

Brussels, 22 December 2005

Questions and Answers on the new EU rules on food and feed hygiene and controls

Food and Feed Hygiene

Why did the Commission draw up new food and feed hygiene legislation?

The aim of the new food and feed hygiene legislation is to simplify, upgrade and consolidate EU rules, with a view to enhancing food safety and consumer protection. The Hygiene Package for food (which consists of 3 Regulations¹ and 2 Directives) and the Feed Hygiene Regulation are an integral part of the EU's "farm to fork" strategy for food safety. They provide for a single, transparent EU hygiene policy, applicable to all food and feed and at every point on the food chain. They seek to provide effective tools to ensure food safety and to manage potential food and feed crises.

What are the main provisions for food hygiene within the Hygiene Package?

Under the new rules for food hygiene, general measures are laid down for the production of all food, while specific rules are laid down for meat and meat products, bivalve molluscs, fishery products, milk and dairy products, eggs and egg products, frogs' legs and snails, animal fats and greaves, gelatine and collagen. Among the main provisions introduced by the new food hygiene legislation are:

- Responsibility for ensuring that food hygiene standards are met lies first and foremost with all food operators involved in the production, manufacture, processing, distribution or retail of the food.
- Primary producers must protect, as far as possible, primary products against contamination.
- Establishments involved in food production have to be registered and some will need to be approved by the competent authority
- The HACCP principles (see below) should be applied at every stage in the food chain except primary production
- Guides of good practice should be drawn up by the food business sector at national level for operators to follow.
- Technical requirements on infrastructure and equipment, food handling, water quality, pest control, the maintenance of the cold chain etc must be respected.
- The new rules can be applied in a flexible way, in particular with regard to traditional methods of production, food establishments in regions subject to geographical constraints and small businesses.
- Imported food has to meet the same high standards as EU products.

¹ Regulation 852/2004 on the hygiene of foodstuffs; Regulation 853/2004 laying down specific hygiene rules for food of animal origin; Regulation 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

What special measures are in place for meat under the food hygiene rules?

The general measures of the food hygiene legislation will apply for meat, but other more specific provisions are also laid down. There will be a new, risk-based approach to inspection, while still ensuring that the food safety practices are properly controlled. In the case of fattening pigs post-mortem inspection can be limited to a visual examination where all the food safety production rules have been applied, unless abnormalities are detected. There is also a clear division of responsibilities between the slaughterhouse operator and competent authorities when it comes to inspection. Mandatory documentation and reporting practices by operators will ensure a continuous information flow throughout the production chain. Fresh red meat will continue to be marked with a health mark, and from the beginning of 2006, meat products (like other food products of animal origin) will have to carry an identification mark. When sending animals to slaughter, farmers will have to register all health related problems and send this information to the slaughterhouse prior to sending the livestock. Some flexibility is provided in the rules to allow traditional meat production and processing methods to continue.

Who is responsible for meat inspection?

The inspection of live and slaughtered animals is the responsibility of official veterinarians. They may be assisted by official auxiliaries and, under specific circumstances and only for poultry and rabbit meat, by slaughterhouse staff. At least one official veterinarian needs to be present in the slaughterhouse throughout the inspection of live and slaughtered animals. Inspection of live animals on the farm by an approved veterinarian is also possible. Extensive, mandatory training is laid down for veterinarians, auxiliaries and slaughterhouse staff involved in meat inspection.

At cutting plants, an official vet or auxiliary must be present when meat is being worked upon, although this measure is flexible in terms of how frequently it must be applied (dependant on the risk assessment carried out by the competent authority).

What are the key features of the Regulation on feed hygiene?

The new Regulation on feed hygiene applies to the production of animal feed at all stages, including at primary level, i.e. on the farm. It will therefore provide for higher safety standards and improved traceability throughout the food chain. Under the new rules, operators are responsible for ensuring that the produce they intend to put on the EU market is safe. They will have to comply with the HACCP principles in the manufacture of feed, and keep records of production and marketing to ensure traceability. The feed hygiene Regulation lays down mandatory training for feed producers, and all operators will have to be registered with the national authorities. As with the food hygiene Regulation, the feed hygiene legislation foresees guides to good practice being set up, at either community or national level, which feed operators would be expected to follow. Stringent conditions for the storage, transport and handling of feed are also included in the Regulation, and imported feed will have to meet the same hygiene standards as EU feed.

What are the HACCP principles and who must apply them?

The new rules for both food and feed hygiene introduce Hazard Analysis and Critical Control Points (HACCP) principles for all business sectors except for the primary sector (farms). Food and feed businesses will have to establish, implement and maintain a permanent procedure based on the HACCP principles.

