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FINAL **A5-0416/2001** 

22 November 2001

# \*\*\*II RECOMMENDATION FOR SECOND READING

on the Council common position for adopting a European Parliament and Council regulation laying down the general principles and requirements of food law, establishing the European Food Authority and laying down procedures in matters of food safety

(10880/1/2001 - C5-0414/2001 - 2000/0286(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Phillip Whitehead

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#### 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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#### PROCEDURAL PAGE

At the sitting of 12 June 2001 Parliament adopted its position at first reading on the proposal for a European Parliament and Council regulation laying down the general principles and requirements of food law, establishing the European Food Authority and laying down procedures in matters of food safety (COM(2000) 716 - 2000/0286 (COD)).

At the sitting of 19 September 2001 the President of Parliament announced that the common position had been received and referred to the Committee on the Environment, Public Health and Consumer Policy (10880/1/2001 - C5-0414/2001).

The committee had appointed Phillip Whitehead rapporteur at its meeting of 9 January 2001.

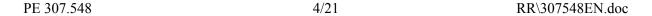
It considered the common position and draft recommendation for second reading at its meetings of 15 October and 21 November 2001.

At the last meeting it adopted the draft legislative resolution by 40 votes to 1.

The following were present for the vote: Caroline F. Jackson, chairman; Guido Sacconi, Alexander de Roo and Ria G.H.C. Oomen-Ruijten, vice-chairmen; Phillip Whitehead, rapporteur; Per-Arne Arvidsson, María del Pilar Ayuso González, Hans Blokland, David Robert Bowe, John Bowis, Philip Bushill-Matthews (for Peter Liese), Martin Callanan, Dorette Corbey, Avril Doyle, Anne Ferreira, Marialiese Flemming, Karl-Heinz Florenz, Robert Goodwill, Françoise Grossetête, Cristina Gutiérrez Cortines, Mary Honeyball (for Anneli Hulthén), Christa Klaß, Eija-Riitta Anneli Korhola, Wolfgang Kreissl-Dörfler (for Béatrice Patrie), Paul A.A.J.G. Lannoye (for Hiltrud Breyer), Giorgio Lisi (for Cristina García-Orcoyen Tormo), Jules Maaten, Jorge Moreira da Silva, Emilia Franziska Müller, Riitta Myller, Giuseppe Nisticò, Marit Paulsen, Dagmar Roth-Behrendt, Giacomo Santini, Karin Scheele, Ursula Schleicher (for Antonios Trakatellis), Horst Schnellhardt, Inger Schörling, María Sornosa Martínez, Bart Staes (for Marie Anne Isler Béguin), Catherine Stihler, Nicole Thomas-Mauro.

The recommendation for second reading was tabled on 22 November 2001.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.





# **DRAFT LEGISLATIVE RESOLUTION**

European Parliament legislative resolution on the Council common position for adopting a European Parliament and Council regulation laying down the general principles and requirements of food law, establishing the European Food Authority and laying down procedures in matters of food safety (10880/1/2001– C5-0414/2001 – 2000/0286(COD))

#### (Codecision procedure: second reading)

The European Parliament,

- having regard to the Council common position (10880/1/2001– C5-0414/2001),
- having regard to its position at first reading<sup>1</sup> on the Commission proposal to Parliament and the Council (COM(2000) 716<sup>2</sup>),
- having regard to the amendments to the Commission proposal (COM(2001) 475<sup>3</sup>),
- having regard to Article 251(2) of the EC Treaty,
- having regard to Rule 80 of its Rules of Procedure,
- having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0416/2001),
- 1. Amends the common position as follows;
- 2. Instructs its President to forward its position to the Council and Commission.

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<sup>&</sup>lt;sup>1</sup> OJ not yet published

<sup>&</sup>lt;sup>2</sup> OJ C 96, 27.03.2001, p.247.

<sup>&</sup>lt;sup>3</sup> OJ not yet published

# Amendment 1 Title

Proposal for a regulation of the European Parliament and of the Council regulation laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food safety

Proposal for a European Parliament and Council regulation laying down the general principles and requirements of food law, establishing the European Food *Safety* Authority, and laying down procedures in matters of food safety

#### Justification

This reiterates the position adopted in the European Parliament's First Reading (Amendment 1), and on the resolution on the Commission's White Paper on Food Safety (A5-0272/2000, on 25 October 2000). Food safety should be the Authority's primary concern.

