

## THE “HYGIENE PACKAGE” – A NEW APPROACH TO FOOD SAFETY

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### BACKGROUND

Following several disease outbreaks and food contamination scandals in Europe in recent years, the Commission adopted the White Paper on Food Safety in 2000. This White Paper contains a number of recommendations aimed at increasing food safety, improve the traceability of food products and regain consumer confidence in the food industry. To this end a package of proposals for new legislation on food and feed has been prepared with the following characteristics: responsibility for food safety lies with the establishment operator, while the competent authority of the Member State verifies correct implementation of the new rules. Production should be based on good hygienic practice and HACCP principles and products are subject to microbiological criteria and temperature limits. The proposals deal with a variety of food types and cover the entire food chain (“from stable to table”).

### General Food Law

The general food law (Regulation (EC) No. 178/2002<sup>1</sup>) lays down guiding principles and establishes common definitions. Furthermore, the Regulation puts the overall responsibility for producing safe food on the food business operator. It requires the food business operator to have a system in place enabling them to identify the immediate supplier(s) and immediate customer(s) of their products in order to ensure traceability. Other issues that are covered within this Regulation are the principles of risk analysis, the precautionary principle and withdrawal of food from the market by the food business operator if safety is at stake. Finally, it lays down the principles and requirements for the rapid alert system for food and feed and for the establishment of a European Food Safety Authority.

### Hygiene package

The “hygiene package” consists of a total of five legislative parts, of which four were adopted in April 2004, and provided the Member States and the stakeholders with a preparatory period of 18 months before becoming applicable with effect from 1 January 2006. The package consists of the following parts:

- Regulation (EC) No 852/2004 on the hygiene of foodstuffs<sup>2</sup>
- Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin<sup>3</sup>

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<sup>1</sup> OJ L 31, 1.2.2002, p. 1

<sup>2</sup> OJ L 226, 25.6.2004, p. 3

<sup>3</sup> OJ L 226, 25.6.2004, p. 22

- Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>4</sup>
- Council Directive 2002/99/EC<sup>5</sup>, which deals with animal health issues
- Directive 2004/41/EC<sup>6</sup>, which repeals the old legislation, a total of 17 Directives.

#### **Regulation (EC) No 852/2004**

The Regulation lays down general hygiene requirements to be respected by food businesses at all stages of the food chain including primary production. The Regulation does not apply to small quantities of primary products supplied directly by the producer to the final consumer or to local retail establishments directly supplying the final consumer.

The Regulation requires all food business operators to put in place, implement and maintain a permanent procedure based on Hazard Analysis and Critical Control Point (HACCP) principles with the exception of those involved in primary production. Food hygiene is the result of the implementation by food businesses of prerequisite requirements (such as concerning infrastructure and equipment, pest control, water quality, personal hygiene, etc.) and procedures based on the HACCP principles. The prerequisite requirements provide the foundation for effective HACCP implementation and should be in place before a HACCP based procedure is established. The prerequisite requirements to be respected are laid down in an annex of the Regulation. The Regulation allows the HACCP based procedures to be implemented with flexibility so as to ensure that they can be applied in all situations. Guides to good practice for hygiene and for the application of the HACCP principles developed by the food business sectors themselves, either at national or at Community level, should help businesses to implement HACCP-based procedures tailored to the characteristics of their production.

In addition, the Regulation requires food businesses to be registered with the competent authority, this being a simple procedure whereby the competent authority is informed about the address of the establishment and the activity carried out.

#### **Regulation (EC) No 853/2004**

The Regulation lays down the hygiene requirements to be respected by food businesses handling food of animal origin such as meat, live bivalve molluscs, fishery products, raw milk and dairy products, eggs and egg products, frogs' legs and snails, collagen and gelatine at all stages of the food chain. The Regulation does not apply to retail, which for food hygiene purposes means all activities involving direct sale or supply of food of animal origin to the final consumer. In such cases Regulation (EC) 852/2004 will apply. Establishments (except those carrying out only primary production, transport operations, the storage of products not requiring temperature controlled storage conditions or most retail operations) handling products for which the Regulation lays down requirements in an annex, must be approved. Approval procedures involve an on-site visit by the competent authority to verify if the establishment fulfils all the requirements concerning infrastructure, equipment and hygiene.

