

**COUNCIL OF
THE EUROPEAN UNION**

**Interinstitutional File:
2000/0179 (COD)**

Brussels, 9 October 2003

**5420/1/03
REV 1 ADD 1
AGRILEG 12
CODEC 49**

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 laying down specific hygiene rules for food of animal origin

DRAFT STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

The Commission proposed a Regulation laying down specific hygiene rules for food of animal origin 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 2001.¹

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

II. OBJECTIVE

The proposed Regulation is the second 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.²

The second Regulation would lay down specific hygiene rules for food business operators handling food of animal origin. In particular, it would provide for:

- the approval of establishments;
- identification marking;
- specific requirements concerning imports; and
- flexibility for special cases.

III. ANALYSIS OF THE COMMON POSITION

A. Generalities

The common position incorporates many changes compared to the Commission's original proposal. These are often consistent with the aims of amendments that the European Parliament proposed in its first-reading opinion. The Commission has accepted the 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 178/2002³;
- to ensure the overall coherence of the hygiene package⁴;
- to ensure the internal coherence of the Regulation and its clarity, in particular by moving key principles from the Annexes to the Articles⁵; and
- to clarify the text⁶.

It also contains a number of technical amendments consistent with the overall objectives of the Regulation stated in Section II above.⁷

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 certain products of animal origin to the final consumer and local retail establishments.

The common position therefore contains provisions on the direct supply of small quantities of primary products identical to those in the common position on the first hygiene Regulation. It would also exclude the direct supply of small quantities of wild game, wild game meat or meat from poultry and lagomorphs slaughtered on the farm from the scope of the Regulation.⁸ However, it would make clear that:

- direct supply to local retail establishments covers only shops and - except in the case of poultry and lagomorphs slaughtered on the farm - restaurants, but does not cover wholesale or processing operations; and
- Member States must establish national rules for such direct supply and these rules must ensure the achievement of the objectives of the Regulation.

The Council also agrees that the Regulation should not apply to **composite products** (that is, food containing both products of plant origin and *processed* products of animal origin). The general rules of the Regulation on the hygiene of foodstuffs are sufficient for such products.⁹

The common position would make clear that composite products (but not products of animal origin used to manufacture them) would fall outside the scope of the Regulation. However, the Regulation would apply to food containing products of plant origin and *unprocessed* products of animal origin. It would also apply to processed products of animal origin containing ingredients of plant origin that are necessary for their manufacture or to give them specific characteristics.

The Council further agrees that the Regulation should not, as a general principle, apply to **retail** activities, since the general rules of the first Regulation would suffice for the most part. However, this general principle requires a degree of elaboration to ensure a proper balance between the protection of public health and practical considerations.

The common position would consequently make clear that the general rule excluding retail from the scope of the Regulation would not:

- affect specific provisions, when the Regulation explicitly states that they apply to retail (for example, the health standards and certain hygiene rules for live bivalve molluscs and fishery products would apply to retail);
- cover wholesale activities (which could fall within the scope of the wide definition of “retail” laid down in Regulation (EC) No 178/2002), except in circumstances that avoid any undue risk for public health;
- prevent Member States from applying stricter national rules to retail activities.

C. Comitology (Articles 2, 9, 10, 11 & 12)

The Council agrees that it should not generally be possible to amend the **definitions** laid down under the Regulation through comitology. However, rather than including a long list of definitions in the Articles, the common position would instead leave them in Annex I but prevent the amendment of this Annex through comitology. To provide flexibility, it would make it possible for Annexes II and III to contain technical definitions that could be amended through comitology.¹⁰

The common position also provides for the adoption of **transitional measures** through comitology and, to supplement the criteria governing amendments to Annexes II and III, contains a **non-exhaustive list** of circumstances in which amendments or implementing rules could be adopted through comitology.

D. Approval of establishments (Article 4)

The Council agrees that the Regulation should contain an Article setting out food business operators' obligations concerning the registration and approval of establishments and that these ought to dovetail with competent authorities' obligations under the Regulation on official controls.¹¹

In addition to providing for this, the common position would clarify that approval would not be a requirement for establishments storing products of animal origin that do not require temperature-controlled storage conditions. It would also make transitional arrangements for existing establishments.

