

APRIL 2007 UPDATE ON FOOD HYGIENE LEGISLATION – COMMISSION PROPOSES TO AMEND REGULATION 852/2004

First consideration in Council Working Group will take place on 13 April. Initial views from stakeholders are sought by 11 April

Background

This proposal arises from the European Commission's *Strategic Review of Better Regulation in the European Union*, which seeks to reduce administrative burdens on business by 25% by 2012. As part of its "Action Programme for Reducing Administrative Burdens in the European Community" (COM(2007)23) of 21 January 2007, the European Commission identified ten proposals for "fast track action". The new Regulation proposed by the Commission would implement two of these fast track actions.

Copies of the Commission proposal and Commission impact assessments are included at the end of this document. The Commission proposal also covers a regulation relating to transport.

Scope

Article 5 (1) of Regulation 852/2004 requires all food business operators to put in place, implement and maintain a permanent procedure or procedures based on HACCP¹ principles. The Commission's proposal would amend Article 5 (3) of that Regulation to exclude from the whole of the Article 5 (1) requirement **all** food business operators with fewer than 10 employees who predominantly sell food direct to the final consumer. Excluded food business operators would still have to comply with all other relevant requirements of Regulation 852/2004. It should be noted in contrast, however, that both in its Explanatory Memorandum and in the draft recitals, the Commission indicates

¹ "HACCP" stands for Hazard Analysis and Critical Control Points and is a structured approach to managing food safety through the identification of hazards and actions to be taken to control them.

that the intention is to exempt **certain** types of food businesses from **certain** aspects of the requirement, namely the record keeping.

Timing

The German Presidency has indicated a timetable for considering the proposal in keeping with its presentation as a fast-track item. The two elements of the proposal will be considered in their respective Council Working Parties (Veterinary Experts (Public Health) on 13 April, Working Party on Land Transport 20 April). The Working Party on Competitiveness and Growth will consider progress on 24 April. It **may** then be referred to the Competitiveness Council on 21 May for political agreement.

Initial UK views

The UK fully supports the Commission in identifying areas where administrative burdens might be reduced, **without compromising public health protection**. As it stands, the proposal gives rise to a number of issues which need to be fully explored, starting with the discussions in the Council Working Party on 13 April.

FSA consultation

The FSA will consult formally on this proposal. In the meantime, if you would like to offer comments on this proposal, add your contact details to the list of stakeholders consulted or ask for this information in hard copy, please contact:

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An initial RIA (which will form part of the formal consultation) is in preparation.



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 14 March 2007

7371/07

**Interinstitutional File:
2007/0037 (COD)**

**TRANS 80
AGRILEG 37
DENLEG 16
COMPET 73
CODEC 219**

PROPOSAL

from: Commission
dated: 7 March 2007

Subject: Proposal for a Regulation of the European Parliament 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 European Economic Community and Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU, to Mr Javier SOLANA, Secretary-General/High Representative.

Encl.: COM(2007) 90 final



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 6.3.2007
COM(2007) 90 final

2007/0037 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT 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 European Economic Community and Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs

{SEC(2007) 301}

{SEC(2007) 302}

{SEC(2007) 303}

{SEC(2007) 304}

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Grounds for and objectives of the proposal**

A large part of EC legislation was introduced to correct market failures and ensure a level playing field. These goals could often only be achieved by imposing obligations on businesses to provide information and report on the application of the legislation.

With time, some of these procedures have become needlessly time-consuming or obsolete. These unnecessary administrative burdens hamper economic activity and have a negative impact on the competitiveness of European enterprises.

The Commission is committed to reducing these unnecessary burdens to the maximum extent possible. This is a part of the Better Regulation strategy and it is of vital importance for achieving our "Lisbon" targets of more growth and jobs.

- **General context**

On 14 November 2006, the Commission presented a Strategic Review of Better Regulation in the European Union (COM(2006) 689), including a proposal for a target to reduce the administrative burdens on businesses by 25% by 2012.

