APRIL 2008 UPDATE ON FOOD HYGIENE LEGISLATION

COMMISSION PROPOSAL TO AMEND ARTICLE 5 OF REGULATION 852/2004

In March 2007 the Commission tabled a proposal to exempt from the requirement for food safety management procedures based on HACCP certain types of micro businesses (see previous reports below). The proposal is subject to co-decision by the European Parliament and the Council. To date, the Council had not been able to agree to the Commission proposal as drafted, nor had it been able to agree modifications to the proposal.

The Environment Committee of the European Parliament has now considered the proposal and adopted a report (enclosed), suggesting amendments to the Commission proposal. There has since been a meeting of the Commission, Council and the European Parliament to consider what scope might exist for reaching agreement.

At that meeting the Commission produced a compromise text (enclosed). This has been discussed initially within the Council (at Attaché level), where it was agreed that the words “to the competent authority” in the new text should be deleted. While a majority of Member States could accept the new text, a blocking minority could not.

The Presidency will put this matter to COREPER on 7 May, where it will look to obtain a qualified majority in favour. This would pave the way for agreement with the Parliament on the basis of the compromise at first reading.
REPORT


Committee on the Environment, Public Health and Food Safety

Rapporteur: Horst Schnellhardt
Symbols for procedures

* Consultation procedure
  majority of the votes cast

**I Cooperation procedure (first reading)
  majority of the votes cast

**II Cooperation procedure (second reading)
  majority of the votes cast, to approve the common position
  majority of Parliament’s component Members, to reject or amend
  the common position

*** Assent procedure
  majority of Parliament’s component Members except in cases
  covered by Articles 105, 107, 161 and 300 of the EC Treaty and
  Article 7 of the EU Treaty

***I Codecision procedure (first reading)
  majority of the votes cast

***II Codecision procedure (second reading)
  majority of the votes cast, to approve the common position
  majority of Parliament’s component Members, to reject or amend
  the common position

***III Codecision procedure (third reading)
  majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission.)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in **bold italics**. Highlighting in **normal italics** is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.
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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION


(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2007))0090),

– having regard to Article 251(2) and Article 152(4)(b) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C6-0211/2007),

– having regard to the decision of the Conference of Presidents of 5 July 2007 to authorise the Committee on the Environment, Public Health and Food Safety and the Committee on Transport and Tourism to draw up one legislative report each on the basis of the above-mentioned Commission proposal,

– having regard to the opinion of the Committee on Legal Affairs on the proposed legal basis,

– having regard to Rule 51 and 35 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety (A6-0143/2008),

1. Approves the Commission proposal, as regards the hygiene of foodstuffs, as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.
Amendment 1

Proposal for a regulation – amending act
Title

Text proposed by the Commission

Amendment

Justification
This amendment follows from the decision of the Conference of Presidents of 5 July 2007 authorising the ENVI and TRAN committees to each draw up a legislative report on the basis of Commission proposal COM(2007)0090. The references to transport rates and conditions and the parts of the Commission proposal relating to this area have been deleted.

Amendment 2

Proposal for a regulation – amending act
Citation 1

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

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

See justification to amendment to the title.

The reference in the German version of the Commission document to Article 154 is incorrect. As in all the other language versions, reference should be made to Article 152(4)(b) (public health).

Amendment 3
Proposal for a regulation – amending act
Recital 2

Text proposed by the Commission
(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 11. 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.

Justification

See justification to amendment to the title.

Amendment 4
Proposal for a regulation – amending act
Recital 4 a (new)

Text proposed by the Commission
(4a) Food business operators may be exempted from the requirement to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. This should apply only to certain businesses the activities of which consist predominantly
in the direct sale of food to the final consumer, and provided the competent authority considers, on the basis of a regular hazard analysis, that either there are no hazards that must be prevented, eliminated or reduced to acceptable levels, or that identified hazards are sufficiently and regularly controlled through the implementation of general and specific food hygiene requirements.

Amendment 5
Proposal for a regulation – amending act
Recital 5

Text proposed by the Commission

(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.