There are 7 HACCP principles:

- Identification of potential food safety risks through hazard analysis
- Identification of critical control points to prevent such hazards

- Establishment of critical limits
- Monitoring of the critical control points
- Corrective actions if something goes wrong
- Verification that monitoring is being properly carried out, corrective actions are being taken in time and measures are working effectively
- Documenting the process

Example of HACCP application: When carrying out a hazard analysis, slaughterhouse operators may decide to identify important critical control points such as the prevention of faecal contamination of carcasses or ensuring the correct temperature of carcasses during storage. Such critical control points must then be further monitored by the slaughterhouse operator. HACCP is a vital system to enhance food safety.

The system is a flexible one so as to be applicable in all situations, including in small businesses. The need for documentation and record keeping, for example, will be proportionate with the nature and the size of the food business. Guides for the application of the HACCP principles may also constitute a means to facilitate HACCP implementation.

Where does responsibility lie when it comes to food and feed hygiene?

Under the new legislation, food operators at each stage in the food chain are responsible for ensuring that EU hygiene rules are respected – farmers, processors, manufacturers, distributors, retailers and caterers. The obligation also lies with feed operators to guarantee the safety of any animal feed marketed. The competent authority in each Member State must control the situation through regular inspections and on-the-spot checks. All food and feed business operators need to be registered, and some businesses, such as slaughterhouses and cutting plants, need approval before they can operate. Moreover, certain establishments such as slaughterhouses and cutting plants must also guarantee other rules are complied with, such as animal welfare, humane killing procedures and the prevention of cross-contamination.

What provisions are made for small businesses and local producers?

The new legislation on food hygiene does provide some flexibility for small businesses, traditional food manufacturers and businesses in remote regions. For example, in slaughterhouses, this could include flexibility regarding the presence of a vet during post-mortem examination, or regarding the content and frequency of information the operator must deliver. The rules will not apply to primary production for domestic use, nor to local producers who wish to sell small quantities directly to the consumer e.g. farm gate sales or local retail shops.

Likewise, the Feed Hygiene Regulation provides derogations for local trade of small quantities of feed and the private production of feed given to animals for home consumption.

How will the hygiene rules affect imports?

Imported food and feed products have to meet EU food safety standards, including the hygiene rules. The import of products of animal origin is only allowed from countries and establishments placed on an EU list managed by the European Commission. (See below for how countries can be listed).

Official Food and Feed Controls

Why was new legislation drawn up for official food and feed controls?

The Regulation on Official Food and Feed Controls was one of the measures foreseen in the 2000 White Paper on Food Safety, and an integral part in applying the “farm to fork” food safety principle. Official controls on food and feed are reorganised so that they will now be carried out at all stages of production and in all sectors. Among the objectives of this legislation are: the improvement of national and EU control services by creating a clearer, more strategic and defined approach to controls; the provision of enforcement measures, both at national and EU level, to deal with non-compliance; and the development of a common risk-based regime for food and feed import controls.

What new measures does the Official Food and Feed Controls Regulation introduce?

Among other measures, the Regulation provides for:

- A harmonised EU-wide approach to the design and development of national food and feed control systems
- Administrative assistance and co-operation between competent national authorities where the results of official controls require action by more than one Member State
- General audits of national control systems against control plans, to verify the effectiveness of national measures
- Enforcement measures at national level to address problems of non-compliance with feed and food law, including animal health and welfare rules, as well as enforcement measures at EU level
- A common approach to imports of food and feed, including food of non-animal origin such as fruit and vegetables which were not previously covered
- The provision of technical assistance to developing third countries, including training of control officials from these countries;

Will any of the current official control measures remain in place?

The Regulation provides for new general rules applicable to controls for all food and feed production, whether produced within the EU or imported. However, specific controls that have already been established in order to deal with particular situations (e.g. residues, pesticides, BSE, zoonoses) will be kept in place. The Regulation does not rule out the development of more specific rules to deal with any additional problems that may arise in future.

Who is responsible for carrying out the controls under this legislation?

Under the official food and feed controls legislation, the focus is on defining the role and duties of the competent authorities. This Regulation does not, therefore, set out obligations for food and feed operators, although it complements the hygiene legislation where operators' responsibilities are clearly laid down and it contains procedures that will have an effect on operators (e.g. import procedures).

National control authorities must meet a number of operational criteria in order to ensure their efficiency, effectiveness and impartiality. They shall, in particular, have access to a sufficient number of suitably qualified staff and adequate resources, and implement documented control procedures. In addition to current requirements for contingency plans in the feed and veterinary sectors, contingency plans for food crises must be established and staff must be properly trained to implement these plans. Audits subject to independent scrutiny shall be carried out to ensure that the authorities achieve the objectives of this Regulation.