# Amendment 2 Recital 14a (new)

14a. In order to play an efficacious prevention role on potential health risks for citizens, Member States are recommended to activate and coordinate a network of excellence laboratories, localised at regional and/or interregional level, with the aim to proceed to a continuous monitoring of food safety.

#### Justification

# Amendment 3 Article 1

- 1. This Regulation provides the basis for the assurance of a high level of protection of human *life and* health and consumer's interest in relation to food, whilst ensuring the effective functioning of the internal
- 1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, whilst ensuring the effective functioning of the internal market *geared*

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market. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food *and feed* safety.

towards diversity in the supply of food, without therefore penalising typical or traditional products. It establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food safety.

#### Justification

The expression 'protection of human life' may lead to misunderstandings and is already included in the expression 'protection of human health'. It must also be emphasised that the internal market must be made to work effectively and at the same time a European food model must be developed which is based on diversity and safety and which does not therefore penalise typical or traditional products, as is often the case. Food safety is the major objective of the new authority and of European food law.

# Amendment 4 Article 5, paragraph 3a (new)

3a. Ensure that consistency between International Standards and EU food legislation is effectively achieved; so long as this would not result in reducing existing EU standards:

# Justification

To reinstate text agreed by the Parliament at the first reading (amendment 84).

# Amendment 5 Article 6, paragraph 3

- 3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the precautionary principle where the
- 3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration, in particular those relevant for the health protection of consumers and for the

conditions laid down in Article 7(1) are relevant.

*protection of fair trade,* and the precautionary principle where the conditions laid down in Article 7(1) are relevant.

#### Justification

This wording is modelled on Codex Alimentarius principles, already adopted, concerning other legitimate factors and accordingly has been proposed in line with the obligation to comply with international standards.

# Amendment 6 Article 7, paragraph 1

- 1. In circumstances where, following an assessment of available information, *the possibility of harmful effects on* health *has been* identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.
- 1. In *specific* circumstances where, following an assessment of available *pertinent* information, *a risk to* health *is* identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

#### Justification

This will ensure that European standards are complied with and distortions of competition prevented.

# Amendment 7 Article 9

There shall be public consultation, directly or through representative bodies, *at an appropriate stage*, during the preparation of food law, except where the urgency of the matter does not allow it.

There shall be *open and transparent* public consultation, directly or through representative bodies, during the preparation, *evaluation and revision* of food law, except where the urgency of the matter does not allow it.

This reflects Amendment 207 from the Parliament's First Reading. Such consultation should be open and transparent and, is important at all stages of policy.

# Amendment 8 Article 12 (1), subparagraph 1

- 1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.
- 1. Food and feed exported or re-exported from the Community for placing on the market of a third country shall comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country.

This shall not apply to food exported from the Community to be returned to the supplier, which, to that extent, shall not be subject to any constraints.

#### Justification

Export for the purpose of return to the supplier must be permissible without any further formalities. In particular, re-export should not be made dependent on the agreement of the exporting country, since it has as little interest as the exporter concerned in taking back the goods.

# Amendment 9 Article 15 (3)

- 3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or
- 3. Where a feed which has been identified as not satisfying the feed safety requirement is part of a batch, lot or consignment of feed of the same class or description, it shall be presumed that all of the feed in that batch, lot or consignment is so affected, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment fails to satisfy the feed safety

consignment fails to satisfy the feed safety requirement.

requirement. That batch, lot or consignment shall be destroyed, unless the relevant control authority states the reasons for its continued use.

#### Justification

Re-tabling of Amendment 68 from 1st reading (modified) but allowing for instances whereby a particular feed may be used for other purposes.

# Amendment 10 Article 19 (1)

- 1. If a food operator considers or *suspects* that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market and inform the competent authorities thereof.
- 1. If a food operator considers or *has reason to believe* that a food which it has imported, produced, processed, manufactured or distributed is not in compliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market *where the food has left the immediate control of that initial food business operator* and inform the competent authorities thereof.

