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## Questions and Answers on the proposed Regulation on Official Food and Feed Controls

### **What are the main changes in the new system?**

#### ***Why is a specific Regulation dealing with official food and feed controls being introduced?***

The Regulation is one of the measures announced in the White Paper on Food Safety. It reorganises official controls on food and feed so as to integrate controls at all stages of production and in all sectors, using “the farm to fork” principle. The basic principles relating to the responsibilities of EU Member State authorities are laid down in Regulation No. 178/2002, including the general principles of food law and establishing the European Food Safety Authority (EFSA). The Regulation on official food and feed controls describes in more detail how these basic principles shall be interpreted and implemented.

#### ***What is the new Regulation intended to achieve?***

The Regulation aims:

- To improve the efficiency of Member State control services through the introduction of performance criteria for the competent authorities, a better definition of tasks, harmonisation of the role of control services and integration of controls across the entire food and feed chain (“the farm to fork” principle);
- To improve the efficiency of the Commission control services by developing a more transparent, strategic and integrated approach to controls;
- To define enforcement measures, including sanctions, to be imposed in the case of non-compliance with food and feed law;
- To assist developing countries in meeting import requirements.

#### ***What new measures/initiatives are proposed?***

The proposal 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 authorities in the Member States where the results of official controls require action by more than one Member State;
- A common approach to imports of food and feed;

- The inclusion of general audits of national control systems against national control plans as part of the Commission's approach to verifying the effectiveness of national control systems;
- The corresponding inclusion of general audits as part of the Commission approach to verifying compliance or equivalence of third country legislation and control systems with EU requirements;
- The provision of technical assistance to developing third countries, including training of control officials from these countries;
- Administrative and criminal sanctions for non-compliance with food and feed law.

***How much is new / how much is a re-enactment of existing legislation?***

The Regulation provides for new general rules applicable to 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.

The following rules that are currently in place will be repealed and replaced by the provisions of the new Regulation: rules on sampling and analysis for the official control of feedingstuffs (Council Directive 70/373/EEC); rules on official inspections in the field of animal nutrition (Council Directive 95/53/EEC) and on the Official Control of Foodstuffs (Council Directives 89/379/EEC and 93/99/EC).

***Is the scope wider than existing measures?***

The principles set out in the proposed Regulation are generally applicable to all food and feed law and to animal health and animal welfare legislation. However, for certain areas of food law where there are already comprehensive and specific control measures in place to verify compliance with EU legislation, the Regulation will not have an impact. In certain cases the impact of the proposal will be limited to EU inspections and the requirement to present and report on a multi-annual control plan. The proposal also fills a number of loopholes that exist under current EU legislation. For example, it introduces a common approach on imports of food and it introduces a general requirement for official laboratories to be accredited.

***Will the new system imply more or less EU (FVO) inspections?***

The overall level of the Commission's Food and Veterinary Office (FVO) activity will not decrease. However, the new system of general audits will allow for a more integrated approach to inspections.

**Control systems**

***What are the main requirements for national control systems?***

The national control authorities shall meet a number of operational criteria that must ensure their efficiency, effectiveness and impartiality. They shall in particular have access to a sufficient number of suitably qualified staff 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.

The proposal requires controls to be carried out on imported food and feed with a control frequency based on risk. It also provides the possibility to delegate specific and defined tasks to non-governmental control bodies such as the analysis of samples by private accredited laboratories.

***Why is provision made for delegation of official controls by national competent authorities?***

This is to take account of developments in several Member States where certain control tasks have already been delegated. This applies particularly to laboratory examination of official samples. The proposal lays down criteria for such delegation in order to ensure that consumer protection is not compromised. It also recognises that certain control tasks cannot be delegated and provides for a procedure to define at EU level the tasks that can, or cannot, be delegated to such bodies. See next question.

***What type of official controls can be delegated?***

No specific list is proposed, but there is provision for the possibility of establishing a list of tasks that can be delegated. Criteria for which tasks may be delegated are laid down. These include: the tasks must be specific, the conditions under which the delegated competence shall be exercised must be accurately described, and there must be proof that the control body has the necessary expertise, equipment, infrastructure, and sufficient numbers of suitably qualified and experienced staff to carry out the control. In addition, the control body must be impartial and free from any conflict of interest.

***When controls are delegated, who remains ultimately responsible for ensuring the control is properly carried out?***

The Central Competent Authority remains ultimately responsible for ensuring that controls are carried out correctly. For the purpose of ensuring that tasks are properly performed, the control bodies shall be subject to audit by the delegating authority.

***Is there an increased role for operators of food and feed businesses?***

The proposal defines the obligations and duties of the competent authorities, not those of food and feed business operators. It brings into practice the principle laid down in the White Paper on Food Safety that there must be a clear distinction between the tasks of the competent authority and the food and feed operators. The proposal contains however procedures that will have an effect on food and feed business operators, in particular the procedures on food and feed imports.

Specific rules for operators are laid down in the relevant sectoral legislation such as the Regulation on the hygiene of foodstuffs and the Regulation laying down specific hygiene rules for food of animal origin.

***What systems will be put in place to ensure the reliability of operators' own controls?***

Official controls shall include the verification of the efficacy of control systems put in place by operators of food and feed businesses. These shall include on-the-spot controls to inspect and check premises, facilities and equipment including recording and measuring instruments, machinery, installations, and materials. Also included are the sampling and analysis of food and feed, checks on hygiene, examination of written, documentary or other records and examination and verification of the operators' control system and the results obtained from their own checks.