Ten concrete proposals for "fast track action" were thereupon identified the Action Programme for reducing administrative burdens in the EU (COM(2007) 23), based on broad stakeholder consultation and suggestions from Member States and Commission experts. The "fast track actions" aim at significantly reducing administrative burdens on businesses through minor legislative changes without challenging the level of protection or the original purpose of the legislation.

One of these "fast track action" proposals concerns Regulation No 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. It is envisaged to delete outdated requirements and to modify certain requirements in order to minimise the administrative burdens on businesses. Article 5 notably requested transport undertakings (as well as Member States' governments) to provide information on transport tariffs, rates and conditions before 1 July 1961. This Article can be deleted since the information requirements imposed on transport undertakings are outdated. Article 6(1) of the Regulation requires a transport document containing several information elements concerning the consignor, the nature of the goods carried, the place of origin and destination of the goods as well as the route to be taken or distance to be travelled, including frontier crossing points where appropriate. Since these latter elements i.e. the route to be taken or distance to be travelled and frontier crossing points where appropriate are no longer indispensable to achieve the objectives of the Regulation, they can be deleted. The third sentence of Article 6(2) of the Regulation requires the carrier to retain a copy showing the full and final transport charges and any other charges and any rebates or other factors affecting the transport rates and conditions. This sentence can be deleted as nowadays, this information is available in the carriers' accounting systems anyway, so there is no need for the carriers to fill out and keep a separate document anymore. Article 6(3) shall contain an explicit reference to consignment notes, which are very well-

known and often used in the inland transport sector. This reference improves legal certainty for transport undertakings as it clarifies that these consignment notes, if containing all details required by paragraph 1 of Article 6, suffice.

Another "fast track action" relates to Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs. The purpose is to exempt small food businesses able to control food hygiene simply by implementing the other requirements of Regulation (EC) 852/2004 from the requirement to putting in place, implementing and maintaining a permanent procedure or procedures based on the hazard analysis and critical control points ("HACCP") principles. This exemption applies to micro-enterprises¹ that are predominantly selling food directly to the final consumer. These enterprises have less than ten employees and have an annual turnover or annual balance sheet total that does not exceed 2 million EUR. The exemption would therefore not apply to large surface supermarkets and franchisers of supermarket chains.

- **Existing provisions in the area of the proposal**

The existing provisions that this proposal seeks to modify are Articles 5 and 6 of Regulation No 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 Article 5 of Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

Consultation methods

In the Action Programme of 24 January 2007, the Commission presented ten concrete proposals for "fast track actions". These proposals were based on consultations with experts and in particular on a pilot project comparing the baseline measurements of administrative burdens in the Czech Republic, Denmark, The Netherlands and the United Kingdom in 2006.

One of these "fast-track actions" concerned the transport sector and proposed to "ease certain obligations to provide transport statistics". Regulation No 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 requires transporters to carry a transport document stating inter alia distances, routes and frontier crossing points.

Another "fast track action" concerned food hygiene, proposing to "exempt small businesses from certain HACCP (hazard analysis and critical control points) requirements". Article 5 of Regulation (EC) No 852/2004 requires that all food business operators put in place, implement and maintain a procedure based on the HACCP (Hazard Analysis Critical Control Point) principles.

¹ As within the meaning of Commission Recommendation 2003/361/EC concerning the definition of micro, small and medium-sized enterprises of 6 May 2003, C(2003) 1422 OJ L 124/36.

Summary of responses

Experts and industry have expressed concern that these requirements from 1960 in Regulation No 11 are outdated in the highly liberalised transport sector. Certain articles are found to be obsolete while others impose unnecessary burdens on businesses.