Amendment

(5) It is appropriate therefore that the competent authorities apply the flexibility provided for in Regulation (EC) No 852/2004, in particular Article 5(2)(g) and (5) thereof, in order to avoid undue burdens for small businesses.

Amendment 6
Proposal for a regulation – amending act
Recital 6

Text proposed by the Commission

(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.

Amendment

deleted

Justification

See justification to amendment to the title.
Amendment 7
Proposal for a regulation – amending act
Article 1
Regulation No. 11
Article 5 and Article 6 - paragraphs 1, 2 and 3

Text proposed by the Commission Amendment

Article 1 deleted

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.

(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."

Justification

See justification to amendment to the title.

Amendment 8
Proposal for a regulation – amending act
Article 2
Regulation No 852/2004
Article 5 - paragraph 3

Text proposed by the Commission Amendment

Without prejudice to the other 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 2003 and the activities of which consist predominantly in the direct sale of food to the final consumer.

food business operators may be exempted from the requirement to put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles. This shall apply only to businesses within the meaning of Commission Recommendation 2003/361/EC of 6 May 2003 (with a particular focus on micro-enterprises) and the activities of which consist predominantly in the direct sale of food to the final consumer, and provided the competent authority considers, on the basis of a regular hazard analysis, that either there are no hazards that must be prevented, eliminated or reduced to acceptable levels, or that identified hazards are sufficiently and regularly controlled through the implementation of general and specific food hygiene requirements laid down in Article 4(2) to (6).

In requiring evidence of compliance with the requirements laid down in Article 4(2) to (6), the competent authority shall take due account of the nature and size of the food business.
EXPLANATORY STATEMENT

Procedural aspects

- This proposal forms part of the so-called 'fast track actions' which were included in the Communication on the Action Programme for Reducing Administrative Burdens in the European Union (COM(2007)23).

- A characteristic feature of the proposal is the fact that it covers two completely different areas, namely, on the one hand, alleviation of the administrative burden in the area of transport rates and conditions and, on the other, provisions exempting micro-enterprises from basic HACCP obligations.

- For that reason the Conference of Presidents decided on 5 July 2007, at the request of the chairman of the Transport Committee, Mr Costa, and of the chairman of the Environment Committee, Mr Ouzký, to authorise both committees to draw up a legislative report.

- Whilst the part of the proposal relating to the hygiene of foodstuffs (for which ENVI is the committee responsible) is subject to the normal codecision procedure, the part of the proposal relating to transport does not even require Parliament to be consulted (although the Economic and Social Committee is required to be consulted). The fact that Parliament is nonetheless being consulted may be considered a voluntary consultation process without any influence on the legislative procedure.

- The Commission's intention in this legislative proposal is to confine the aspects dealt with to reducing administrative burdens, without reopening the two dossiers in terms of their basic principles.

- The Council has also decided to consider the two parts of the proposal separately.

- The ENVI Committee should follow the normal codecision procedure.

Substance

Necessity for rules exempting certain businesses from HACCP procedures

The putting in place, implementing and maintaining of a Hazard Analysis Critical Control Point (HACCP) system is essential. When considering the food hygiene package, Parliament was above all concerned to ensure the highest possible level of food safety and at the same time to establish a practicable and flexible control mechanism. The Regulation succeeded in doing this. It is not advisable to amend the Regulation at the current time:

- Policy at Community level, and in particular food law, must ensure a high level of protection of human life and health and of the interests of consumers. This objective would not be achieved if the HACCP procedure was completely abolished, as this instrument helps food business operators to achieve a higher standard of food safety.
− Experience has shown that these rules and procedures constitute a sound basis for ensuring food safety.

− General implementation of procedures based on HACCP principles has led to, and is continuing to lead to, greater responsibility on the part of food business operators.

− Clear, binding rules are needed in order to maintain and ensure confidence on the part of consumers, trading partners and other parties in the food sector.

− A level playing field in terms of competition and free movement of foodstuffs and feedingstuffs within the Community can only be ensured if food and feed safety requirements in individual Member States do not significantly differ from each other.