# Justification

The change of terminology to "has reason to believe" is to avoid doubt in the intention of the legislation. Legal advice received since the first reading suggests there is a problem of interpretation where the food business operator continues to have an item under his direct control. The requirement to inform the competent authorities should only apply when there is an actual or suspected risk to health from an item placed on the market.

# Amendment 11 Article 19 (3)

- 3. A food business operator shall immediately inform the competent authorities if it *considers or suspects* that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the
- 3. A food business operator shall immediately inform the competent authorities if it *knows or ought to know, on the basis of the information in its possession and as a professional* that a food which it has placed on the market may be

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action taken to prevent risks to the final consumer.

injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall, in conformity with national law and legal practice, not prevent or discourage any person from cooperating with the competent authorities, where this may prevent, reduce or avoid a risk arising from a food.

#### Justification

This amendment takes account of the new legal situation arising from the agreement of the General Product Safety Directive by the Conciliation Committee. The aim is to eradicate all inconsistencies between article 19 of the proposal for a regulation on general food law and the general product safety directive regarding distributors' responsibilities and the precautionary principle.

Last paragraph reflects Amendment 70 of the Parliament's First Reading. This is an important principle which must be enshrined to ensure that lessons are learnt from previous food and feed safety crises.

# Amendment 12 Article 20 (3)

3. A feed business operator shall immediately inform the competent authorities if it considers or suspects that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed.

3. A feed business operator shall immediately inform the competent authorities if it considers or suspects that a feed which it placed on the market may not satisfy the feed safety requirements. It shall inform the competent authorities of the action taken to prevent risk arising from the use of that feed and shall, in conformity with national law and legal practice, not prevent or discourage any person from cooperating with the competent authorities, where this may prevent, reduce or avoid a risk arising from a feed.

Justification

See justification to amendment to Article 19 (3).

# Amendment 13 Article 22 (8)

- 8. The Authority, Commission and Member States shall cooperate to promote the *necessary* coherence between risk assessment, risk management and risk communication functions.
- 8. The Authority, Commission and Member States shall cooperate to promote the *effective* coherence between risk assessment, risk management and risk communication functions.

#### Justification

The Council text recognises the interactive and complementary nature of the risk analysis procedure, as outlined in the Parliament's First Reading amendments. However this new text needs to be strengthened to ensure that all elements of the process work together effectively.

# Amendment 14 Article 23 (c)

- (c) to provide scientific and technical support to the Commission in the areas within its mission;
- (c) to provide scientific and technical support to the Commission in the areas within its mission and when so requested, in the interpretation and consideration of risk assessment opinions;

#### Justification

This reflects the spirit of Amendments 92 & 98 from the Parliament's First Reading.

# Amendment 15 Article 25 (1)

- 1. The Management Board shall be composed of *16 members* appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission which includes a number of
- 1. The Management Board shall be composed of *12 members* appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission which includes a number of

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candidates substantially higher than the number of members to be appointed, and a representative from the Commission. A quarter of the members shall have their background in organisations representing consumers and other interests in the food chain

The members of the Board shall be appointed in such a way as to secure the highest standards of competence, a broad range of relevant expertise and *the broadest possible* geographic distribution within the Union.

candidates substantially higher than the number of members to be appointed, and a representative from the Commission. A quarter of the members shall have their background in organisations representing consumers and other interests in the food chain

The members of the Board shall be appointed in such a way as to secure the highest standards of competence, a broad range of relevant expertise and *a very wide* geographic distribution within the Union.

All appointments shall be made on merit based criteria and be subject to a confirmatory hearing by the European Parliament.

## Justification

The number of members of the Management Board, with the addition of a Commission representative, should otherwise remain consistent with the Parliament's First Reading amendments and resolution on the Commission's White Paper on Food Safety (A5-0272/2000, on 25 October 2000). An appointments procedure based on openness and meritocracy is of the utmost importance and should therefore also be reinstated. The Board should be given added democratic accountability through the use of a confirmatory hearing by the European Parliament.

Whilst recognising that the EFSA management board should draw on expertise from all EU Member States, it should be made clear to existing and future Member States that they do not have an automatic right to representation on the Board.

# Amendment 16 Article 25 (2)

- 2. Members' term of office shall be four years. However, for the first mandate, this period shall be six years for half of the members.
- Members may be represented by alternates, appointed at the same time.
- 2. Members' term of office shall be four years, *and may be renewed once*. However, for the first mandate, this period shall be six years for half of the members.

