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signed by Mr Jordi AYET PUIGARNAU, Director

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to: Mr Javier SOLANA, Secretary-General/High Representative

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Subject: Report from the Commission to the Council and the European Parliament on  
the experience gained from the application of the hygiene Regulations (EC)  
No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 of the European  
Parliament and of the Council of 29 April 2004

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 28.7.2009  
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**REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN  
PARLIAMENT**

**on the experience gained from the application of the hygiene Regulations (EC)  
No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and  
of the Council of 29 April 2004**

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## 1. EXECUTIVE SUMMARY

Article 16 of Regulation (EC) No 852/2004<sup>1</sup>, Article 14 of Regulation (EC) No 853/2004<sup>2</sup> and Article 21 of Regulation (EC) No 854/2004<sup>3</sup> contain the legal requirement for the Commission to submit a report to the European Parliament and to the Council, reviewing the experience gained from their application and, if appropriate, accompanying the report with relevant proposals, not later than 20 May 2009. In addition, Regulation (EC) No 852/2004 requires the Commission to consider if it is desirable and practicable to extend the Hazard Analysis Critical Control Point (HACCP) requirements to food business operators in the primary production area.

The present report followed a thorough consultation process. It is based on information received from the competent authorities in the Member States, representatives of the food business operator and consumer organisations at European level, and the Commission's Food and Veterinary Office.

The report aims at presenting factually the experience gained, including the difficulties encountered, in 2006, 2007 and 2008 from the implementation of the hygiene package by all interested actors.

The report concludes that overall Member States have taken the necessary administrative and control steps to ensure compliance but that there is still room for improvement in relation to implementation. These conclusions are supported by the findings of audits and inspections carried out by the Commission's Food and Veterinary Office. Consulted stakeholders consider that the new principles and requirements introduced by the hygiene package have had a positive impact. It also indicates the clear position expressed by the Member States and private stakeholders not to extend at present the requirement for HACCP-based procedures to food business operators carrying out primary production.

The main difficulties identified are in relation to certain exemptions from the scope of the hygiene Regulations, certain definitions laid down in the Regulations and the procedure for adapting those definitions, certain practical aspects concerning the approval of establishments handling foods of animal origin and the marking of such foods, the import regime for certain foods, the implementation of HACCP-based procedures in certain food businesses and the implementation of official controls in certain sectors.

This report does not suggest any detailed solutions to the difficulties reported and is, therefore, not accompanied by proposals. However, on the basis of the difficulties identified, the Commission will consider the need for any proposals to improve the food hygiene package.

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<sup>1</sup> OJ L 139, 30.4.2004, p. 1. Regulation as last amended by Regulation (EC) 1019/2008 (OJ L 277, 18.10.2008, p. 7).

<sup>2</sup> OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Regulation (EC) 1020/2008 (OJ L 277, 18.10.2008, p. 8).

<sup>3</sup> OJ L 226, 25.6.2004, p. 83. Regulation as last amended by Regulation (EC) 1021/2008 (OJ L 277, 18.10.2008, p. 15).

The report is accompanied by a staff working document (SWD) where Annexes referred to in the report can be found. Annex I of this accompanying document sets down the abbreviations and technical terms used in the report.

## **2. BACKGROUND**

On 29 April 2004, the European Parliament and the Council adopted the "food hygiene package". It comprises three basic Acts, Regulations (EC) No 852/2004 and 853/2004, addressed to food business operators (FBO) and Regulation (EC) No 854/2004, along with Regulation (EC) No 882/2004 on official controls, to competent authorities (CA)<sup>4</sup>. The basic Acts are further specified in three Commission Regulations laying down implementing measures (see SWD – Annex III). In addition, guidance documents have been established by the Commission and the MS (see SWD - Annex IV).

These new Regulations introduced a shift in approach to food hygiene policy. The clear objective of this package was to simplify the existing legal corpus on food hygiene (see SWD - Annex V), make it more coherent by separating the different disciplines (public health, animal health and official controls) and concentrate on objectives to be reached by FBO rather than maintaining very detailed requirements. The Regulations provide ample possibilities to adapt the technical requirements of the food hygiene package in function of the nature of the food business concerned.

