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## **REPORT**

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from: Committee of Permanent Representatives

on: 24 June 2002

to: Council

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Subject: Proposal for a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs

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### **I. INTRODUCTION**

The Commission proposed the above-mentioned Regulation in July 2000 as part of a package of five proposals with the aim of consolidating, updating and simplifying Community legislation on food hygiene. The Regulation would lay down general hygiene rules for all foodstuffs and all food business operators.

The European Parliament adopted its opinion at first reading on 15 May 2002 (doc. 8868/02).

The Economic and Social Committee adopted an opinion in March 2001, endorsing the Commission's proposals.

The Committee of Permanent Representatives discussed a report from the Working Party of Veterinary Experts (Public Health) (doc. 10122/02) at its meeting on 24 June 2002.

This report summarises the outcome of those discussions. **Annex A** contains the Presidency's compromise suggestions on five key issues.<sup>1</sup> Coreper reached consensus on two of them. This report discusses the three remaining outstanding points.<sup>2</sup>

**Annex B** contains a summary of areas in which all delegations and the representative of the Commission have agreed on modifications to the Commission's proposal (either unreservedly or as part of the global compromise package).

## II. KEY OUTSTANDING ISSUES

### A. Scope (Article 1)

The European Parliament has proposed to **restrict the scope** of the Regulation compared to the Commission's original proposal. Its amendment 103 would exclude from the scope of the Regulation the direct supply of small quantities of primary products to the final consumer or to local shops or restaurants.

Fourteen delegations and the representative of the Commission **can accept** the Presidency's revised **compromise** solution contained in Annex A. This would be consistent with the European Parliament's amendment.

One delegation has a **reservation**, preferring Community rules to apply at all stages of the food chain.

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<sup>1</sup> The suggested modifications relate to the draft Regulation as it appears in document 9240/1/02 REV 1. Document 9240/2/02 REV 2 incorporates these amendments and some additional technical amendments agreed within the Working Party.

<sup>2</sup> One delegation has a Parliamentary scrutiny reservation.

B. HACCP and primary production (Articles 5 & 16)

The Commission originally proposed that the requirement to establish procedures based on the HACCP<sup>1</sup> principles should apply to all food business operators except for those at the level of primary production.

The European Parliament has proposed (amendments 35 and 38) to **extend** the requirement to primary producers, but only in respect of five of the seven principles. It has also proposed that the Commission's report on the implementation of the Regulation address compliance with the requirement.

The Presidency had suggested the following **compromise**:

- no Community-wide requirement on HACCP at the level of primary production;
- consideration through the Commission's report of whether it would be desirable and practicable to extend the requirement to primary production; and
- the option for Member States to establish requirements under national law for domestic producers.

However, in view of the concerns expressed by several delegations and the representative of the Commission, the Presidency has modified its compromise suggestion. Article 5(3) would no longer make explicit provision for the adoption of national requirements. However, Article 16(2) would still require the Commission to review and to report on the possibility of extending the HACCP requirements to primary production.

Fourteen delegations **can accept** this approach, while one delegation has a **reservation** concerning Article 5(3). The inclusion of an explicit provision enabling the adoption of national HACCP requirements is a precondition for its support for the draft Regulation.

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<sup>1</sup> Hazard Analysis and Critical Control Points.

C. Approval of establishments (Article 6)

The Commission, the European Parliament (amendment 51) and a large majority of delegations agree that the Regulation should not require the approval of establishments. Rather, it should make clear that approval may be required under national law, under the Regulation laying down specific hygiene rules for food of animal origin, or through the comitology procedure.

Delegations and the representative of the Commission have further agreed that any Member State with national approval requirements must inform the Commission and other Member States.

One delegation has a **reservation** on this approach, preferring harmonised rules.

The representative of the Council legal service advised that the drafting of Article 6(3)(a) would not enable Member States to use national rules on the approval of establishments to create barriers to trade. The representative of the Commission confirmed that his Institution shared this view.

### III. CONCLUSION

The Committee of Permanent Representatives suggests that the Agriculture Council reach political agreement on the proposed Regulation on the basis of the Presidency's compromise suggestions set out in Annex A.

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As regards Annex II to the proposed Regulation, the Working Party did not resolve some technical issues. However, it noted that there was no objection to the use of the comitology procedure to adopt technical amendments to the Annexes after adoption of the Regulation.

**PRESIDENCY SUGGESTIONS FOR A GLOBAL COMPROMISE PACKAGE**

**1. Date of adoption of the common position**

The Council should include the following declaration in the minutes of its meeting.

“The Council takes note of the fact that the conditions exist to allow political agreement on the proposed Regulation on the hygiene of foodstuffs. However, the Council will not formally adopt a common position until discussions on other parts of the package of proposals have advanced sufficiently to ensure consistency between the elements of the package and their implementation dates.”