Member States will be required to submit and update a multi-annual control plan for the implementation of food and feed legislation, and to report annually on the implementation of that plan

The annual report shall also include information on how recommendations from previous Commission inspections and audit reports have been followed up, as well as actions taken to transpose new EU legislation.

What provisions are made for food and feed crises?

The Official Food and Feed Controls Regulation requires Member States to establish contingency plans for the management of a crisis in the food or feed sectors. These plans should set out the measures to be implemented where food and feed has been found to pose a serious risk to humans or animals. They must specify the authorities to be engaged, their powers and responsibilities, as well as the channels and procedures for transmitting information among the relevant actors.

What does the legislation foresee for sanctions?

Breaches of feed and food law, as well as animal health and welfare rules, may constitute a threat for human health, animal health and the environment. Such breaches should therefore be subject to effective, dissuasive and proportionate measures throughout the EU.

Two levels of sanctions are provided for at national level in the new legislation in the case of non-compliance by operators:

- Administrative sanctions, such as withdrawal or suspension of an approval, destruction or withdrawal of a product from the market or restriction of the scope and scale of activities.
- Criminal sanctions against non-compliant food operators may be imposed by Member States, according to the circumstances and to their national rules.

in addition, where the Commission has proof that a Member State's control system is inadequate, it can take special measures, together with the other Member States in the Standing Committee on the Food Chain and Animal Health, or in serious cases on its own initiative. These may include suspending the placing of a certain food or feed on the market or laying down special interim measures to protect human, animal or plant health, animal welfare or the environment.

What does the legislation foresee for control fees?

The Regulation requires that adequate financial resources should be available for organising official controls. Hence, the Member States must be able to levy fees to cover the costs of official controls. The legislation aims to establish common principles for the collection of these fees. Therefore, minimum recommended fees for food of animal origin are set out. The Regulation also states that if the competent authority detects a situation of non compliance which leads to expenses exceeding those for routine monitoring, these extra expenses can be charged to the non compliant food or feed business operator. In setting the level of fees, the Member States are requested to take into consideration a number of criteria in order to avoid, for example, excessive fees for small businesses or for businesses producing traditional products. With regard to fees applicable for import control, the Regulation establishes the rates for main import items directly, with a view to ensuring their uniform application and to avoid trade distortions.

How does the legislation provide for adequate expertise to carry out controls?

The Regulation imposes training requirements for control officials. In practice, this means that Member States must organise adequate and regular training for officials. In addition, provision is made for training at EU level. Such training is necessary in order to ensure a uniform application of the control requirements and of the decisions that are taken following controls.

What are the changes in import controls?

The import procedures for food and feed of animal origin do not change significantly. However, a new aspect of the legislation provides for the introduction of a more harmonised approach to controls on imports of food and feed of non-animal origin from third countries, such as fruit and vegetables or cereals. The frequency of controls on these imports will be based on risk. In addition, provision is made for drawing up a list of products of non-animal origin which are known to potentially pose serious risks to human or animal health, e.g. products which can be contaminated with aflatoxins. It is proposed that these products should be subject to stricter scrutiny and checking at the point of entry, as is the case for products of animal origin.

Does the official food and feed controls Regulation have an impact outside the EU?

For all imported food and feed, the general principle is that the product must meet EU food and feed safety standards or conditions recognised by the Community to be at least equivalent to EU standards.

Under current arrangements, third countries wishing to export products of animal origin to the EU must be authorised for the relevant commodity and the products must come from an EU approved establishment. In order to be included on this EU list, third countries must provide guarantees that exports to the EU meet the standards prescribed in the relevant EU legislation. There is flexibility for the manner in which guarantees can be presented, but an example would be the provision of detailed information on the organisation and management of sanitary control systems, and results of national controls. Guarantees are verified by on-the-spot-inspections by the Commission's Food and Veterinary Office (FVO).

A similar system where third countries are approved and their establishments listed does not exist for food and feed of non-animal origin, nor is it systematically introduced under the new rules. However, the new legislation provides for procedures that would allow the import procedures for feed and food of non-animal origin to be reinforced where greater risks appear to warrant it. Finally third countries may be requested, in accordance with the Sanitary and Phytosanitary (SPS) provisions, to provide information on their food and feed safety systems.

Will this new legislation be difficult for developing countries to comply with?

The Regulation provides for a full range of initiatives to make it easier for developing countries to implement the EU food and feed control requirements. The following measures, amongst others, may be adopted and maintained so long as they have a demonstrable effect to ensure that developing countries are able to comply with the provisions of this Regulation:

- Phased introduction of certain specific requirements
- Technical assistance projects
- Twinning projects between developing countries and Member States

- the development of guidelines to assist developing countries in organising official controls on products exported to the EU
- Visits by EU experts
- Participation of developing countries' control staff in the training courses organised in the EU.