Because of its innovative nature, the European Parliament and the Council requested the Commission to submit a report already after only three years of implementation (see SWD - Annex VI). The report shall, in particular, review the experience gained from the application of the new Regulations and consider whether it would be desirable and practicable to extend the implementation of the HACCP principles to the level of primary production.

In order to establish the report, the Commission consulted all major stakeholders bilaterally or collectively (see SWD - Annex VII).

The purpose of the report is to present factually the experience gained in 2006, 2007 and 2008 from the implementation of the hygiene package by the CA and by private stakeholders' organisations, and to identify the difficulties that arose from this implementation.

## **3. EXPERIENCE GAINED SINCE 1 JANUARY 2006**

### **3.1. Overall experience**

The overall experience of applying the hygiene Regulations may be regarded as positive. The MS are, in general, satisfied with the structure and the principles of the hygiene legislation. They are clearly not of the opinion that the legislation requires a fundamental overhaul. For most MS it is too early to give a balanced and detailed evaluation of the experiences encountered when implementing the hygiene package.

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<sup>4</sup> See diagram on the current legal framework in SWD - Annex II.

FVO inspection missions confirmed this finding, as in general, the application of the hygiene package did not lead to major difficulties for FBO and CA. The problems identified during the missions were, to a variable extent, more important in small establishments.

The MS also regard the establishment of guidance documents, where appropriate, to help FBO and the CA to implement the hygiene Regulations, as positive.

### **3.2. Scope**

MS are, in some instances, required to lay down under national law specific rules to cover certain activities excluded from the scope of the hygiene package.

MS noted difficulties in relation to the local supply of small quantities of foods when applied to cross-border trade into a MS of destination having a different approach to these activities. Some MS identified other difficulties in relation to the notion of "undertakings", which are characterised by a certain continuity of activities and a certain degree of organisation, and its application to private persons occasionally handling, preparing or serving foods.

The non-applicability of Regulation (EC) No 853/2004 to retail activities has also generated difficulties. For a majority of MS, there is an inconsistency in that cold stores carrying out similar activities are subject to different rules and approval regimes, this being dependent on whether the cold store falls under the definition of retail or not. In the same way, the interpretation of the terms "marginal, localised and restricted" in relation to the exemption from approval of retail establishments have also been the source of difficulties.

Many private stakeholder organisations have, for competitiveness reasons, also raised concerns on the exclusion of retail, some requesting a full extension of the scope of Regulation (EC) No 853/2004 to retail, others pleading for a review of the legislation as regards certain activities carried out at retail level (e.g. mincing, slicing) with a view to applying the same rules to the same activities throughout the Community.

### **3.3. Definitions**

The concept of 'composite product' remains difficult to implement and gives rise to uncertainties for both FBO and CA.

The definition of retail as provided for in Regulation (EC) No 178/2002 is perceived as a continued source of difficulties as it appears not to be totally adapted for the purpose of the hygiene package (see also point 3.2.).

MS and many private stakeholders' organisations have questioned other definitions (e.g. dwelling-houses, lagomorphs, invertebrates, blood, casings). They have also questioned the procedure for establishing or amending such definitions.

### **3.4. Primary production**

The current food hygiene rules for primary production are generally considered appropriate and adequate for the protection of primary products against

contamination. However, certain MS considered it premature to assess the impact of the hygiene package requirements on primary production. Other MS reported difficulties with regard to the vague nature of certain objectives set down in Regulation (EC) No 853/2004 and the lack of clear guidance for primary producers. Guides to good practice, where available, have proven to be crucial tools to help primary producers to fulfil their obligations (see points 3.5 and 3.8.).

Record-keeping was perceived as a source of difficulties in some MS, but to varying extents.

### **3.5. HACCP**

- In general, the implementation of HACCP principles is not called into question, as it is perceived as relevant to allow FBO to achieve their food safety objectives and as sufficiently flexible to be adapted even to small food businesses.

