



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 19 September 2003**

---

**Interinstitutional File:  
2000/0178 (COD)**

---

**10543/1/02  
REV 1 ADD 1**

**AGRILEG 143  
DENLEG 42  
CODEC 848**

**DRAFT STATEMENT OF THE COUNCIL'S REASONS**

Subject: Common position adopted by the Council with a view to the adoption of a Regulation of the European Parliament and of the Council on the hygiene of foodstuffs

---

**DRAFT STATEMENT OF THE COUNCIL'S REASONS**

## I. INTRODUCTION

The Commission proposed a Regulation on the hygiene of foodstuffs in July 2000.

The European Parliament adopted an opinion on the proposed Regulation in May 2002.

The Economic and Social Committee adopted an opinion in March 2001.<sup>1</sup>

After considering these opinions, the Council adopted a common position on [...] 2003.

## II. OBJECTIVE

The proposed Regulation is the first element of a package of five proposals with the aim of consolidating, updating and simplifying Community legislation on food hygiene while ensuring a high level of protection of public health. The Council simultaneously adopted common positions on all of the four proposals subject to the co-decision procedure.<sup>2</sup>

The Regulation would lay down general hygiene rules for all foodstuffs and all food business operators. In particular, it would:

- make clear that food business operators bear the primary responsibility for food safety;
- lay down hygiene rules for all stages of the food chain, from primary production to retail;
- require food business operators to notify competent authorities of their establishments, with a view to their registration;
- widen existing requirements concerning hazard analysis and critical control points (HACCP);
- provide flexibility for special cases.

---

<sup>1</sup> The Committee of the Regions decided not to provide an opinion.

<sup>2</sup> In December 2002, the Council adopted Directive 2002/99/EC laying down animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption, on the basis of the Commission's fourth proposal.

### III. ANALYSIS OF THE COMMON POSITION

#### A. Generalities

The common position incorporates several changes compared to the Commission's original proposal, many of which are consistent with the amendments that the European Parliament proposed in its first-reading opinion. The Commission has accepted these changes to its proposal.

In addition to the more substantive modifications described below, the common position contains a number of editorial changes, in particular:

- to ensure consistency with Regulation (EC) No 178/2002<sup>1</sup>;
- to ensure the overall coherence of the hygiene package<sup>2</sup>;
- to ensure the internal coherence of the Regulation<sup>3</sup>; and
- to clarify the text<sup>4</sup>.

It also contains a number of minor technical amendments consistent with the overall objectives of the Regulation stated in Section II above.<sup>5</sup>

---

<sup>1</sup> These include changes consistent with the aims of EP amendments 1, 11, 12, 14, 15, 17 to 24, 27, 50, 54, 56, 57, 61 and 107.

<sup>2</sup> This consideration prevented incorporation of EP amendment 108, which deals with official controls. However, provisions with the same aim appear in the common position on the third Regulation.

<sup>3</sup> These include changes consistent with the aims of EP amendments 9 and 60. However, this consideration prevented the incorporation of amendment 10, which would have created an inconsistency between the recitals and the Articles.

<sup>4</sup> These include changes consistent with the aims of EP amendments 2 to 7, 16, 25, 26, 40 to 46, 49, 51, 52, 64, 65, 67, 69 to 75, 78 and 106, and partially consistent with amendments 39 and 47.

<sup>5</sup> These include changes consistent with the aims of EP amendments 68, 79, 80 to 88, 90, 91, 94, 96, 99, 100 and 102.

B. Scope (Article 1)

The Council agrees that it is not appropriate for Community legislation to lay down hygiene rules for the **direct supply of small quantities of primary products** to the final consumer and local retail establishments. However, the common position makes clear that:

- direct supply means supply by the primary producer;
- direct supply to local retail establishments covers only shops and restaurants (and not wholesale or processing operations); and
- Member States must establish national rules for such direct supply that ensure the same level of food safety as the Regulation.<sup>1</sup>

It also contains an exemption for collection centres and tanneries that carry out no operations related to food production other than the storage of raw material for the production of **collagen or gelatine**. The Regulation laying down specific hygiene rules for food of animal origin contains appropriate rules for such establishments.

C. HACCP (Articles 5 & 16)

The Council does not believe that it would be practicable, in the short term, to apply the principles of hazard analysis and critical control points (HACCP) to **primary production**. It agrees, however, that the Commission should review this issue and report on its conclusions within five years of entry into force of the Regulation, as part of its report on the implementation of the Regulation. The Council also agrees that HACCP requirements for other food business operators need to be flexible, so as to be practicable for all types of establishments.<sup>2</sup>

---

<sup>1</sup> The common position is therefore consistent with the aim of EP amendment 103.