**2. Scope of application**

Article 1(2) and (3) should read as follows.

“2. This Regulation shall not apply to:

- (a) primary production for private domestic use;
- (b) the domestic preparation, handling or storage of food for private domestic consumption;
- (c) **the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer.**

3. Member States **shall** establish, under national law, rules **governing the activities referred to in paragraph 2(c)**. Such national rules shall ensure the achievement of the objectives of this Regulation.”

In addition, some consequential amendments should be made. In Annex I, paragraph 1(d) of Part A.I should be deleted and the rules on record keeping clarified. Recital 13 should be amended as follows.

“Food hazards present at the level of primary production must be identified and adequately controlled to ensure the achievement of the objectives of this Regulation. However, in the case of the direct supply of small quantities of primary products, by the food business operator producing them, to the final consumer or to a local retail establishment, it is appropriate to protect public health through national law, in particular because of the close relationship between the producer and the consumer. [...]”

### 3. Flexibility

Article 13(4) should read as follows.

“4. The national measures referred to in paragraph 3 shall:

- (a) have the aim of enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food; or
- (b) have the aim of accommodating the needs of food businesses situated in regions suffering from special geographical constraints; or
- (c) in other circumstances, concern only the construction, layout and equipment of establishments.”

In addition, a new recital 20a should be added.

“Flexibility is particularly important for regions suffering from special geographical constraints, including the outermost regions referred to in Article 299(2) of the Treaty.”

#### 4. HACCP and primary production

The second sentence of Article 5(3) should be deleted and recital 14 amended as follows.

“The [...] application of HACCP principles to primary production is not *yet generally* feasible. However, [...] guides to good practice should encourage the use of appropriate hygiene practices at farm level. Where necessary, specific hygiene rules for primary production should supplement these guides. It is appropriate for the hygiene requirements applicable to primary production and associated operations to differ from those for other operations.”

In addition, the square brackets should be deleted from Article 16(2) and a minor modification made, so that the provision reads as follows.

“2. The report shall in particular review the experience gained from the implementation of this Regulation and consider whether it would be desirable and practicable to *provide for the extension of* the requirements of Article 5 to food business operators carrying out primary production and those associated operations listed in Annex I.”

#### 5. Approval of establishments

A new subparagraph should be added at the end of Article 6(3).

“Any Member State requiring the approval of certain establishments located on its territory under national law, as provided for in subparagraph (a), shall inform the Commission and other Member States of the relevant national rules.”

SUMMARY OF AGREED CHANGES TO THE DRAFT REGULATION

Technical amendments

Discussions have resulted in agreement on many technical amendments to clarify the proposed Regulation. In several cases, these amendments have the same objective as amendments that the European Parliament has proposed.

Many of these amendments seek to ensure an appropriate division between the content of the Regulation and that of other Community legislation, in particular by:

- ensuring that the wording of the Regulation is consistent with the general principles and definitions laid down in Regulation (EC) No 178/2002<sup>1</sup>;
- incorporating some general principles and definitions relevant to all food that previously appeared in the proposed Regulation laying down specific hygiene rules for food of animal origin; and
- avoiding overlap with the forthcoming Commission proposals on official controls.

Substantial amendments

On points of substance, the Delegations and the representative of the Commission have agreed on the following principles:

- The Regulation should have a wide **scope of application**, but its provisions should be sufficiently flexible to be suitable for all types of food businesses.

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<sup>1</sup> Regulation of the European Parliament and of the Council of 28 January 2002 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.

- The scope for altering food business operators' duties through the **comitology** procedure must not be open-ended. The European Parliament has opposed the use of the comitology procedure to amend the Annexes or to grant exemptions. The text that delegations and the representative of the Commission have agreed retains these possibilities but lays down criteria for the amendment of the Annexes.
  
- Delegations and the Commission do not share the European Parliament's view that the Regulation's requirement to establish procedures based on the principles of **HACCP** should apply to primary production. They agree, however, that consideration of the feasibility of the extension of the requirement would be one element of the review that the Commission would carry out following implementation of the Regulation.
  
- The HACCP requirements should be sufficiently flexible for **small businesses** (in particular, by providing for the use of procedures set out in guides to the application of HACCP principles).
  
- **Flexibility** is appropriate: (a) to enable the continued use of traditional methods at any of the stages of production, processing or distribution of food; (b) to accommodate the needs of food businesses situated in regions suffering from special geographical constraints; and (c) in other circumstances, in relation to the structural requirements for establishments. However, such flexibility must not compromise food hygiene objectives. Moreover, since all food produced in accordance with the hygiene rules will be in free circulation throughout the Community, the procedure allowing Member States to exercise flexibility must be fully transparent. It should provide for discussion within the Standing Committee on the Food Chain and Animal Health where necessary to resolve disagreements. This approach is consistent with amendments that the European Parliament has proposed.