Most industrial food businesses have HACCP-based procedures in place. Delays in implementation were noted in former small capacity abattoirs benefiting from a transitional arrangement.

However, in most MS, difficulties with such procedures were identified in small food businesses and more particularly, in micro and small catering and retail establishments. Provision of generic systems from outside consultants have been reported in some cases not to reflect the reality of the establishment and to impose more documentation and records than are mandatory. They seem therefore to be less than efficient and overly expensive for small businesses. In some MS, the CA have alleviated the issues, either by conducting risk analyses for certain types of activities or by participating in the creation of simplified and practical material for the attention of small businesses. In other MS, food sectors were encouraged to develop guides to good practices, which have proven to be very useful tools.

Record-keeping is sometimes perceived as an administrative burden by small food businesses. MS have taken initiatives to simplify this step and minimise the documentation to be kept.

Some private stakeholder organisations claimed that MS differed regarding the assessment of HACCP-based procedures by CA. Some organisations indicated a tendency of CA to have high expectations of small businesses and to exaggerate documentary requirements in some instances. Others indicated that the size and nature of the business was taken into account and that the majority of CA makes use of flexibility in the implementation of HACCP-based procedures.

Difficulties were also identified during FVO inspection missions regarding CA capability in adequately assessing HACCP-based procedures. Progress has been noted since the first inspection round in 2006 but there is still room for improvement.

- MS and private stakeholders consider it impracticable to extend the requirement for HACCP-based procedures to FBO carrying out primary

production. Guides to good practices are generally considered to be better and more practical tools for primary producers than HACCP-based procedures.

### **3.6. Registration and approval procedures**

- In general, no major difficulties were noted as regards registration of food businesses. Specific systems or existing databases were used to register food businesses (e.g. primary producers). Efforts were also made to harmonise and minimise the information which businesses are required to supply to CA to reduce the administrative burden.

However, ensuring that all FBO meet their obligation to register is sometimes difficult, e.g. FBO who do not contact their authorities before opening a food business, food brokers and Internet traders who are not easily targetable. Other problems arose from the need for private persons occasionally handling, preparing or serving foods to be registered.

No charge is generally levied by CA for processing registration.

- No particular problems were noted concerning the supply of approval information to the CA. However, difficulties have been identified in relation to the type of establishment requiring approval, in particular for those carrying out general activities, such as cold storage (see point 3.2.) and repacking establishments.

Approval of former small capacity establishments was raised by a few MS. Solutions can be found through flexibility provisions contained in the hygiene package. However, such provisions have to be promoted at national level, which may have created difficulties in certain MS (see point 3.9.).

Two MS indicated that all food businesses had to be approved on their territory.

- While access from the Commission website to every national site containing lists of approved food establishments is now possible, certain MS have not used the agreed specifications aiming at harmonising and codifying the presentation of the lists to draw up or update their lists. The maintenance of active links to national sites has also to be improved.

### **3.7. Health and identification marking**

No major difficulties have arisen in relation to health or identification marking principles. However, difficulties were reported in relation to certain practical aspects, e.g. situations where a new mark should be applied to wrapped/consumer-packaged products and food is repacked. In such cases, some MS are of the opinion that marking must also meet the needs of official control and traceability objectives.

### 3.8. Guides to good practice<sup>5</sup>

- The MS have greatly promoted the development of national guides. The participation of CA differs from one MS to another, but in general, guidelines for developing such guides, practical advice and guidance have been given by CA to food sectors. CA are involved in the assessment process of these guides and sometimes financially support their diffusion.

Most private stakeholders' organisations have expressed a positive attitude to national guides to good practice and to the encouragement given by the CA. No figure as to the extent of their use can be given.

The use of guides is taken into account in a variable way by CA when performing official controls. Some MS have developed an award system to deserving FBO who apply validated guides, resulting in reduction of the control frequency and of the level of fees charged by CA for official controls. In other MS, the inspection bears on the correct use of the guide when claimed to be applied. Some further MS do not require FBO to prove the adequacy of their control measures if they follow the guide. Guides may also offer useful guidance to CA and indicate what is best practice when the terms 'where appropriate', 'where necessary', 'adequate' and 'sufficient' are used in the legislation.