E. Health and identification marking (Article 5 & Annex II, Section I)

The Council does not accept that all meat should receive a health mark.¹² The health mark should be applied only in slaughterhouses and only to carcasses and part-carcasses of red meat, to reflect the special role that the official veterinarian plays in such cases. All other meat, and all other products of animal origin handled in approved establishments, ought instead to bear an identification mark. The common position primarily provides for this by means of cross-references to the Regulation on official controls, which would lay down rules on health marking.

The common position would make clear that the specific requirements on identification marking do not affect food business operators' general duty to put in place systems and procedures to ensure traceability. It would avoid any unnecessary duplication of existing requirements for the labelling and marking of eggs.

F. Imports (Article 6)

To be consistent with the Regulation's focus on food business operators' obligations, the common position does not contain procedural rules concerning imports.

These appear in the common position on the Regulation on official controls.

Consequently, the remaining provisions deal solely with food business operators' obligations concerning imports, principally by means of cross-references to the relevant Articles of the Regulation on official controls.¹³

G. Special guarantees (Article 8)

The Council agrees that the provisions on salmonella guarantees should appear in an Article. The common position would also:

- limit the scope of such guarantees to those products of animal origin to which they currently apply in relation to Finland and Sweden, with the addition of minced poultry meat (which is not currently in free circulation within the Community);
- provide flexibility to update the requirements for trade with Finland and Sweden;
- provide a mechanism for establishing similar temporary requirements in respect of trade with other Member States with national control programmes exceeding the minimum Community requirements concerning salmonella.¹⁴

H. Flexibility (Article 10)

The Council agrees that an Article should provide 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. The common position therefore contains provisions identical to those in the common position on the Regulation on the hygiene of foodstuffs.¹⁵

A recital would make clear that the structural and hygiene requirements laid down in the Regulation would apply to all types of establishments, including small businesses and mobile slaughterhouses. The general provisions on flexibility mean that there is no need to have a specific reference to mobile slaughterhouses in the body of the Regulation.¹⁶

The common position would also make clear that Member States could maintain or establish appropriate health measures concerning raw milk and raw cream intended for direct human consumption.

I. 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.¹⁷ 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.

J. HACCP (Annex II, Section II)

The Regulation on the hygiene of foodstuffs contains general requirements on hazard analysis and critical control points (HACCP). The Commission's proposal for the Regulation on official controls specified key outcomes that the implementation of HACCP procedures in slaughterhouses should achieve. To ensure the internal coherence of the different elements of the hygiene package, the Council has moved the requirements for slaughterhouse operators to the Regulation laying down specific hygiene rules for food of animal origin.

K. Food chain information (Annex II, Section III)

The common position includes requirements for slaughterhouse operators concerning food chain information. These rules are necessary to complement the requirements for primary producers under the Regulation on the hygiene of foodstuffs and for competent authorities under the Regulation on official controls.

The rules provide considerable flexibility to avoid unnecessary bureaucracy¹⁸ and to reflect the fact that this is new system that it will be necessary to review and to adapt in the light of experience.

L. Emergency slaughter (Annex III, Section I, Chapter VI)

The common position would considerably strengthen the rules on emergency slaughter.

It would, in particular:

- limit the emergency slaughter procedure to animals that were healthy before suffering an accident;
- provide for meat from animals having undergone emergency slaughter to bear a special mark;
- restrict the placing on the market of such meat to the Member State of slaughter (subject to national rules, which may impose additional restrictions); and
- oblige food business operators to follow any requirements that the official veterinarian may impose concerning the use of such meat.

M. Wild game (Annex III, Section IV)

The Council supports the introduction of minimum Community requirements for the training of hunters. It agrees, however, that these requirements should apply to commercial hunters only, that Member States need not organise the training themselves; and that the list of topics that training should cover should be a recommendation only.¹⁹

In addition to clarifying these points, the common position incorporates a number of changes aimed at simplifying and clarifying the hygiene requirements for large and small wild game.²⁰ In particular, it clarifies which body parts must (and which need not) accompany the animal to the game handling establishment for post-mortem inspection.

N. Minced meat, meat preparations and MSM (Annex III, Section V)

Regulation (EC) No 999/2001 bans the use of certain ruminant material to produce mechanically separated meat (MSM) to prevent the spread of **transmissible spongiform encephalopathies**. The Council does not believe that it would be desirable or appropriate to repeat this ban. It is clear from Article 1 that it takes precedence over the rules of the Regulation.²¹

The common position would establish general requirements for raw material used to manufacture **meat preparations**. These are sufficiently flexible to make it unnecessary to provide for national derogations.