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<sup>4</sup> OJ L 226, 25.6.2004, p. 83

<sup>5</sup> OJ L 18, 23.1.2003, p. 11

<sup>6</sup> OJ L 195, 2.6.2004, p. 12

**Regulation (EC) No 854/2004**

The Regulation deals, among other things, with the official controls of animals sent for slaughter, official controls with regard to fresh meat, fishery products, raw milk and dairy products and with procedures concerning imports. Modern meat inspection should be based on risk assessment and should prevent cross contamination in the slaughter hall. In addition, meat inspection can be improved by imposing stricter hygiene measures at the farm level and by requiring the farm operator to send relevant management and health information to the slaughterhouse for those animals that are to be slaughtered in the next 24 hours, called food chain information. These principles have been introduced in the Regulation.

**Regulation (EC) No 882/2004 (Official feed and food controls)<sup>7</sup>**

The Regulation on Official Feed and Food Controls is the result of a review of the existing Community rules on the subject, which were adopted separately for the animal feed sector, the food sector and the veterinary sector. It covers the entire range of activities covered by feed and food law, including animal health and animal welfare. It applies with effect from 1 January 2006, except for the provision on financing of official controls which applies with effect from 1 January 2007.

As a consequence of the new rules, the Member States have to reorganise their official controls systems so as to integrate controls at all stages of production and in all the concerned sectors, using the ‘farm to fork’ principles. They have to submit and annually update a general control plan for the implementation of feed and food legislation and to report annually on the implementation of that plan. National control plans and reports shall take into account guidelines drawn up by the Commission (as mentioned under point 9).

There will also be an evolution of the Community approach to controls. At present, Community controls in the Member States and in third countries are organised largely on a sectoral basis and are related to the mandates the Commission has in different sectoral legislation. By means of this Regulation the Community approach to controls will evolve. The Food and Veterinary Office’s role will be essentially based on audit with the main purpose to verify the efficiency of the control systems in the Member States and auditing the compliance or equivalence of third country legislation and control systems with EU rules. The requirement for all Member States to submit a multi-annual control plan will facilitate the carrying out of these audits. Account will also be taken of Member States’ own audits and of their annual reports.

The Regulation provides for a set of general rules applicable to the official controls of all feed and food at any stage of production, processing and distribution, whether produced within the EU, exported to or imported from third countries. In addition to these rules, there are other specific control measures which are important in order to maintain a high level of protection and therefore must be kept in place. This is, for example, the case for the specific veterinary control rules on imports of animals and food of animal origin or for the specific controls rules for organic products.

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<sup>7</sup> OJ L 191, 28.5.2004, p. 1

## Implementing measures

### 8.1. Implementing measures

A wide range of implementing measures has been adopted on the basis of the hygiene package as foreseen in Article 12 of Regulation (EC) 852/2004, Articles 9 and 11 of Regulation (EC) 853/2004 and Articles 16 and 18 of Regulation (EC) 854/2004.

The measures laid down in Commission Regulation (EC) 2074/2005<sup>8</sup> include provisions concerning food chain information, fishery products, recognised testing methods for detecting marine biotoxins, calcium content of mechanically separated meat, lists of establishments, model health certificates for a number of products (frogs' legs, snails, gelatine and collagen), a derogation for foods with traditional characteristics and a number of amendments to Regulations (EC) No 853/2004 and (EC) No 854/2004.

### 8.2. Transitional arrangements

The principle of granting transitional arrangements was agreed by the European Parliament and the Council through Article 12 of Regulation (EC) No 852/2004, Article 9 of Regulation (EC) No 853/2004 and Article 16 of Regulation (EC) No 854/2004. Transitional arrangements in respect of certain new provisions have been taken to permit a smooth change-over from the old to the new regime.