- Five Community guides have already been developed and are under evaluation. Two more guides are under preparation and will be submitted to evaluation once ready. However, about half of the organisations at EU level were considering, or were in consultation with their members, if they should develop draft documents and follow the procedure to obtain recognition. The other half of the organisations indicated that they had no plans to develop Community guides.

### 3.9. Flexibility

In order to protect food diversity and to serve consumers and the needs of small-scale producers, provisions were included in the legislation for flexibility. In accordance with the principle of subsidiarity, MS are best placed to find appropriate solutions based on local situations and on appropriate levels of hygiene in these businesses, without compromising the objective of food safety.

MS and private stakeholders have indicated that they were in general very satisfied with the flexibility provided for in the hygiene package, which is considered as well designed to give appropriate responses to local problems. However, based on the few notifications of national measures to this effect received so far and criticisms emanating from certain food businesses (see point 3.6.), MS may not have availed of all flexibility possibilities offered in the legislation.

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<sup>5</sup> See overview of guides to good practice in SWD - Annex VIII.

### **3.10. Imports**

- MS considered it necessary to further harmonise the import rules for products of animal origin for which Regulation (EC) No 853/2004 lays down specific requirements (e.g. frogs' legs, snails, rendered animal fats). They also face difficulties with the listing and controls of third country vessels for which the responsibility for inspection has been delegated to a country or to a MS other than the flag state.

Experience shows that clarification of situations where national import rules apply in the absence of harmonised Community rules is necessary.

- Recent crises due to imported composite products have confirmed the need for greater control of such products. This may require implementation of more detailed legislation and checks upon importation (e.g. importers role, specific health certificate).
- Experience has shown that the current listing procedure for third country establishments presents difficulties (e.g. listing period). With the development of new Community IT tools, consideration may be given to reviewing this procedure.

### **3.11. Official controls in relation to products of animal origin**

- Many MS have developed specific control tools, including check-lists and standard operating procedures. They also put their efforts into training as auditing activities imply an important conceptual change for inspectors. MS expressed satisfaction with the Commission training initiative, "Better training for safer food", which complemented their own training activities and offered specific training on key-aspects of the hygiene package (e.g. HACCP).

However, difficulties persist in many MS with regard to audits as demonstrated by FVO inspection missions. Even if significant progress has been made since 2006, there is still room for improvement.

- Although elements of modernisation have already been incorporated in the hygiene package since its entry into application in January 2006, many MS and interested private stakeholders' organisations consider that meat inspection should be reviewed. This position is driven by human resources problems encountered by certain MS in appointing official veterinarians (OV) to slaughterhouses and by the increasing public health importance of hazards that cannot be easily detected by conventional meat inspection. It was pointed out that the role of official auxiliaries should be enhanced, the division of responsibilities between FBO running slaughterhouses and CA should be further clarified and additional inspection tasks be delegated to slaughterhouse staff.

Certain MS and private stakeholders' organisations consider that the use of slaughterhouse staff should be extended to slaughterhouses slaughtering species other than poultry and lagomorphs.

- FVO missions have shown that in a few MS *Trichinella* testing is not properly implemented. In addition, difficulties exist in relation to the accreditation of in-house slaughterhouses laboratories in some MS. However, one MS claimed to use only accredited laboratories.

Denmark has been recognised as a region presenting a negligible *Trichinella* risk and can derogate from the testing regime in domestic swine. Requests from two other MS have also been received. This derogation is today limited to EU MS and consideration may be given to extending it to third countries. Two MS expressed interest in recognising holdings as *Trichinella*-free.