Representatives of small businesses have expressed worries with regard to the general implementation of the HACCP system in all food businesses. In spite of the flexibility that was introduced in the Regulation, clarification was requested. The Commission has held a series of meetings with experts from the Member States. In addition, and in the interest of transparency, the Commission has promoted discussion with stakeholders so as to allow different socio-economic interests to express an opinion. To this end, a meeting with representatives from producers, industry, commerce and consumers was organised to discuss issues related to the implementation of HACCP based procedures and to HACCP flexibility. The results of these discussions are laid down in a guidance document that was endorsed by the Standing Committee of the Food Chain and Animal Health and published at:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

Due to the significant impact on SMEs that a strict application of the HACCP requirements would lead to and the fact that some businesses can provide the same level of hygienic protection by implementing all the other requirements of Regulation (EC) No 852/2004, without there being a need to implement fully fledged HACCP procedures and despite a guidance document explaining the extent to which flexibility can be applied with regard to HACCP, there is a need for an exemption for some enterprises from all the HACCP requirements. It must be considered however that an exemption should not apply to businesses reaching a wide public. The exemption should therefore be limited to businesses with fewer than 10 employees which can be classified as micro-enterprises within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises.

• **Impact assessment**

The impact assessment concerning Regulation No 11 considered two options:

Option 1 No-Policy Change.

Option 2 Abolishing the obligation to provide information on routes, distances, rates and other transport conditions, and allowing the use of consignment notes to provide information on the remaining requirements related to the current transport document.

Option 2 was the preferred option because it provides for a reduction of unnecessary administrative burdens while the same level of essential information continues to be available.

The impact assessment concerning Regulation (EC) No 852/2004 considered three options:

Option 1 No-Policy Change.

Option 2 Exempting certain businesses from the HACCP requirements.

Option 3 Abolition of HACCP procedures for all businesses.

Option 2 was the preferred option because it provided a sound balance between reducing administrative burdens on businesses while maintaining a high level of consumer protection.

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Summary of the proposed action**

The aim of the action regarding Regulation No 11 is to reduce administrative burdens for transport enterprises by removing outdated documentation requirements regarding the route to be taken, distance to be travelled, frontier crossing points etc.

The actions concerning HACCP requirements aims at introducing an amendment to Regulation (EC) No 852/2004 excluding micro-enterprises from the requirement to putting in place, implementing and maintaining a permanent procedure or procedures based on the HACCP principles. This exemption applies to businesses with less than ten employees that are predominantly selling food directly to the final consumer.

- **Legal basis**

The legal base of Community action in the area of Transport is laid down in Article 75 EC Treaty, and the legal base of Community action in the area of Food hygiene is laid down in Article 95 and 152 (4) (b) EC Treaty.

- **Subsidiarity principle**

Action by the Member States would not suffice to reduce administrative burdens in these areas as the information requirements were imposed for transport enterprises and food businesses by way of EC Regulations. A reduction can therefore only be achieved by way of modifications of the Regulations concerned at European Union level.

EU action will ensure that all European transport enterprises and food businesses concerned can benefit from these administrative burdens reductions.

The proposal therefore complies with the subsidiarity principle.

- **Proportionality principle**

The proposal complies with the proportionality principle for the following reason(s).

The goal of reducing administrative burdens caused by the information requirements imposed by Regulation No 11 and Regulation (EC) No 852/2004 can only be reached by modifying these Regulations, which can only be done by way of a binding EC legal instrument of the same level, a Regulation. This is in line with the proportionality principle contained in Article 5 EC Treaty.

This proposal ensures that the administrative burdens falling upon transport enterprises and small food businesses caused by the information requirements contained in Regulations No 11 and (EC) No 852/2004 are minimized.

- **Choice of instruments**

Proposed instruments: Regulation.

Other means would not be adequate for the following reason(s).

The objective of reducing administrative burdens caused by the information requirements imposed by Regulation No 11 and Regulation (EC) No 852/2004 can only be reached by modifying these Regulations, which can only be done by way of a binding EC legal instrument of the same type and level, a Regulation.

4. BUDGETARY IMPLICATION

The proposal has no implication for the Community budget.

5. ADDITIONAL INFORMATION

- **Simplification**

The proposal provides for simplification of administrative procedures for private parties.

