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PROGRESS REPORT

From : General Secretariat

To : Coreper/Council

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Subject : Proposed Regulations of the European Parliament and of the Council:
- on the hygiene of foodstuffs
- laying down specific hygiene rules for food of animal origin

I. INTRODUCTION

In July 2000, the Commission proposed a package of five acts relating to food hygiene.

To date, the Working Party of Veterinary Experts has discussed two of these proposals.

Under the French and Swedish Presidencies, the Working Party completed an initial examination of the proposed Regulation on the hygiene of foodstuffs (the “**general hygiene Regulation**”) and began examining the proposed Regulation laying down specific hygiene rules for food of animal origin (the “**specific hygiene Regulation**”).

Under the Belgian Presidency, the Working Party completed its initial examination of the specific hygiene Regulation, discussing all the Sections of Annex II laying down rules for products of animal origin other than meat and considering the rules on imports contained in Annex III.

These discussions have enabled the Presidency to suggest many detailed technical improvements to the specific hygiene Regulation. They have also enabled it to identify a few areas where consequential amendments to the general hygiene Regulation might be desirable. In line with the objectives of the Commission's proposal, many of the changes would:

- clearly distinguish food business operators' duties from those of the competent authorities; and
- establish clear and simple rules which, wherever possible, are of general application.

To complement this progress report, the Secretariat General will issue a document containing a consolidated draft of the specific hygiene Regulation incorporating these changes, indicating the issues that remain to be resolved, and listing possible consequential amendments to the general hygiene Regulation.

II. STATE OF PLAY

The discussions within the Working Party of Veterinary Experts have brought to light a few key issues that concern all sectors. These issues were brought to the attention of the Working Party of Chief Veterinary Officers at its meeting on 22 November 2001.

The following sections summarise these issues and the outcome of the discussions to date.

A. Registration and Approval of Establishments

Delegations have agreed that all establishments handling food of animal origin must:

- meet the requirements of the specific Regulation;
- be registered; and
- be subject to official controls.

A majority of delegations believes that the specific hygiene Regulation should, as a general principle, require the approval of most establishments handling food of animal origin. The only exceptions¹ would be establishments carrying out primary production, retail sales to the final consumer or transport operations. Approval would imply that the competent authority would carry out an on-site visit to inspect the establishment before it began operating². However, some delegations doubt whether such a wide requirement for approval is appropriate, preferring a risk-based approach.

Delegations have agreed that the Regulation should establish minimum standards. As envisaged in the general hygiene Regulation³, Member States should be free to extend the requirement for approval to other establishments.

B. Scope of, and Amendments to, the Annexes

No delegation has objected to the principle of providing for the amendment of detailed technical requirements through the comitology procedure, in certain specified circumstances. However, there is agreement on the need to restructure the specific hygiene Regulation, so as to ensure that important points of principal and fundamental concepts are subject to amendment only *via* the co-decision procedure.

¹ Consequently, these delegations believe that establishments carrying out storage operations should be subject to approval.

² Some delegations believe that the competent authority should initially provide a preliminary approval, which would become a full approval only after a further visit to inspect the establishment once it had started operating.

³ Document 11017/01, Article 6(2).

In particular, delegations have agreed that it should not be possible to amend the definitions through the comitology procedure. As a consequence, the Presidency has suggested the deletion of two technical definitions, those of “mechanically separated meat” and “mechanically recovered fish flesh”. The rules contained in these definitions could instead appear in the relevant Sections of Annex II, to enable their updating in the light of technological developments and scientific advice. Some delegations supported this suggestion, while others reserved their position.

C. Flexibility / Special Conditions

This is the issue that divides delegations the most. The Presidency has suggested that the hygiene Regulations provide some flexibility for the granting of special conditions, as envisaged in the Commission’s proposal, but that this take place only through two transparent procedures:

- a **Community procedure**, permitting the adoption of general exemptions for food business operators throughout the Community at the initiative of the Commission through the SVC comitology procedure; and
- a **national procedure**, permitting the adoption of specific national exemptions from certain structural requirements for food business operators in one Member State (with a requirement to notify the Commission and other Member States and provision for the use of the SVC procedure to resolve disputes).

Some delegations welcomed this suggestion. Other delegations believed that the Regulations should lay down rules that were applicable to all food business operators in all Member States or that, if special conditions were to be granted, it should only be through the Community procedure, at the initiative of the Commission.

D. Retail Trade

The emerging consensus appears to be that:

- the hygiene legislation should use the definition of “retail” laid down in the proposed Regulation laying down the general principles and requirements of food law, establishing the European Food Authority and laying down procedures in matters of food safety¹;
- since this definition is very wide, the specific hygiene Regulation should not exclude all forms of retail trade from its scope, but only retail outlets delivering products of animal origin directly to the final consumer (for which the rules of the general hygiene Regulation alone would be sufficient);
- notwithstanding this general exclusion, some specific requirements should apply to all forms of retail trade, particularly the health standards for live bivalve molluscs and fishery products.