The measures laid down in Commission Regulation (EC) 2076/2005<sup>9</sup> include provisions concerning stocks of food of animal origin, placing of food of animal origin on national markets, materials bearing pre-printed health or identification marks, marking equipment, health import conditions, food chain information, composition criteria for minced meat, use of clean water, raw milk and dairy products, eggs and egg products, training of slaughterhouse staff, certification of establishments, accreditation of laboratories carrying out official controls and some amendments to Regulations (EC) No 853/2004 and (EC) No 854/2004.

### 8.3. Examination of meat for *Trichinella* parasites

The adoption of Directive 2004/41/EC on 21 April 2004 by the European Parliament and the Council resulted in the repeal of Council Directive 77/96/EEC, which specified in detail the examination for *Trichinella* of carcasses of swine, horses and other susceptible species. Commission Regulation (EC) 2075/2005<sup>10</sup> has retained many elements from the previous legislation such as the sampling procedure, the various examination techniques in the laboratory and the derogations granted. However, at the same time the Commission Regulation has introduced a number of new elements to increase food safety for the consumer and facilitate the sampling procedure for those establishments where the parasite has not been encountered for a long time. The new elements are the following:

- A larger amount of sample has to be collected and examined from those animal species that pose the greatest risk for infecting humans, mainly horses and wild boar;
- Freezing is no longer allowed to replace the examination of horsemeat (because in this host certain *Trichinella* species such as *T. spiralis*, *T. pseudospiralis* and *T. britovi* can survive freezing temperatures);

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<sup>8</sup> OJ L 338, 22.12.2005, p. 27

<sup>9</sup> OJ L 338, 22.12.2005, p. 83.

<sup>10</sup> OJ L 338, 22.12.2005, p. 60.

- The use of the trichoscopic method for examining meat samples is no longer allowed, because it fails to detect *T. pseudospiralis*. A transitional arrangement for four years will give the competent authority the possibility to switch to a more reliable examination method. A number of additional requirements have to be applied whenever the trichoscopic method is used;
- The most important regulatory change is the introduction of *Trichinella*-free holdings or category of holdings or regions having a negligible prevalence. The competent authority can recognise a holding as free from *Trichinella* following an on-site inspection. Animals coming from a *Trichinella*-free holding are exempted from examination for *Trichinella*. The derogation applies only to fattening pigs. Inspection procedures can be very much simplified when the competent authority decides to recognise a category of holdings as free from *Trichinella*. Finally, the draft Regulation provides the possibility for a Member State to declare a region as having a negligible prevalence for *Trichinella*. Third countries will be able to apply the derogation of declaring a holding as free from *Trichinella* as well.

#### 8.4. Regulation on microbiological criteria for foodstuffs

Previously existing microbiological criteria were reviewed taking into account recent developments in food microbiology and scientific advice from the European Food Safety Authority (EFSA). Commission Regulation (EC) No 2073/2005<sup>11</sup> revised these criteria and introduced additional ones. The main objectives of the Commission Regulation are to ensure a high level of consumer protection with regard to food safety and to harmonise the microbiological criteria in the Member States. In particular, the target of the Commission Regulation is to reduce the number of *Salmonella* and *Listeria* cases in humans. A main component of the Regulation is to set two different types of criteria for foodstuffs, which need to be complied with by the food business operator:

- A food safety criterion defining safety of a product or a batch applicable to products placed on the market
- A process hygiene criterion indicating the correct functioning of the manufacturing process.

Microbiological criteria have been laid down for certain micro-organisms which are common causes of foodborne diseases in humans, such as *Salmonella*, *Listeria*, *E. coli*, toxins produced by *Staphylococci* bacteria and histamine. If food safety criteria are exceeded, the batch has to be withdrawn from the market. Food safety criteria have been set for the following combinations of food category/micro-organism:

- A *Listeria* criterion for all ready-to-eat foods
- A *Salmonella* criterion for certain ready-to-eat foods, minced meat, meat preparations and meat products
- A criterion for staphylococcal toxins in certain types of cheeses and milk powder
- An *Enterobacteriaceae* criterion for dried infant formulae
- An *E. coli* criterion in live bivalve molluscs
- A histamine criterion for fishery products

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<sup>11</sup> OJ L 338, 22.12.2005, p. 1.