The administrative procedure to be followed by transport enterprises will be simplified in the sense that some documentation requirements that are not absolutely indispensable regarding the route to be taken, distance to be travelled, and frontier crossing points will be removed. The administrative procedures for small food businesses able to control food hygiene simply by implementing the other requirements of Regulation (EC) No 852/2004 will be simplified as micro-enterprises predominantly selling food directly to consumers will be exempted from the requirement to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.

- **European Economic Area**

The proposed act concerns an EEA matter and should therefore extend to the European Economic Area.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT 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 European Economic Community and Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 75(3), Article 95 and Article 152(4)(b) thereof,

Having regard to the proposal from the Commission²,

Having regard to the opinion of the European Economic and Social Committee³,

Having regard to the opinion of the Committee of the Regions⁴,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁵,

Whereas:

- (1) Community policies on Better Regulation, in particular the Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: "A strategic review of Better Regulation in the European Union"⁶ and the Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions: "Action Programme for Reducing Administrative Burdens in the European Union"⁷, stress the importance of reducing the administrative burdens imposed on enterprises by existing legislation as a crucial element for improving their competitiveness and for achieving the objectives of the Lisbon agenda.

² OJ C , , p. .

³ OJ C , , p. .

⁴ OJ C , , p. .

⁵ OJ C , , p. .

⁶ COM(2006) 689.

⁷ COM(2007) 23.

- (2) The Community rules required under Article 75 of the EC Treaty in order to abolish certain forms of discrimination, as regards inland transport within the Community, have been laid down in Regulation No 11⁸. In the interest of reducing administrative burdens on businesses that Regulation should be simplified by removing outdated and unnecessary requirements in particular, the requirement to retain on paper certain information which, on account of technical progress, is now available in the carriers' accounting systems.
- (3) Article 5(1) of Regulation (EC) No 852/2004⁹ requires that all food business operators put in place, implement and maintain a procedure based on the Hazard Analysis Critical Control Point (HACCP) principles.
- (4) Experience has shown that in certain food businesses, food hygiene can be ensured by the correct implementation of the food hygiene requirements laid down in Regulation (EC) No 852/2004 without having recourse to the HACCP system. The businesses concerned are in particular small businesses predominantly selling their products directly to the final consumer, such as bakeries, butchers, grocery shops, market stalls, restaurants, and bars, , which are micro-enterprises within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises¹⁰.
- (5) It is appropriate therefore to provide an exemption to those businesses from the requirement of Article 5(1) of Regulation (EC) No 852/2004, it being understood that they must comply with all the other requirements of that Regulation.
- (6) As the amendment of Regulation (EC) No 852/2004 and that of Regulation No 11 have the common aim of reducing administrative burdens on businesses, without changing the underlying purpose of those Regulations, it is appropriate to combine these amendments in a single Regulation

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation No 11 is amended as follows:

- (1) Article 5 is deleted.
- (2) Article 6 is amended as follows:
 - (a) In paragraph 1 the fifth and sixth indents are deleted;
 - (b) In paragraph 2, the third sentence is deleted.

⁸ OJ P 52, 16.8.1960, p. 1121. Regulation as last amended by Regulation (EEC) No 3626/84 (OJ L 335, 22.12.1984, p. 4).

⁹ OJ L 139, 30.4.2004, p. 1; corrected version in OJ L 226, 25.6.2004, p. 3.

¹⁰ OJ L 124, 20.5.2003, p. 36.

(c) Paragraph 3 is replaced by the following:

"3. Where existing documents such as consignment notes or any other transport document give all the details specified in paragraph 1 and, in conjunction with carriers' recording and accounting systems, enable a full check to be made of transport rates and conditions, so that the forms of discrimination referred to in Article 75(1) of the Treaty may be thereby abolished or avoided, carriers shall not be required to introduce new documents."

Article 2

In Article 5(3) of Regulation (EC) No 852/2004, the following sentence is added:

"Without prejudice to the other requirements of this Regulation, paragraph 1 shall not apply to businesses which are micro-enterprises within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003¹¹ and the activities of which consist predominantly in the direct sale of food to the final consumer."