Any Board member should be firmly committed to his/her position and that of the Authority's mission necessitating a full attendance at Board meetings. Amendment 102 from the Parliament's First Reading is therefore re-tabled. Of course, there may be occasions, for example due to illness, when a Board member is unable to participate in a meeting.

# Amendment 17 Article 25 (10)

- 10. The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat.
- 10. The Executive Director shall take part in the meetings of the Management Board, without voting rights, and shall provide the Secretariat. The Management Board shall invite the chairperson of the Scientific Committee to attend its meetings.

#### Justification

This reflects Amendment 106 from the Parliament's First Reading.

# Amendment 18 Article 26 (1)

- 1. The Executive Director shall be appointed by the Management Board, on the basis of a list of candidates proposed by the Commission after an open competition, following publication in the Official Journal of the European Communities and elsewhere of a call for expressions of interest, for a period of five years which shall be renewable. He may be removed from office by the Management Board.
- 1. The Executive Director shall be appointed by the Management Board, on the basis of a list of candidates proposed by the Commission after an open competition, following publication in the Official Journal of the European Communities and elsewhere of a call for expressions of interest, and after a hearing of the short listed candidates in the European Parliament, for a period of five years which shall be renewable. He may be removed from office by a majority of the Management Board.

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Not all of the key changes from the Parliament's Amendment 107 to Article 26 (1) were adopted by the Council. These key elements should therefore be reinstated.

# Amendment 19 Article 27 (5)

- 5. The Advisory Forum shall be chaired by the Executive Director, *who shall convene its meetings*. Its operational procedures shall be specified in the Authority's internal rules and shall be made public.
- 5. The Advisory Forum shall be chaired by the Executive Director. It shall meet regularly at the Chairperson's invitation or at the request of at least a third of its members, and not less than four times per year. Its operational procedures shall be specified in the Authority's internal rules and shall be made public.

# Justification

This reiterates Amendment 113 from the Parliament's First Reading with an acknowledgement of the view of the Commission, that the Advisory Forum should meet at a minimum of four times per year.

# Amendment 20 Article 38 (2)

- 2. The Management Board, acting on a proposal from the Executive Director, *may decide to hold some of its meetings* in public and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.
- 2. The Management Board, acting on a proposal from the Executive Director, *shall hold its meetings* in public and may authorise consumer representatives or other interested parties to observe the proceedings of some of the Authority's activities.

Re-tabling of Amendment 143 from the Parliament's First Reading.

# Amendment 21 Article 40 (3)

- 3. The Authority shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk-communication process.
- 3. The Authority shall act in close collaboration with the Commission and the Member States to promote the necessary coherence in the risk-communication process.

The Authority shall publish all opinions issued by it in accordance with Article 38.

# Justification

Re-tabling of Amendment 14 (modified).

# Amendment 22 Article 43 (1)

- 1. The revenues of the Authority shall consist of a contribution from the Community and, in addition, any fees received by the Authority in payment for the services it provides.
- 1. The revenues of the Authority shall consist of:

a contribution from the Community and from any other State with which the Community has concluded agreements referred to in Article 49 and

charges for publications, conferences, training and any other similar activities provided by the Authority.

# Justification

To take account of the fact that third countries which have concluded agreements with the EC must be able to make financial contributions to EFSA's budget should they so wish. This is consistent with Article 49 of the Common Position. Equally, whilst the EFSA shall not be a fee raising body at this stage, it should be given the opportunity to charge for publications it

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# Amendment 23 Article 43 (5)

5. By 31 March each year at the latest, the Management Board shall adopt the draft estimates including the provisional list of posts accompanied by the preliminary work programme and forward it to the Commission, which on that basis shall enter the relevant estimates in the preliminary draft general budget of the European Union to be put before the Council pursuant to Article 272 of the Treaty.

5. By 31 March each year at the latest, the Management Board shall adopt the draft estimates including the provisional list of posts accompanied by the preliminary work programme and forward it to the Commission and the States with which the Community has concluded the agreements referred to in Article 49. On the basis of that draft budget, the Commission shall enter the relevant estimates in the preliminary draft budget of the European Union to be put before the Council pursuant to Article 272 of the Treaty..

