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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 rules for the organisation of official controls on products of animal origin intended for human consumption

COMMON GUIDELINES

Consultation deadline: 22/10/2003

DRAFT STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

In July 2002, the Commission proposed a Regulation of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

The European Parliament adopted an opinion on the proposed Regulation in June 2003. The Economic and Social Committee adopted an opinion in February 2003.¹

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

II. OBJECTIVE

The proposed Regulation is the third 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 Regulation would lay down specific rules for official controls on products of animal origin. In particular, it would:

- provide for audits of food business operators' implementation of good hygienic practices and HACCP-based procedures;
- lay down specific requirements for official controls in respect of fresh meat, live bivalve molluscs, fishery products and raw milk; and
- establish procedures governing the importation of products of animal origin.

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.

III. ANALYSIS OF THE COMMON POSITION

A. Generalities

The common position incorporates several changes compared to the Commission's original proposal. Several of these changes are 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 the overall coherence of the hygiene package¹;
- to ensure the internal coherence of the Regulation and its clarity, in particular by moving key principles from the Annexes to the Articles²; and
- to clarify the text³.

It also contains a number of technical amendments consistent with the overall objectives of the Regulation stated in Section II above.⁴

¹ These include a change consistent with the aim of EP amendment 79.

² These include changes consistent with the aims of EP amendments 1, 3, 20, 21, 78, 115 and 117.

³ These include changes consistent with the aims of EP amendments 5, 7 to 9, 13, 16 to 18, 22 to 24, 26, 39 to 45, 53, 54, 58 to 60, 66, 74, 84, 89, 104, 108, 110 to 113 and 124.

⁴ These include changes consistent with the aims of EP amendments 52, 61, 82, 91 to 98 and 134.

B. Regulation on official food and feed controls

The Commission's original proposal contained a number of references to the Regulation on official food and feed controls, which would establish general rules for official controls on all types of food and on feed.¹

However, it appears likely that adoption of the new food hygiene legislation will take place some time before that of the Regulation on official food and feed controls. The common position therefore contains no reference to that Regulation. Instead, it incorporates some of its provisions, particularly as regards definitions (Article 2) and enforcement action (Article 9).²

C. Scope (Article 1)

There are close links between the second and third Regulations in the hygiene package. The second Regulation would lay down specific hygiene rules for products of animal origin. The third Regulation provides for official controls on such products.

The Council agrees that both Regulations ought to have the same scope. The common position is therefore consistent with the aim of the European Parliament amendments that seek to import into the third Regulation the scope and exemptions provided for in the second.³

The common position also clarifies that the performance of official controls in no way diminishes food business operators' responsibility for ensuring food safety.

¹ The Commission adopted a proposal for such a Regulation in February 2003 (COM(2003) 52 final - interinstitutional file 2003/0030 COD).

² Article 9 is partly consistent with EP amendment 25.

³ Amendments 11 and 12.

D. Definitions (Article 2)

For the reasons given under B above, the common position incorporates four definitions from the proposed Regulation on official food and feed controls.¹

In addition it:

- would preserve the definition of “competent authority” used in several existing veterinary Directives;
- provides for a definition of an “approved veterinarian” to cover private veterinarians carrying out specific official controls on holdings;
- clarifies that, while “official auxiliaries” must be appointed by the competent authority, they need not be “officers” (civil servants);²
- provides for the incorporation of certain definitions laid down in Regulation (EC) No 1774/2002.

E. Approval of establishments (Article 3)

Compared to the Commission’s original proposal, the common position:

- provides some additional flexibility as regards conditional approval, particularly for factory and freezer vessels;
- contains clarification concerning existing establishments and wholesale markets;
- incorporates and generalises provisions on enforcement that initially appeared in Annex I; and
- provides for Member States to make lists of approved establishments available to the public.³

¹ The definitions of “official control”, “verification”, “audit” and “inspection”.

² This definition is consistent with the aim of EP amendment 14.

³ This provision is consistent with the aim of EP amendment 19.

F. Audits (Article 4)

The Commission's origin proposal provided for audits in respect of fresh meat.

The common position establishes audits as a general principle for all food business operators handling products of animal origin falling within the scope of the Regulation. In view of their specific expertise, it would require official veterinarians to carry out audits of slaughterhouses, game-handling establishments and certain cutting plants. It would give Member States discretion to choose the most appropriate staff for audits of other establishments.