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

¹¹ OJ L 124, 20.5.2003, p. 36.



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 14 March 2007

**Interinstitutional File:
2007/0037 (COD)**

**7371/07
ADD 1**

**TRANS 80
AGRILEG 37
DENLEG 16
COMPET 73
CODEC 219**

ADDENDUM TO PROPOSAL

from: Commission
dated: 7 March 2007

Subject: Commission Staff Working Document
Accompanying document to the
Proposal for a Regulation of the European Parliament 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 European Economic Community and Regulation (EC) No
852/2004 of the European Parliament and the Council on the hygiene of
foodstuffs
Impact assessment
(Regulation 852/2004 Food hygiene - Hazard Analysis and Critical Control
Point requirements)

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU, Director, to Mr Javier SOLANA, Secretary-General/High Representative.

Encl.: SEC(2007) 301



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 6.3.2007
SEC(2007) 301

COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

**Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT 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
European Economic Community and Regulation (EC) No 852/2004 of the European
Parliament and the Council on the hygiene of foodstuffs**

**Impact assessment
(Regulation 852/2004 Food hygiene - Hazard Analysis
and Critical Control Point requirements)**

{COM(2007) 90 final}
{SEC(2007) 302}
{SEC(2007) 303}
{SEC(2007) 304}

COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT 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 European Economic Community and Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs

Impact assessment

(Regulation 852/2004 Food hygiene - Hazard Analysis and Critical Control Point requirements)

1. PROBLEM DEFINITION

Regulation (EC) No 852/2004 on food hygiene lays down that all food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. This entails the following activities:

- Identify hazards,
- Identify critical control points to prevent or eliminate hazards,
- Establish critical limits at critical control points,
- Establish and implement monitoring procedures at the critical control points,
- Establish corrective action when a critical control point is out of control,
- Establish procedures to verify that measures are working effectively,
- Establish documents and records to demonstrate application of the above.

To be applied properly, the obligation to implement HACCP procedures requires a multidisciplinary team of staff that is capable of identifying hazards, identifying critical control points, establishing critical limits, establish monitoring procedures at the critical points etc. Businesses are also required to establish documentation for backing-up the procedures and keep records. These requirements entail significant annual costs at EU-level (estimated at € 220.000.000¹), although bigger businesses may consider these costs marginal because for them they represent a smaller proportion of overall costs. However, for smaller businesses (SMEs) these requirements prove extremely costly and burdensome (as evidenced by the stakeholder consultation and the analysis contained in the guidance document quoted

¹ Figures from the measurement of administrative burdens in Denmark have been extrapolated to the EU-level based on the relative percentage of GDP (World Bank data, 2005) and the country distribution list developed by Kox (2005) in order to correct the extrapolated figures according to different estimated levels of administrative burdens in different Member States. However, this figure states the estimated total administrative cost at EU-level and not necessarily the reduction potential.

hereunder). From the time of adoption of the Regulation, representatives of small businesses have expressed their concerns with regard to the general implementation of the HACCP system in all food businesses. Whilst the Regulation has some flexibility, analysis shows that clarification is necessary.

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

In addition, and in the interest of transparency, the Commission's Health and Consumer Protection Directorate General promoted discussion with stakeholders so as to allow different socio-economic interests to express an opinion. To this end a meeting with representatives from producers, industry, commerce and consumers was organised to discuss issues related to the implementation of HACCP based procedures and to HACCP flexibility.

The results of these discussions are laid down in a guidance document that was endorsed by the Standing Committee of the Food Chain and Animal Health. This document is available via the following link:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

Due to the significant impact on SMEs that a strict application of the HACCP requirements would lead to and the fact that some businesses can provide the same level of hygienic protection by implementing all the other requirements of Regulation (EC) No 852/2004, without there being a need to implement fully fledged HACCP procedures and despite a guidance document explaining the extent to which flexibility can be applied with regard to HACCP, there is a need for an exemption for some enterprises from all the HACCP requirements. The exemption should therefore be limited to businesses with fewer than 10 employees which can be classified as micro-enterprises within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises.