The common position would set differential rules for the **production and use of MSM**, depending on the nature of the manufacturing process. Modern manufacturing methods do not alter the structure of the bones used as raw material and produce MSM with a calcium content not significantly higher than that of minced meat.

Simplified requirements would apply to MSM manufactured using such modern methods. It would be possible to use such MSM in meat preparations, under certain conditions. Stricter requirements would apply to MSM manufactured using more intensive methods.

Member States would have the option of imposing **labelling requirements** on products that are not currently in free circulation within the single market, to enable consumers to make an informed choice.

O. Milk and dairy products (Annex III, Section IX)

The common position would simplify the requirements for heat-treated milk.

There would be no reference to commercial standards for heat-treated milk (such as pasteurisation). Instead, the Regulation would simply lay down the hygiene requirements necessary to safeguard public health, including specific requirements for heat-treatment to supplement the general requirements of the Regulation on the hygiene of foodstuffs.

The common position also makes clear that “raw milk” does not include milk that has been heated to more than 40 °C or undergone any treatment that has an equivalent effect.²²

P. Gelatine and collagen (Annex III, Sections XIV & XV)

The common position would maintain the current requirement for a document to accompany raw materials destined for the production of gelatine during transport. This is desirable to ensure traceability in a sector that involves both food businesses and undertakings manufacturing technical products from animal by-products. It would not lay down any quality requirements for gelatine, since these are not appropriate in a Regulation on food hygiene.

The common position also incorporates rules on collagen derived from the rules that Commission Decision 2003/42/EC added to Directive 92/118/EEC.

Q. Other

The common position would require the Commission:

- to consult EFSA when necessary; and
- to report on the implementation of the Regulation after five years.²³

The common position does not reflect those of the Parliament's amendments that the Commission was not able to accept.²⁴

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. It hopes that this will permit the rapid adoption of the Regulation and of the remainder of hygiene package.

1 The Committee of the Regions decided not to provide an opinion.
2 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.
3 These include changes consistent with the aims of EP amendments 1 to 4, 6, 14, 111 and 120.
4 These include changes consistent with the aims of EP amendments 20, 23 and 47.
5 These include changes consistent with the aims of EP amendments 11, 12, 22, 24 to 27, 30,
32, 43, 52, 56, 62, 67 and 128.
6 These include changes consistent with the aims of EP amendments 16, 18, 19, 42, 45, 49, 83,
84 and 117.
7 These include changes consistent with the aims of EP amendments 34, 35, 37, 40, 46, 50, 51,
54, 59, 60, 62 to 64, 66, 68, 70 to 76, 79, 80, 100, 103 to 109, 111 to 115, 118, 122 to 124,
133 and 134.
8 The common position is therefore consistent with the aim of EP amendments 82, 97 and 129.
9 The common position is therefore consistent with EP amendment 5.
10 The common position is therefore consistent with the aim of EP amendment 6.
11 The common position is therefore consistent with the aim of EP amendments 7, 57, 77, 98,
102, 110 and 125.
12 Consequently, the common position is not consistent with EP amendments 8 and 58.
13 The common position is thus consistent with EP amendments 28 and 29.
14 The common position is therefore partially consistent with EP amendments 10 and 61.
15 The common position is consistent with EP amendments 31 and 53 and with part of
amendment 9.
16 As a result, the common position is consistent with the aim of EP amendments 41 and 81.
17 The common position is therefore consistent with the aim of EP amendment 15.
18 The common position is therefore consistent with the aim of EP amendments 47 to 51 on the
Regulation on official controls.
19 The common position is therefore consistent with the aim of EP amendments 83 and 84.
20 The common position is therefore consistent with the aim of EP amendments 85 to 90, 92 to
96 and 132.
21 Consequently, the common position is consistent with only part of EP amendment 107.
22 Consequently, the common position is consistent with the objective of EP amendment 21.
23 The common position is therefore partially consistent with EP amendment 13.
24 Amendments 8, 17, 33, 38, 44, 55, 58, 65, 69, 101 and 116.