G. Official controls in respect of fresh meat (Article 5)

The Council agrees that the **key principles** applying to official controls in respect of fresh meat ought to appear in an Article.

It also agrees that Member States should follow a risk-based approach to assess the **number of official staff** that need to be present on the slaughter line in any particular slaughterhouse, but does not believe that it would be appropriate to extend this assessment to cover the food business operator's staff.

It further agrees that there need to be strict and clear rules determining when **slaughterhouse staff** may assist with official controls. In particular, when carrying out certain specific tasks related to official controls, such staff must always work under the supervision of the official veterinarian and act independently from production staff.

However, the Council does not believe that it is appropriate to place unnecessary restrictions on the scope of the procedure. The common position would initially give Member States the choice of allowing slaughterhouse staff to assist with official controls on animals reared as a group under the same conditions (poultry, lagomorphs, fattening pigs and fattening veal). The system could subsequently be extended through comitology to other types of animals in the light of experience.¹

¹ Article 5 is therefore consistent with parts of EP amendments 21, 83 and 87.

H. Imports (Articles 10 – 15)

The Council agrees that it is more appropriate for procedural rules concerning imports to appear in the Regulation dealing with official controls.¹ It also believes that the rules must have the aim of ensuring that trade between the Community and third countries respects the principle of equivalence, while not imposing unnecessary or impracticable burdens on the parties involved.

The common position would therefore:

- establish the general rule that no third country may appear on a list of third countries from which imports are permitted unless a Community control has taken place in that third country, while providing flexibility for cases where such a control would provide no added value;
- limit the requirement for third country establishments to appear on lists drawn up and updated through a Community procedure to those establishments that are a priority for enforcement action, while not affecting the basic requirement for all establishments involved in the manufacture of products of animal origin destined for export to the Community to comply with Community food law or equivalent rules;
- make special provisions for vessels to reflect the fact that they may operate far from the territory of the third country the flag of which they are flying and that the administrative arrangements applying to establishments on land might not be applicable to vessels.

Since most of the provisions concerning imports are points of principle, they appear in Articles. In addition, new Annexes V and VI list certain technical details, so that these might be amended through comitology if necessary.

¹ Articles 10 to 15 are therefore consistent with the aim of parts of EP amendments 26 to 29, 32, 34 and 35.

I. Flexibility and comitology (Articles 16 – 18)

The Council agrees that the Regulation should, like the other hygiene Regulations, contain a procedure enabling Member States to adopt national provisions adapting certain technical provisions in a transparent manner. It believes, however, that this **flexibility** should only apply to Annex I, since Annexes II to VI contain rules that should remain of general application. In the context of official controls, it is also appropriate to provide for the use of the flexibility procedure to enable pilot projects to take place to try out new approaches to hygiene controls on meat.¹

The Council also agrees that it should be possible to lay down **transitional arrangements** through comitology in addition to amendments to the Annexes and implementing measures.² In addition, it believes that it should be possible to grant exemptions through the same procedure.

In the interest of clarity, the common position lists in a single Article a number of **specific decisions** that could be taken through comitology.³

J. Date of application (Article 22)

The Council considers 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. 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.

¹ Article 17 is therefore partly consistent with EP amendment 138.

² Articles 16 and 17 are therefore consistent with EP amendments 38, 130 and 131.

³ Article 18 is consistent with the aim of parts of EP amendments 56, 87, 116, 118, 120, 121 and 131.

K. Detailed rules for fresh meat (Annex I)

The common position incorporates a number of changes to the detailed requirements for official controls with respect to fresh meat. In particular, these rules:

- no longer contain provisions that appear in the common position on the **second Regulation** (laying down specific hygiene rules for products of animal origin);
- place greater emphasis on controls on meat from animals that have undergone **emergency slaughter**; ¹
- limit the scope of **health marking** to carcasses and part-carcasses of red meat to reflect the special role that the official veterinarian plays in such cases;
- clarify the circumstances in which meat is to be declared **unfit** for human consumption, including meat with a pronounced sexual odour and blood; ²
- establish a short list of official controls that only official veterinarians may carry out, rather than a long list of tasks with which **official auxiliaries** may assist.