Although Member States participated in developing the guidance document and agree on the principles, there is significant uncertainty regarding whether businesses actually do benefit from this new guidance as it is not being applied evenly across Member States and as it is not legally binding. This leads to unequal treatment of food businesses, with some SME food businesses being disadvantaged. In addition, there are questions concerning legal security for the above mentioned establishments when following the guidance document. In summary, the present situation leads to unnecessary information obligations being maintained *de facto*.

2. OBJECTIVES

The main objective of this initiative is to contribute to the Lisbon strategy for growth and jobs, in particular by reducing the costs of doing business for certain SMEs in the food sector. The operational objective in this case is to ensure that information obligations do not disproportionately affect the day-to-day running of a business and that they are not disproportionately costly. In this particular case it is to assess whether there are ways in which the burden on SMEs in the food sector can be eased while maintaining the same adequate level of health protection.

As the objectives are to reduce the administrative burden on business and the improvement of EU competitiveness, while preserving levels of protection, they are fully consistent with the Lisbon strategy and the Sustainable Development strategy.

3. POLICY OPTIONS

Given the objectives stated above, the scope for some firms to a possible exemption from the HACCP requirements must be based on the capacity of the food business to control food hygiene and to deliver food hygiene results by implementing good hygienic practices that are at least equivalent to those currently achieved by adhering to the HACCP requirements. Otherwise the current obligations should not be relaxed at all. Thus, the following policy options lend themselves to further examination:

Option 1 No-Policy Change

This options means that the existing Regulation is unchanged and that no additional steps are taken in addition to the existing guidance which is mentioned in the Problem Definition above.

Option 2 Exempting certain businesses from the HACCP requirements

This option involves exempting certain businesses from the HACCP requirements as long as it can be guaranteed that they can meet the same food hygiene standards as if they applied all the HACCP requirements. This means that the same level of protection needs to be ensured by adhering to the other requirements laid down in Regulation (EC) No 852/2004, whether or not completed with guides to good practice, and called "prerequisite requirements". The guidance document referred to above already identifies that by having "prerequisite" food hygiene requirements in place, some businesses can achieve the same level of protection. The businesses to be exempted are micro-enterprises with less than ten employees predominantly selling food directly to the final consumer without processing the food. The exemption does not apply to large surface supermarkets and franchisers of supermarket chains.

It is unlikely that in the course of their work the exempted businesses add new hazards to food that must be controlled by implementing HACCP procedures. If new hazards emerge from handling food in these businesses, they can be controlled by implementing non-HACCP control measures.

Option 3 Abolition of HACCP procedures for all businesses

Under this option HACCP procedures for all business in the food sector would be abolished.

4. ANALYSIS OF OPTIONS

Option 1

Under this option the current situation would not change. The seemingly high level of consumer health protection would be maintained and standards and procedures that are required for meeting those standards would be the same across the food sector. This would imply that SMEs would continue to face significant costs to meet existing information requirements. The guidance document mentioned above could offer some smaller businesses

an exemption but the current problem with regard to implementation and particularly the legal uncertainty would persist since the guidance document is not enforceable. Member States may prefer not to implement these solutions or to impose different solutions thus leading to unequal treatment of food businesses.

Option 2

Exempting micro-enterprises as stated above from the HACCP requirements that were mentioned above in the Problem Definition section would have a real impact on their day-to-day running and allow them to become more efficient. However, any such exemption must not come at the expense of lowering hygiene standards. In food businesses such as small retail outlets selling their products directly to the final consumer, e.g. bakeries, grocery shops, market stalls, fish retail shops, restaurants, and bars, food hygiene can be ensured by complying with all the other requirements of Regulation (EC) No 852/2004, without having to implement the HACCP system.

