c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;

(d) establishing and implementing effective monitoring procedures at critical control points;

(e) establishing corrective actions when monitoring indicates that a critical control point is not under control;

(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively;

and

(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.

3. Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I.

4. Food business operators shall:

(a) provide the competent authority with evidence of their compliance with paragraph 1 in the manner that the competent authority requires, taking account of the nature and size of the food business;

(b) ensure that any documents describing the procedures developed in accordance with this Article are up-to-date at all times;

(c) retain any other documents and records for an appropriate period.

5. Detailed arrangements for the implementation of this Article may be laid down in accordance with the procedure referred to in Article 14(2). Such arrangements may facilitate the implementation of this Article by certain food business operators, in particular by providing for the use of procedures set out in guides for the application of HACCP principles, in order to comply with paragraph 1. Such arrangements may also specify the period during which food business operators shall retain documents and records in accordance with paragraph 4(c).”

Key point: Ensure application of HACCP principles, taking into account the nature and dimension of the FBO and clarify in which cases and which principles to apply, notably the 1st principle.

Guidance Document, n° 5.3

“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 for hygiene and for the application of the HACCP principles 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.”

Key point: Definition of flexibility criteria for identified cases.

Guidance Document, n° 8:

FBOs establish, under the HACCP-based procedures, documentation commensurate with the nature and the size of the business.

FBOs may establish also other documentation that could assist in meeting the objectives (structural and operational requirements) in different possibilities (guides to GHP; ad hoc documentation appropriate for their situation or under the HACCP-based procedures + flexibility needed, in particular for small businesses).

Key point: Ensure reduction of administrative burden where relevant.

Guidance Document on the implementation of procedures based on the HACCP principles, and on the facilitation of the implementation of the HACCP principles in certain food businesses

Annex II:

3. FBOs eligible for HACCP facilitation:

Reg. (EC) No 852/2004 is not specific on the nature of FBOs that are eligible. The impact of the requirement to put in place, implement and maintain a permanent procedure based on the HACCP principles should be proportionate and based on risk hazards linked to certain types of food and to the process that is applied to food).

Key point: Identify eligible FBOs

4. Procedure based on the HACCP principles:

The seven HACCP principles are a practical model for identifying and controlling significant hazards on a permanent basis. This implies that where the objective can be achieved by equivalent means - replacing in a simplified but effective way the seven principles -it must be considered that the obligation laid down in Article 5, paragraph 1 of Regulation (EC) No 852/2004 is fulfilled.

Key point: Identification of equivalent means to ensure that hygiene requirements are fulfilled despite non exhaustive application of all HACCP principles.

6. Prerequisite requirements and the control of food hazards:

Where the prerequisite requirements (whether or not supplemented with guides to good practices) achieve the objective of controlling hazards in food, it should be considered, based on the principle of proportionality, that the obligations laid down under the food hygiene rules have been met and that there is no need to proceed with the obligation to put in place, implement and maintain a permanent procedure based on the HACCP principles.

Maintenance of the cold chain needs monitoring and verification (and possibly record keeping).

Possible FBOs (simple food preparation operations (such as the slicing of food)): marquees, market stalls and mobile sales vehicles; establishments mainly serving beverages (bars, coffee shops etc.), small retail shops (such as grocery shops) and the transport and storage of pre-packed food or non perishable food.

Key point: To point out which FBOs achieve the objectives with the prerequisite and when application of 1st HACCP principle is enough and applicable.

7. Guides GHP and for the application of HACCP principles:

Simple but efficient way to overcome difficulties that certain FBOs may encounter in implementing a detailed HACCP procedure.

Use of guides GHP can be applied by any food sector, and in particular where the handling of food is in accordance with procedures that are well known and that are often part of the usual vocational training of the operators in the sectors concerned such as: restaurants, including food handling facilities on board means of transport, catering sectors dispatching prepared food from a central establishment, bakery and confectionary sector and retail shops, including butcher shops.

Key point: Legal reference to the application of guides to GHP.

8. Flexibility with regard to the HACCP principles:

Examples of simplified application of the HACCP principles.

Key point: Clear definition of which principles are to be applied and in what way.

CODEX - Recommended International Code of Practice General Principles of Food Hygiene - CAC/RCP 1-1969, Rev. 4-20031

Annex: - Guidelines for the application of the HACCP System:

“The application of the HACCP principles should be the responsibility of each individual businesses. However, it is recognised by governments and businesses that there may be obstacles that hinder the effective application of the HACCP principles by individual business. This is particularly relevant in small and/or less developed businesses. While it is recognized that when applying HACCP, flexibility appropriate to the business is important, all seven principles must be applied in the HACCP system. This flexibility should take into account the nature and size of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints.

Small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan. In such situations, expert advice should be obtained from other sources, which may include: trade and industry associations, independent experts and regulatory authorities. HACCP literature and especially sector-specific HACCP guides can be valuable. HACCP guidance developed by experts relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing the HACCP plan.

Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration. More detailed information on the obstacles in implementing HACCP, particularly in reference to SLDBs, and recommendations in resolving these obstacles, can be found in “Obstacles to the Application of HACCP, Particularly in Small and Less Developed Businesses, and Approaches to Overcome Them” (document in preparation by FAO/WHO).”

Key point: Clear definition of which principles are to be applied and in what way.

PRESIDENCY COMPROMISE TEXT, TABLED 20 SEPTEMBER

New Art. 5 (3) of Reg. (EC) n° 852/2004

“3. a) No change:

Paragraph 1 shall apply only to food business operators carrying out any stage of production, processing and distribution of food after primary production and those associated operations listed in Annex I;

b) New:

Where individual or collective hazard identification, referred to in paragraph (2) a), applied to certain food business operators demonstrates to the competent authority, that hazards can be controlled through the implementation of general and specific hygiene requirements laid down in Article 4, no further implementation of the other HACCP principles mentioned in paragraph (2) is necessary.”