− Your rapporteur expressly supports the key concern in the Commission proposal to reduce red tape. However, particular criticism should be directed at the fact that, under the proposal, the high European level of food safety would be reduced on the basis of exclusively economic considerations. In the light of the stated intention of Regulation (EC) No 852/2004 that would be unacceptable.

− The Regulation in question only came into force on 1 January 2006. It has not yet been implemented in full in all of the Member States. It does not make sense to amend it at the present time. In addition, Regulation (EC) No 852/2004 provides for a review to be carried out in 2009. It would not be advisable to introduce amendments before the final results of the review have been published.

Dear Mr Chairman,

At its meeting of 19 December 2007 the Committee on Legal Affairs decided on its own initiative, pursuant to Rule 35(3), to consider whether the legal basis of the above Commission proposal was valid and appropriate.

The committee continued its consideration of the above question at its meeting of 14 January 2008.

Background


As appears from the title of the proposal, the Commission's intention was to propose a single regulation, based on Article 75(3), Article 95 and Article 152(4)(b) of the EC Treaty, which would amend Regulation No 11 concerning the abolition of discrimination in transport rates and conditions, based on what is now Article 75(3), and Regulation No 852/2004 on the hygiene of foodstuffs, based on Articles 95 and 152(4)(b) of the Treaty. That proposal was subject to the codecision procedure as provided for in Articles 95 and 152(4)(b).

However, given that Article 75(3) - on which Regulation No 11 is based - does not even provide for consultation of Parliament\(^1\) (although it appears that in practice the Council has

\(^1\) *Article 75*
Regularly consulted Parliament on instruments based on that provision, the Commission made the codecision procedure available for its amendments to Regulation No 11 as well as for the amendments to Regulation No 852/2004 by proposing one instrument amending both Regulation No 11 and Regulation No 852/2004.

On 5 July 2007, the Conference of Presidents authorised the Committee on the Environment and the Committee on Transport to draw up one report each on the basis of the Commission proposal.

On 13 December 2007, it appears that COREPER approved splitting the original "omnibus regulation" into two separate regulations.

On 19 December 2007, the Transport Committee adopted a report in which it separated out from the proposal for a regulation those parts amending Regulation 11 and changed the legal basis to Article 75(3) alone.

On 19 December 2007, the rapporteur for the Environment Committee presented a draft report, which purports to split off the proposal for a regulation amending Regulation No 852/2004 on the hygiene of foodstuffs and to base that regulation on Articles 95 and 152(4)(b) of the EC Treaty.

To summarise, the present position is that the Environment Committee is dealing with the part of the original proposal for a regulation which sought to amend Regulation No 852/2004 on the hygiene of foodstuffs as a separate proposal for a regulation. Likewise, the Transport Committee is dealing with the part of the original proposal for a regulation which sought to amend Regulation No 11 as a separate proposal for a regulation. If the procedure goes through in this way, the upshot will be two separate regulations, a food hygiene regulation adopted under the codecision procedure and a transport regulation adopted under a procedure not requiring even the consultation of Parliament.

As far as the proposal dealing with food hygiene is concerned, it appears to raise delicate political problems and the Environment Committee is in no hurry to vote. In contrast, the transport proposal falls under the heading of "fast track action" for which the European Council has called on Parliament to give the items concerned special priority with a view to their adoption as soon as possible in 2007. For this reason, the Transport Committee is not proposing any amendment to the provisions proposed by the Commission for Regulation No 11, has already adopted its report and is going to this plenary session.

The Commission is prepared to accept this approach.

1. In the case of transport within the Community, discrimination which takes the form of carriers charging different rates and imposing different conditions for the carriage of the same goods over the same transport links on grounds of the country of origin or of destination of the goods in question shall be abolished.
2. Paragraph 1 shall not prevent the Council from adopting other measures pursuant to Article 71(1).
3. The Council shall, acting by a qualified majority on a proposal from the Commission and after consulting the Economic and Social Committee, lay down rules for implementing the provisions of paragraph 1.
   The Council may in particular lay down the provisions needed to enable the institutions of the Community to secure compliance with the rule laid down in paragraph 1 and to ensure that users benefit from it to the full.
Legal basis

Given that what is involved is undoubtedly a change in the legal basis of the Commission's original proposal, the Legal Affairs Committee considered at its meeting of 19 December 2007 that it should take this question up on its own initiative pursuant to Rule 35(3) of the Rules of Procedure.