<sup>2</sup> The common position is therefore consistent with EP amendment 62 and with part of amendments 36 and 38, but is not consistent with amendment 8, 35 or 37.

In particular, the Council agrees that it should be possible in certain establishments to use procedures contained in **guides** rather than carrying out a full application of HACCP principles. To ensure that this possibility does not undermine food safety objectives, however, it is appropriate to regulate the use of guides through comitology.

D. Comitology (Articles 4 & 13)

The Council agrees that it would not be appropriate for Article 4 to impose a duty on food business operators to comply with the provisions of Annexes that could be added to the Regulation through comitology. It does not accept, however, that there should be no scope for granting exemptions or for amending the existing Annexes through comitology. The common position maintains this possibility, but contains criteria specifying the circumstances in which the Annexes could be amended.<sup>1</sup>

E. Guides (Articles 7 – 9)

The Council agrees that it is desirable to emphasise that all stakeholders should be involved in the development of guides to good practice for food hygiene or for the application of the HACCP principles. It also accepts the need for regular reviews of Community guides. However, since food business operators would use guides on a voluntary basis, it does not agree that it would be appropriate to establish a hierarchy between Community and national guides.<sup>2</sup>

---

<sup>1</sup> The common position is therefore consistent with EP amendments 28 and 29, but is not consistent with amendments 30, 58 or 59.

<sup>2</sup> The common position is therefore consistent with the aim of EP amendments 40 to 46 and with part of amendment 47, but is not consistent with amendment 48.

F. Flexibility (Article 13)

The Council agrees that there should be flexibility for Member States to adopt national measures adapting the detailed requirements laid down in Annex II, if this does not compromise the objectives of the Regulation. It also agrees that it is appropriate to enhance the transparency of the procedure through which Member States would exercise this flexibility, to ensure that all envisaged measures undergo a proper review. However, the Council does not believe that it is appropriate to extend the procedure to Annex I, which sets general objectives rather than laying down detailed requirements.<sup>1</sup>

G. Date of application (Article 18)

The Council agrees that the scale of the reform of food hygiene legislation requires there to be a reasonable delay between adoption of the new rules and their application.<sup>2</sup> It is also necessary to ensure that all elements of the hygiene package take effect at the same time.

The common position therefore provides for the Regulation to apply eighteen months after the date on which all elements of the package are in force, but not before 1 January 2006.

---

<sup>1</sup> The common position is therefore consistent with EP amendment 32 and with part of amendment 31.

<sup>2</sup> The common position is therefore consistent with the aim of EP amendment 63.

#### H. Requirements for primary producers (Annex I)

The Council agrees that the rules for primary producers should not just apply to primary production but also to certain operations intimately associated with primary production.

These operations should include:

- operations carried out at the place of production that do not substantially alter the nature of primary products;
- the transport of live animals; and
- the delivery of products of plant origin, fishery products and wild game from the place of production to another establishment.

#### I. Technical requirements for operations after primary production (Annex II)

The common position incorporates a number of technical modifications to Annex II.

Key among these are:

- stricter **equipment requirements**;
- simpler rules on **heat treatment** and the transfer and generalisation of requirements that used to be specific to heat treatment; and
- deletion of specific rules on **salting and smoking**, since they did not add anything to the general requirements.

#### J. Other

The common position does not in general reflect the Parliament's amendments when the initial position of the Commission was not to accept them<sup>1</sup>. In some cases, however, the Commission was able finally to accept modifications to its proposal that are fully<sup>2</sup> or partially<sup>3</sup> consistent with the proposed amendments.

---

<sup>1</sup> Amendments 13, 30, 35, 37, 48, 53, 55, 58, 59, 67, 69, 71, 76, 77, 92, 93, 95, 105 and 108.

<sup>2</sup> Amendments 5, 16, 28 and 29.

<sup>3</sup> Amendments 38, 47 and 89.

#### IV. CONCLUSION

The Council is pleased to note that the Commission accepts its common position and that the draft Regulation is consistent with many of the amendments that the European Parliament adopted at first reading.

Moreover, even when the Council and the Commission could not fully accept the Parliament's amendments, the common position is often closer to the Parliament's position than the Commission's original proposal. For example, while common position would not provide for the **application of HACCP principles to primary production**, it would establish basic risk-based hygiene rules for primary producers and provides for a review of the application of HACCP principles to take place within five years. Similarly, although the common position would maintain the possibility of making technical amendments to the Annexes through the **comitology procedure**, it would place limits on the scope of such amendments.

---