It should be pointed out that *'HACCP systems are not a replacement for other food hygiene requirements'*² rather they are one element of a integrated and wide ranging strategy that provides for food safety. Before establishing HACCP procedures 'prerequisite' food hygiene practices must already be in place. In particular, these prerequisites are:

- Infrastructural and equipment requirements,
- Requirements for raw materials,
- The safe handling of food (including packaging and transport),
- Food waste handling,
- Pest control procedures,
- Sanitation procedures (cleaning and disinfection),
- Water quality,
- Maintenance of the cold chain,
- The health of staff,
- Personal hygiene,
- Training.

These so-called prerequisite requirements are aimed at controlling hazards and are clearly prescribed in Community law. Furthermore, there are other Community law based requirements such as traceability (Article 18 of Regulation (EC) No 178/2002) and on the withdrawal of food and the duty of informing the competent authorities (Article 19 of Regulation (EC) No 178/2002) that could, although not covered under the food hygiene rules, also be considered as prerequisite requirements.

² See page 18 of the guidance document
http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidance_doc_haccp_en.pdf

Where there is no processing, manufacturing or only limited preparation of food, such as the slicing of food, good adherence to and correct application of the prerequisite requirements produces the same levels of hygienic protection that HACCP practices do. This is especially the case where sector specific guides exist that complement the Community law based prerequisite requirements, for example, for operators in the restaurant and catering sectors. In other words, where these things are in place the additional benefit from implementing all HACCP requirements is not given.

According to the estimates presented above, the annual costs of these requirements are approximately EUR 220 million. These costs will obviously be significantly reduced by exempting certain businesses from the requirements as companies will have to spend less time on administrative activities.³ However, giving a precise estimate of the total administrative burden savings is fraught with difficulty at this stage. The EUR 220 million estimated annual costs are likely to contain some compliance costs (sunk costs) that strictly speaking cannot be counted towards the administrative burden. The final reduction of the administrative burden will depend on the number of businesses eligible for the exemptions from the HACCP requirements and the amount of the annual cost estimate that forms the administrative burden element. The Commission will produce more concrete data on these aspects in due course.. Once that is available, a better estimate of the contribution this proposal can make towards the overall 25% reduction target will become available.

It is not excluded that other businesses could also be exempted from the systematic implementation of HACCP procedures at a later stage, in particular those businesses that process food in accordance with standard practices for which experience has shown that they ensure the safety of food. However, this will require an in-depth analysis and further consultation and discussion. It is suggested that such analysis is undertaken under the review that is to be undertaken by virtue of Article 16 of Regulation (EC) No 852/2004, not later than 20 May 2009.

Option 3

If this option was followed all HACCP requirements for all food businesses would be abolished. It is mentioned above that there is evidence based on experience that shows that those companies mentioned in option 2 could offer the same level of hygiene by following normal hygiene procedures. The same however does not necessarily apply to the big food industry, particularly if it involves food processing. Hence, while a wider ranging exemption would generate more significant savings (EUR 220 million); it would also risk lowering food hygiene standards and could, therefore, be at odds with one of the main objectives of the Administrative Burden reduction exercise.

5. COMPARING THE OPTIONS

Option 3 risks not fulfilling the fundamental objective of not lowering standards. Option 1 would not change the status quo, meaning the legal uncertainty regarding the existing guidance would persist and smaller businesses in several Member States would continue to incur unnecessarily high costs. Option 2 seems to offer the best way forward by combining exemptions for micro-enterprises predominantly selling food directly to the final consumer

³ It is not possible to assess the exact number of businesses that would be exempted by this option. Therefore, it is not possible to estimate expected savings at present.

and significant reduction of the administrative burdens with maintaining the same food hygiene standards. It should be stressed that the available evidence indicates that food hygiene standards would not be lowered and that therefore these estimated cost savings are not offset by other impacts.

6. MONITORING AND EVALUATION

Member States and trade associations would be asked to communicate the exemption to businesses concerned, but it would be disproportionate to collect data at EU level on how many of the businesses that are eligible for the exemption would use it. Any lingering health and safety concerns would be picked up by existing food hygiene monitoring provisions.