## Justification

This amendment takes account of the fact that third countries which have concluded agreements with the EC must be able to make financial contributions to EFSA's budget should they so wish. This is consistent with Article 49 of the Common Position.

#### Amendment 24 Article 45

Within three years following the date of entry into force of this Regulation and after consulting the Authority, the Member States and the interested parties, the Commission shall publish a report on the feasibility and advisability of *introducing fees payable by undertakings in connection with obtaining a Community authorisation and* for other services provided by the Authority.

Within three years from the date of entry into force of this Regulation, the Commission shall publish, after consulting the Authority, the Member States and the interested parties, a report on the feasibility and advisability of presenting a legislative proposal under the co-decision procedure and in accordance with the Treaty for other services provided by the Authority.

#### Justification

For reasons of consistency with Amendments to Article 43, paragraphs 1 and 5.

# Amendment 25 Article 51

The measures for implementing Article 50 shall be adopted by the Commission, after *consulting* the Authority, in accordance with the procedure referred to in Article 58(2). These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information.

The measures for implementing Article 50 shall be adopted by the Commission, after *discussion with* the Authority, in accordance with the procedure referred to in Article 58(2). These measures shall specify, in particular, the specific conditions and procedures applicable to the transmission of notifications and supplementary information *and the specific rules applicable to information transmitted by business operators. Ultimate responsibility shall rest with the Commission.* 

#### Justification

Retabling of amendment adopted at first reading. It is essential to spell out unequivocally that, in this respect, the Commission is responsible.

# Amendment 26 Article 53 (1) (a) (i)

- (i) suspension of the placing on the market of the food in question;
- (i) suspension of the placing on the market *or use* of the food in question;

#### Justification

This reflects Parliament's First Reading Amendment 178 on the issue of food aid.

# Amendment 27 Article 53 (2) 2

As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred

As soon as possible, and at most within 10 working days, the measures taken shall be confirmed, amended, revoked or extended in accordance with the procedure referred

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to in Article 58(2).

to in Article 58(2), and the reasons for the Commission's decision shall be made public immediately.

#### Justification

Re-tabling of Amendment 179 from the Parliament's First Reading.

Amendment 28 Article 63 a (new)

> The seat of the Authority shall be decided by the Council, after consulting the Commission and the European Parliament. It shall be, and be seen physically to be, independent of the Commission and other institutions.

> The location of the Authority should meet the following criteria:

it should have a long standing tradition in food safety in order to lend credibility to the Authority in the eyes of EU citizens;

it should enhance the Authority's independence and integrity

it should provide a good scientific infrastructure and facilities in the field of food safety

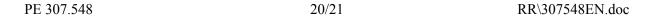
It should be easily accessible in terms of communications and have good and rapid transport connections;

It should enable the Authority to work closely and efficiently with those Commission services which deal with public health and consumer protection issues;

It should be cost-effective and enable the Authority to start its work immediately;



Re-tabling of Amendment 188 from Parliament's First Reading.



#### **EXPLANATORY STATEMENT**

Out of the 189 amendments adopted by the European Parliament at its First Reading in June 2001, a large number have been included in the Council's Common Position.

The Commission and the Council are still intent upon an early 2002 start date for the new Authority. Your rapporteur emphatically supports this. Therefore, time is of the essence. However, as co-legislator the Parliament's scrutiny of this second reading text must be no less thorough. We accept that the Council's Common Position builds positively on the Commission's original proposal by incorporating a number of the Parliament's first reading objectives. For instance, the principles of transparency and openness both in the creation and workings of EFSA have been improved upon, and the Commission, not the Authority, is now placed in charge of operating the Rapid Alert System. On food law, a number of the Parliament's definitions have also been incorporated.

Parliament must be true to the deep-rooted support achieved at First Reading, in anticipation of the more formal discussions ahead. The strength of that renewed position, endorsed by a Second Reading majority will allow the European Parliament to play its full role in the introduction of the EFSA (as my first amendment reasserts it should be called).

Nevertheless, the Council's text cannot be accepted without amendments. With this in mind your rapporteur recommends to the committee the following 19 key amendments for second reading, supported by a number of shadow rapporteurs across the political spectrum, who also deserve the thanks of their colleagues for this united stand.