There would be some **flexibility** as regards official veterinarians' presence at slaughterhouses and game-handling establishments. The presence of at least one official veterinarian throughout ante-mortem and post-mortem inspection would remain the basic requirement, but competent authorities could adapt it on the basis of a risk assessment and under strict conditions ensuring that proper inspection takes place. ³

With respect to **training**, the common position would enable competent authorities to appoint official veterinarians without testing them, if the candidate has acquired all the required knowledge as part of a university degree, or through continuing education resulting in a post-graduate qualification. However, the Council does not believe that it would be appropriate in other circumstances for competent authorities to appoint practising veterinarians as official veterinarians without testing them. ⁴

¹ Annex I is therefore consistent with the aim of EP amendment 57.

² Annex I is therefore broadly consistent with the aim of EP amendments 132 and 133.

³ Annex I is therefore consistent with part of EP amendment 85.

⁴ Annex I is therefore consistent with part of EP amendment 88.

The common position also slightly alters the division between theoretical and practical training for official auxiliaries, without changing the overall requirement for 900 hours of training. It no longer includes a provision providing for an increase in the number of hours by a given date, since this was a political objective rather than a legal requirement. However, the Commission has undertaken, when preparing its report on the experience gained from the implementation of the Regulation, to consider whether it would be opportune to increase the minimum training requirements for official auxiliaries.¹

L. Detailed rules for live bivalve molluscs (Annex II)

The Council believes that the **sampling frequency** for toxin analysis in live bivalve molluscs should as a general rule be weekly during harvesting periods. It agrees, however, that there should be flexibility to increase or to decrease the frequency in the light of a risk assessment.²

The common position contains modernised criteria for the **classification of production and relaying areas**. The criteria for areas of classes B and C now refer only to *E.coli*, since there is agreement that faecal coliforms are not a reliable indicator of faecal contamination. It would be possible to amend these criteria and to specify sampling plans, methods and analytical tolerances through comitology.³

M. Detailed rules for fishery products (Annex III)

The common position contains clarification concerning official controls on the production and placing on the market of fishery products. In particular, it includes detailed rules concerning official controls of vessels, to clarify which controls are necessary and which are possible taking account of the practical and legal specificities.

¹ This commitment is consistent with the aim of EP amendment 99.

² Annex II is therefore consistent with part of EP amendment 122.

³ Articles 18(13)(c) and 20(3).

N. Detailed rules for raw milk (Annex IV)

The common position contains only those requirements that are specific to official controls on the production and collection of raw milk. It no longer includes rules that would have duplicated general requirements applicable to all products of animal origin.

O. Other

To be consistent with other parts of the hygiene package, the common position would require the Commission:

- to consult EFSA when necessary (Article 20); and
- to report on the implementation of the Regulation after five years (Article 21).

The common position does not reflect those of the Parliament's amendments that the Commission was not able to accept, in particular those that:

- would extend **health marking** to meat from poultry and lagomorphs;¹
- deal with **food business operators' responsibilities**;²
- would place undue restrictions on the scope for **slaughterhouse staff** to assist with official controls;³
- would eliminate the possibility of **visual post-mortem inspection** of certain categories of fattening pigs;⁴
- anticipate the outcome of discussions that should take place in the context of negotiations on the proposed Regulation on **official food and feed controls**;⁵ or
- would introduce specific provisions for **small artisanal businesses**, rather than flexibility on the basis of a risk assessment.⁶

¹ Amendments 62 to 64.

² Amendments 65 and 129.

³ Amendments 81, 100, 127, 135, 136, 139 and 140.

⁴ Amendment 109.

⁵ Amendments 4, 69, 70, 76 and 77.

⁶ Amendments 15 and 90.

In addition, the Council and the Commission cannot accept amendments that would unnecessarily tighten¹, weaken², or complicate³ the new hygiene legislation or that are not consistent with its scope or with other provisions.⁴

IV. CONCLUSION

The Council is pleased to note that the Commission accepts its common position and that the draft Regulation is consistent with the aim of several 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 Amendments 2, 30, 33, 55, 67, 68, 75, 105, 106, 119 and 128.

² Amendments 46, 73, 101 to 103, 107 and 123.

³ Amendments 6, 10, 31, 36, 37, 71, 72, 125 and 126.

⁴ Amendments 80, 114 and 137.