As mentioned above, the baseline measurement exercise will produce more concrete data regarding the actual administrative burden reduction that this proposal is going to lead to.



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 14 March 2007

**Interinstitutional File:
2007/0037 (COD)**

**7371/07
ADD 2**

**TRANS 80
AGRILEG 37
DENLEG 16
COMPET 73
CODEC 219**

ADDENDUM TO PROPOSAL

from: Commission
dated: 7 March 2007

Subject: Commission Staff Working Document
Accompanying document to the
Proposal for a Regulation of the European Parliament 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 European Economic Community and Regulation (EC) No
852/2004 of the European Parliament and the Council on the hygiene of
foodstuffs
Impact Assessment Summary
(Regulation 852/2004) Food hygiene - Hazard Analysis and Critical Control
Point requirements)

Delegations will find attached a proposal from the Commission, submitted under a covering letter from Mr Jordi AYET PUIGARNAU, to Mr Javier SOLANA, Secretary-General/High Representative.

Encl.: SEC(2007) 302



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 6.3.2007
SEC(2007) 302

COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

**Proposal for a
REGULATION OF THE EUROPEAN PARLIAMENT 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
European Economic Community and Regulation (EC) No 852/2004 of the European
Parliament and the Council on the hygiene of foodstuffs**

**Impact Assessment Summary
(Regulation 852/2004 Food hygiene - Hazard Analysis and
Critical Control Point requirements)**

{COM(2007) 90 final}
{SEC(2007) 301}
{SEC(2007) 303}
{SEC(2007) 304}

COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT 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 European Economic Community and Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs

Impact Assessment Summary

(Regulation 852/2004 Food hygiene - Hazard Analysis and Critical Control Point requirements)

Executive Summary

The proposal this Impact Assessment accompanies is part of the wide ranging administrative burden reduction exercise. Regulation (EC) No 852/2004 on food hygiene lays down that all food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. To be applied properly, the obligation to implement HACCP procedures requires a multidisciplinary team of staff that is capable of, for example, identifying hazards and critical control points, and that can establish critical limits and monitoring procedures at the critical points. These requirements may entail significant annual costs at EU-level (estimated to be € 220.000.000). Although for bigger businesses these costs may be less significant as they may represent only a fraction of overall costs, these requirements can be extremely costly and burdensome for smaller businesses (SMEs).

Due to the significant impact on SMEs that a strict application of the HACCP requirements would lead to and the fact that some businesses can provide the same level of hygienic protection by implementing all other requirements of Regulation (EC) No 852/2004, without there being a need to implement fully fledged HACCP procedures and despite a guidance document explaining the extent to which flexibility can be applied with regard to HACCP, there is a need for an exemption for some enterprises from all the HACCP requirements.

The main objective of this initiative is to contribute to the Lisbon strategy for growth and jobs, in particular by reducing the costs of doing business for SMEs in the food sector if the same adequate levels of hygienic protection can be maintained. The operational objective in this case is to ensure that information obligations do not disproportionately affect the day-to-day running of a business and that they are not disproportionately costly. The impact assessment considered three policy options to meet this end:

- Option 1** No-Policy Change
- Option 2** Exempting certain businesses from the HACCP requirements
- Option 3** Abolition of HACCP procedures for all businesses

Option 3 risks not fulfilling the fundamental objective of not lowering standards. Option 1 would not change the status quo, meaning the legal uncertainty regarding the existing guidance would persist and smaller businesses in several Member States would continue to incur unnecessarily high costs. Option 2 seems to offer the best way forward by combining exemptions for some smaller businesses in the food sector that can provide the same level of food hygiene protection by implementing all other requirements of Regulation (EC) No 853/2004 with a significant reduction of the administrative burden. It should be stressed that the available evidence indicates that food hygiene standards would not be lowered and that therefore these estimated cost savings are not offset by other, negative impacts elsewhere.