- Varied fraudulent practices have been disclosed since 2006 in cold stores located in a number of Member States. As also discussed in the frame of the animal by-products legislation, most of the MS considered it necessary to reinforce the control instruments at their disposal.
- Other specific difficulties arose from the use, in certain MS for animal welfare reasons, of non-fully validated chemical methods instead of mouse bio-assays in routine analyses. The European Food Safety Authority (EFSA) is expected to deliver a scientific opinion on the current limits for marine biotoxins and their detection methods by December 2009.

### **3.12. Microbiological criteria**

Based on FVO reports, it appears that food business operators' procedures only occasionally ensured, in the first year of application of Regulation (EC) No 2073/2005, that process hygiene criteria and food safety criteria were met or even taken into consideration. This was, in addition, quite often not addressed by CA official supervision. Although the situation has improved in 2007/2008, there are still some MS where this Regulation is not implemented satisfactorily.

From a MS perspective, the main difficulty reported relates to the implementation of the *Listeria monocytogenes* criterion for ready-to-eat foods which are able to support the growth of such a pathogen.

### **3.13. Removal of surface contamination**

The use of substances to remove surface contamination from foods of animal origin is subject to approval by Comitology procedure. Based on EFSA opinions, an attempt to authorise the use of four substances to remove surface contamination from poultry carcasses was proposed by the Commission in 2008. The European Parliament, the MS and a great majority of private stakeholders' organisations clearly indicated their opposition to such an authorisation, even under strict conditions.

The possible use of other decontamination techniques, including steam, hot water and other physical treatments, are under discussion with the MS.

### **3.14. Food Chain Information (FCI)**

Provisions were made for FCI to be progressively introduced until the end of the transitional period (31.12.2009). Two MS indicated having not used these provisions.

- FCI was to be implemented on 1 January 2006 in the poultry sector. No major difficulties were reported since similar provisions applied in previous legislation.
- FCI is compulsory in the pig sector since 1 January 2008 and in the veal calf and horse sectors since 1 January 2009. Few difficulties were identified in the pig sector (see below). Reports on the veal calf and horse sectors are not yet available.
- FCI is to be available for the other species (sheep, goats and adult bovines) by 1 January 2010. Some MS anticipate difficulties, in particular, with individually identified animals.

The delay for supplying FCI before the arrival of the animals has been considered as difficult to comply with in all instances in the pig sector. Similar difficulties are expected in future for other animal sectors. MS and certain private stakeholders' organisations are in favour of greater flexibility in this regard.

As the responsibility for organising FCI and its practical arrangements (e.g. documents, way for exchanging information) was left to MS, difficulties were noted in intra-Community trade of animals and are also expected with imports. A first step to ease the access to the information required by the different MS is in operation at Commission level. However, some MS indicated that it may also be appropriate to develop at EU level a specific form for intra-Community trade and possibly imports.

Experience has also shown that clarification on the relation between FCI and animal health certificates required when trading live animals is necessary.

### **3.15. Emergency slaughter**

MS did not report particular difficulties regarding the practical rules for emergency slaughter, but questioned the special mark and the marketing limitation for such meat. Some MS stressed the need for applying the special mark also to derived products. Other MS consider that there are no food safety reasons that can justify a restriction on the placing on the market of such meat if recognised fit for human consumption after ante- and post-mortem inspection.

## **4. CONCLUSIONS**

Member States and food business operators have indicated that they are generally satisfied with the hygiene Regulations and that they have made good progress in adjusting to them. There is broad support for the principles introduced by the Regulations. Member States consider that the legislation requires slight adjustments but not a fundamental overhaul.

According to the MS and private stakeholders' organisations, the application of the hygiene package did not lead in general to major difficulties for food business operators and competent authorities. However, the inspections carried out by the Food and Veterinary Office since early 2006 have revealed that on-going control problems and hygienic production standards require further improvement in a number of Member States. As a first step, better enforcement by all involved actors,

FBO and CA, is therefore necessary to address the most outstanding issues identified in the report.

On that basis, the Commission will consider how to address the identified difficulties. In submitting its proposals, the Commission will pay particular attention to the fact that the benefits of the simplification achieved with this new legal framework are, as far as possible, maintained.