In addition, the Commission Regulation includes process hygiene criteria, such as *Enterobacteriaceae* and *Salmonella* in carcasses of slaughtered animals, *Staphylococci* in certain types of cheese, *E. coli* in pre-cut fruit and vegetables.

### **Guidance documents**

A number of guidance documents have been prepared to assist the food business operators and the competent authorities of the Member States with the implementation of the Hygiene Regulations (those with an \* have been placed on the DG SANCO internet site):

- Guidance document on Regulation (EC) No 852/2004\*
- Guidance document on Regulation (EC) No 853/2004\*
- Guidance document on the implementation of HACCP and facilitation of the implementation of the HACCP principles in certain food businesses\*
- Guidance document on community guides to good practice\*
- Guidance document on import requirements\*
- Guidance document on the preparation of multi-annual control plans as laid down in Regulation (EC) No 882/2004 (will be published as a Commission Decision)
- Guidance document laying down criteria for the conduct of audits (published as Commission Decision 2006/677/EC<sup>12</sup>)
- Guidance document on official controls, under Regulation (EC) No 882/2004, concerning microbiological sampling and testing of foodstuffs\*.

### **Future aspects**

#### *10.1. Treatment to remove surface contamination*

Article 3(2) of Regulation (EC) No 853/2004 provides a legal basis to permit a substance other than potable water to remove surface contamination from products of animal origin. Such a legal basis did not exist in the previous legislation (Directive 64/433 for red meat, Directive 71/118 for poultry meat, other Directives used to cross reference to the first mentioned), but is available now that Regulation (EC) No 853/2004 is applicable.

With the adoption of the hygiene package and the introduction of the HACCP principles in the entire food chain, establishments are obliged to improve their hygiene and processing procedures. Under such circumstances the use of substances to remove surface contamination of food of animal origin can be reconsidered. It is essential that a fully integrated control programme is applied throughout the entire food chain including on-farm, during transport and in the processing plant. Treatment to remove surface contamination might constitute a useful element in further reducing the number of pathogens, especially with regard to *Salmonella* and *Campylobacter*, provided an integrated control strategy is applied throughout the entire food chain. A draft Commission Regulation has been prepared to allow the use of a number of approved substances for the removal of surface contamination from poultry meat. The draft Commission Regulation is still under discussion.

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<sup>12</sup> OJ L 278, 10.10.2006, p. 15.

### *10.2. Risk-based meat inspection*

Meat inspection has focused traditionally on the detection of the major zoonotic diseases occurring in domestic animals, such as tuberculosis, trichinellosis, cysticercosis, etc. In order to detect these diseases it was necessary to palpate and incise various parts of each slaughtered animal. However, these diseases have either been largely eradicated from herds kept under modern management conditions or do not occur in the majority of the very young and generally healthy animals slaughtered nowadays. Moreover, it has been shown that meat inspection is in some specific cases not the most sensitive way to detect infestation (e.g. in the case of cysticercosis). Furthermore, micro-organisms that are of increasing zoonotic importance in modern animal husbandry systems, like *Salmonella* and *Campylobacter*, are readily transmitted from one carcase to the next by the various manipulations required to be performed during the traditional meat inspection procedures. Taking all these factors into account, a detailed visual inspection without any incision or palpation of slaughter animals might be sufficient to ensure food safety. However, under those circumstances it will be necessary to take efficient preventive measures during the rearing of the animals and to provide sufficient information to the slaughterhouse on the life history of the animals. A draft Commission Regulation has been prepared, which lays down detailed requirements for risk-based meat inspection of fattening pigs and young ruminants.