In view of the short amount of time which the committee and its rapporteur had had to consider this matter, at its meeting of 19 December 2007 the committee considered it advisable to postpone adopting its opinion on this question until it had had time to reflect and to seek the opinion of the Legal Service.

According to an opinion prepared by the Council's Legal Service:

"Following a further examination of the proposal by the Legal Service of the Council it appears that the different legal bases foresee different procedures for the handling of the proposal: the Article (75(3)) foresees a consultation of the European Parliament, whereas the Articles 152 (4)b and 95 imply a codecision procedure.

Due to these differences of the legal bases, it is necessary to split the proposal into two separate proposals, one covering transport rates and the other food hygiene."

Moreover, having regard to the fact that the original Regulation No 11 and subsequent amendments thereto were all based on what is now Article 75(3) of the EC Treaty and to the detailed opinion of Parliament's Legal Service, it is considered that the proper legal basis for the new regulation amending Regulation No 11 is Article 75(3).

As for the legal basis for the regulation amending Regulation No 852/2004 on the hygiene of foodstuffs (Articles 95 and 152(4)(b)), it is considered that this is acceptable, since Article 75(3) has no bearing on food hygiene.

Conclusion

At its meeting of 14 January 2008 the Committee on Legal Affairs accordingly decided, unanimously, to make the following recommendations to you:

(a) the legal basis for the proposal amending Regulation No 11 should be Article 75(3) of the EC Treaty, and

(b) the legal basis for the proposal amending Regulation No 852/2004 on the hygiene of foodstuffs should be Articles 152(4)(b) and 95 of the EC Treaty.

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1 In fact, Article 75(3) does not provide for consultation of Parliament. In practice, however, the Council does consult Parliament on measures proposed under this provision.

2 The following were present for the final vote: Giuseppe Gargani (chairman), Francesco Enrico Speroni (vice-chairman), Marie Panayotopoulo-Cassiotou (draftswoman), Giulietto Chiesa, Beniamino Donnici, Vicente Miguel García Ramón, Jean-Paul Gauzès, Klaus-Heiner Lehne, Katalin Lévai, Manuel Medina Ortega, Hartmut Nassauer, Aloyzas Sakalas, Jaroslav Zvěřina and Tadeusz Zwiefka.
Yours sincerely,

Giuseppe Gargani
## PROCEDURE

| Date submitted to Parliament | 6.3.2007 |
| Committee responsible | ENVII |
| Date announced in plenary | 9.7.2007 |
| Rapporteur(s) | Horst Schnellhardt |
| Date appointed | 3.5.2007 |
| Legal basis disputed | JURI |
| Date of JURI opinion | 14.1.2008 |
| Discussed in committee | 22.1.2008 |
| Date adopted | 2.4.2008 |
| Result of final vote | +: 36 –: 13 0: 2 |
| Substitute(s) present for the final vote | Iles Braghetto, Antonio De Blasio, Christofer Fjellner, Johannes Lebech, Kartika Tamara Liotard, Miroslav Mikolášik, Bart Staes, Andres Tarand, Lambert van Nistelrooij |
Summary of informal trilogue on HACCP (COM/2007/90)

Recital 15 a(new):

*It is important that the competent authorities apply the flexibility provided for in this Regulation, especially in Article 5 (2(g)) and Article 5 (5); in particular for businesses 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 enterprises.*

Article 5(2) EC 852/2004)

Hazard analysis and critical control points

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).
(new) Without prejudice to the other requirements of this Regulation, the measures outlined in Article 5 (2) subparagraphs (b) to (f) shall not apply to food business operators which demonstrate to the competent authority that there are no hazards that must be prevented, eliminated or reduced to acceptable levels, or that identified hazards are sufficiently and regularly controlled through the implementation of general and specified food hygiene requirements laid down in Article 4 para 2-6.

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.