The Commission has also drawn up a guidance document to assist developing countries in organising official controls on products destined for the EU market.

Will the EU provide any financial assistance to cover the costs of the new measures?

The Regulation introduces a number of activities that require financial input from the Community. These include the training of control officials, the standardisation of analysis methods, the designation of new reference laboratories etc. A new financial input of €13 million annually is provided for that purpose.

Microbiological Criteria for Foodstuffs

What are microbiological criteria?

Microbiological criteria are standards laid down for the permissible level microorganisms per unit of food, which can be used to assess the safety and quality of foods. The contamination of foodstuffs by certain microorganisms, such as salmonella, can present intrinsic health hazards. By setting microbiological criteria for food, the aim is to ensure that products which reach the market do not pose a risk to human health. Two types of microbiological criteria are laid down under the new legislation. Food safety criteria will apply to products placed on the market, while process hygiene criteria will apply during the manufacturing process.

Why have new microbiological criteria for foodstuffs been drawn up?

In revising, modernising and extending the microbiological criteria for foodstuffs, the aim of the Commission was to increase consumer protection and reduce the number of food-borne illnesses in the EU. The microbiological criteria Regulation will help with the implementation of food and feed hygiene legislation, as it can be used to verify the HACCP procedures and other hygiene control measures. National authorities can also use the criteria for official food and feed control purposes, when carrying out sampling and analysis as part of their controls.

Up to now, microbiological criteria were only set at EU level for certain foodstuffs of animal origin and for certain microbes, while some Member States set their own non-uniform microbiological criteria for other foodstuff-microbe combinations. The new Regulation harmonises the criteria which must be met throughout the EU, offering benefits for intra-community trade and third country exporters to the EU. It will also create a level playing field for EU food operators who will now have to comply with the same microbiological criteria, regardless of what Member State they are based in.

How were the new criteria defined?

The Commission drew up the new microbiological criteria based on new scientific advice by Scientific Committees and the European Food Safety Authority (EFSA) and in line with internationally approved principles laid down in Codex Alimentarius. Extensive consultations were also held with Member States and EU organisations involved in food production and safety.

What does the legislation cover?

The Regulation covers all the major food groups in relation to the pathogens such as salmonella and listeria, including certain foods not previously covered by EU legislation on microbiological criteria e.g. fruit and vegetables, ready-to-eat foods. Stringent salmonella criteria are now set for minced meat, meat preparations and meat products, whereby all five sample units of meat tested for salmonella must be negative. There is a temporary derogation which will allow Member States to apply less stringent criteria for cooked meat products intended only for the domestic market, on condition that they first notify the Commission and the other Member States that they intend to use this derogation and the products are labelled as such. The Regulation may be extended in the future to cover other pathogens such as Campylobacter and Bacillus, on which the recent EFSA opinion is now available.

Who does this Regulation apply to?

The Regulation on microbiological criteria for foodstuffs applies to all food operators involved in the production and handling of food. They have primary responsibility for ensuring that the criteria are adhered to, and must include sampling and testing plans within their food safety management plans. There is flexibility on the frequency of testing and the manner in which it should be carried out, proportionate to the size and nature of the business. Specific testing frequencies are only laid down for certain products e.g. carcasses, minced meat, meat preparations and mechanically separated meat.

The national authorities are required to verify that food operators comply with the legislation, and can also use the microbiological criteria when carrying out controls laid down in the Official Food and Feed Controls legislation.

What happens if the microbiological criteria are not met?

If the food safety criteria laid down in the legislation are not met, food operators are responsible for ensuring that the product is not put on the market or is withdrawn if already on the market. If process hygiene criteria are not met food business operators have to improve the hygiene of processes.

Helping with implementation

What are the implementing rules for the Food Hygiene Package?

The implementing rules for the hygiene package, adopted by the Commission on December 5th 2005, aim to make sure that the new hygiene legislation is properly interpreted and applied. They include provisions for food chain information, specific testing methods for marine biotoxins, lists of approved establishments, model health certificates for certain products, derogations for traditional foods and specific rules for the control of the parasite Trichinella in certain types of meat. Transitional arrangements until 31 December 2009 are also laid down for some of the new hygiene provisions, to allow a gradual change-over from the current to the new regime.

What are the guidance documents?

The Commission drew up 3 guidance documents on the new food hygiene legislation to provide advice and direction to food business operators and Member States on a number of different aspects of the Hygiene Package. The first 2 guidance documents aim to clarify a number of questions on the hygiene legislation, including the scope of the Regulations, procedural issues such as the registration and approval of establishments, and technical points related to certain products such as meat and milk. The third guidance document aims to assist all players in the food chain in understanding the application of the HACCP system