The representative of the Commission has indicated a willingness to consider new wording with the aim of ensuring that the scope of the exclusion for retail trade is appropriate.

Some delegations believe that the Regulation ought to enable Member States to exclude from its scope retail outlets that sell a limited amount of products of animal origin to other retailers, who process it and supply it to the final consumer.

¹ Document 10880/01 REV 1 contains the common position that the Council adopted on 17 September 2001 with a view to the adoption of this Regulation.

E. Primary Production

There is general agreement that, while the hygiene Regulations ought to lay down rules for primary production and certain associated operations, these rules should not always be the same as those applying to other operations. In particular, food business operators carrying out primary production and certain associated activities should not need to implement a system based on the HACCP principles. They should have to comply with the general principles laid down in Annex I to the general hygiene Regulation, rather than the detailed requirements of Annex II.

There also seems to be wide support for the Presidency's suggestions regarding the associated operations that ought to be subject to the same rules as primary production.

These operations are:

- the storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;
- transport operations within the place of production; and
- in the case of certain products (in particular, products of plant origin, live bivalve molluscs, live echinoderms, live tunicates, live marine gastropods and fishery products), transport operations to deliver unprocessed primary products from the place of production or harvesting to another establishment.

Finally, there is agreement that primary producers should be able to sell certain unprocessed primary products (for example, fruit, vegetables, eggs and snails) directly to the final consumer without having to meet any additional requirements. However, there are differences of opinion on matters of detail (particularly, as regards the products concerned and their method of sale). The Presidency has suggested that it might be desirable further to consider the different circuits *via* which food business operators may place products of animal origin on the market.

F. Identification / Traceability

A large majority of delegations agrees that:

- the term “health mark” should be used only for marks applied under the authority of the official veterinarian (that is, in slaughterhouses);
- marks applied by food business operators under their own authority should be called “identification marks”; and
- the Regulation on official controls should specify which products must have a health mark.

There is general agreement that the identification mark should indicate the Member State in which the establishment is located (by means of the ISO two letter country codes) and the registration or approval number of the establishment. Several delegations support the Presidency's suggestion that the obligation to apply an identification mark should apply to food business operators processing or repackaging products of animal origin at any stage of production, processing and distribution after primary production. However, some delegations believe that it would be desirable to extend the requirement to primary products and to products of plant origin.

There is also wide agreement that documents should accompany certain products of animal origin (animals destined for slaughter, live bivalve molluscs *en route* to a dispatch centre and raw materials destined for the manufacture of gelatine).

These documents would be required either until a health mark or identification mark is applied or in place of such a mark.

G. Composite Products

Most delegations agree that the specific hygiene Regulation:

- should not apply to composite products (that is, food containing both processed products of animal and products of plant origin, such as chocolate and pizzas); but
- should apply to processed products of animal origin to which ingredients of plant origin have been added to give certain characteristics (for example, sausages containing herbs); and
- should apply to raw materials (that is, products of animal origin used to manufacture composite products).

However, some delegations have suggested that the Regulation needs to clarify:

- the position of products composed of different processed products of animal origin. As for composite products, the Regulation does not envisage any specific rules for such products;
- the position of products prepared from unprocessed products of animal origin and products of plant origin. While there is agreement that the Regulation should apply to uncooked kebabs, it is not clear what rules would be relevant for pasta prepared using fresh eggs or cheeses prepared from raw milk; and
- that checks on imports must ensure that products of animal origin used to manufacture composite products meet Community requirements.

H. Imports

Delegations have agreed that a clear distinction should be made between the duties of food business operators and procedural rules. However, views differ as regards the appropriate home for the procedural rules.

- Some delegations agree with the Presidency and the representative of the Commission that the procedural rules should remain in the specific hygiene Regulation, at least for the time being. Moving them to another legal act could create procedural difficulties.
- Other delegations believe that it might be more appropriate to place the procedural rules in the Regulation on official controls. This would enable there to be a single set of rules covering both animal and public health considerations.

On the detail, the most contentious issue discussed was whether a Community inspection should always be necessary before a third country could be placed on a list of countries from which imports of products of animal origin are permitted. However, a Presidency compromise suggestion received a generally positive initial reaction. In the light of information that the Commission services provided on the number of third countries that export to the Community, and how many have undergone a Community inspection, the compromise envisages that, as a general principle, a Community audit of a third country should always take place before it is listed. The audit would be a general check of the systems in place in the third country. It would not necessarily involve specific checks in respect of any particular product of animal origin. There would need to be certain exceptions from this general principle to reflect practical realities.

III. CONCLUSION

The representative of the Commission has a general scrutiny reservation on any modification to the initial proposal. There appears nevertheless to be an emerging consensus among delegations on all of the key horizontal issues, except for the issue of flexibility or special conditions. Coupled with the technical improvements made to the draft Regulation, this should enable a future Presidency to make suggestions with a view to agreeing a common position once the Parliament has adopted an opinion at first reading.

The Committee of Permanent Representatives could take the opportunity to note the progress made to date and forward this report to the Council as it stands.