### ***Why is the establishment of further EU reference laboratories proposed?***

The existing network of EU Reference Laboratories (CRL) plays an important role in providing the scientific and technical support necessary to ensure a high level of consumer protection in the area of food safety. However, they currently only exist in the veterinary sector. There is need for similar specialised expertise in the areas of food and feed additives, food and feed contaminants, microbiological risks/zoonotic agents and articles intended to come into contact with foodstuffs. The proposal provides for new CRLs to be established to assist national laboratories in these areas.

### ***What are the changes in import controls?***

The current regime for controls on the import of products of animal origin remains in place. The Regulation provides for a more systematic and harmonised approach to controls on imports of food and feed of non-animal origin from third countries. In addition, provision is made for drawing up a list of products of non-animal origin, which are known to pose particular and serious risks to human or animal health, e.g. the possible contamination of certain products of plant origin with aflatoxins. It is proposed that these products should be subject to stricter scrutiny and checking at the point of import, including restricting import to a list of approved border inspection posts, as is the case for products of animal origin.

### ***How will a high level of expertise among control officials be ensured?***

The proposal 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.

### ***How will a number of new activities be financed?***

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

## **Impact on Member States**

### ***What type of plans/reports will member states have to forward to the Commission?***

Member States will be required to submit and annually update a high-level general 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 inspection and audit reports have been followed up, as well as actions taken to transpose new EU legislation.

The Regulation does not alter specific requirements for the submission of plans or reports already laid down in other EU legislation, such as contingency plans for animal health diseases or reports on residue surveillance.

### ***Is provision made for measures to be taken in case of emergencies?***

The proposal provides for Member States to establish contingency plans for the management of a crisis in the food and feed sectors. These plans 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.

### **Impact on third countries**

#### ***Will the new rules apply to third countries and how will they be applied in third countries?***

Yes. For all food and feed the general principle that the product meets or is equivalent to EU standards applies. In addition, under current arrangements, in order to export products of animal origin to the EU, the country must be approved for the relevant commodity and, the products must originate in an establishment which is approved to export to the EU. Lists are maintained at EU level of countries and establishments from which imports are permitted. Countries and establishments approved in this manner are commonly referred to as "listed". In order to be listed the third country concerned must provide guarantees that exports to the EU meet, or are equivalent to, the standards prescribed in the relevant EU legislation. There is no standardisation of the manner in which guarantees are presented. Guarantees are verified by on-the spot-inspections by the Commission's Food and Veterinary Office. In accordance with EU rules, the FVO's inspections in third countries currently only cover the veterinary and the feed sector. The proposed Regulation extends the FVO's role to include inspections in the food and plant health sectors.

For all food and feed, third countries will be required to present guarantees that exported products meet EU standards. These guarantees will take the form of control plans covering the relevant product sectors as well as records kept of the implementation of these controls. The control plans will be similar to the control plans and reports required from EU Member States. The control plans shall be proportionate and technically feasible taking account of the specific situation of the third country and the nature of the products exported. Guidelines will be drawn up to assist third countries in meeting these requirements. The new system should assist third countries in meeting EU standards by improving the transparency of the approval system and clarifying the requirements.

When the regulation enters into force specific import conditions for the import of food and feed may be drawn up depending on the type of product and risks associated with it. These conditions for the import of food and feed may include the establishment of lists of third countries from which food and feed may be imported. The new conditions may replace some, or all of the current import conditions. Pending the adoption of such rules current EU legislation setting down specific rules for import of food and feed will remain in force.

***What will be the position of developing countries that have difficulties conforming to the new requirements?***

The requirement to present national control plans will be introduced on a phased basis. Furthermore, the Regulation foresees the provision of technical assistance to developing third countries (such as sending EU experts to assist in organising controls and developing control plans and twinning projects). Officials of developing third countries will also be able to participate in special training programmes organised for control officials from EU Member States.

***What will happen to listed third countries following the introduction of the new system?***

Transitional measures shall apply to enable listed third countries (see previous question on how "listing" works) to have continued access to the EU market pending their assessment for approval under the new system. Listings and approvals already granted under the current assessment system will continue in force until new rules are adopted and countries are assessed in accordance with the new rules.

Third countries shall present guarantees that they meet Community import conditions in the form of national control plans. Following assessment of these guarantees new lists will be established in accordance with the specific rules.

**Impact on the role of EU controls**

***How will the new Regulation impact on EU (FVO) inspection missions?***

Two types of Commission control are provided for by the Regulation. Firstly, most routine inspections will be replaced by a general audit of the national control plan, which will seek to verify that the control plan has been properly implemented, and that the standards prescribed by EU food and feed law are met. These inspections will involve a multi-disciplined approach to audit all the main production sectors, involving larger inspection teams and a longer duration than the traditional sector-based inspections. Where necessary, these general audits will be supplemented by inspections of specific areas of production or legislation, for example in case of emergencies or where there are emerging or recurring problems.

***Will the Commission services still inspect production establishments, farms etc. in the course of missions?***

Yes, on-site visits to facilities such as farms and production establishments will be required to verify the implementation of control plans or specific legislation by national competent authorities.

***Will Commission reports be published?***

Finalised reports of inspection missions and the Commission's annual reports on the implementation of general control plans will be published in the usual manner on the Commission's website: [http://europa.eu.int/comm/food/fs/inspections/index\\_en.html](http://europa.eu.int/comm/food/fs/inspections/index_en.html). Reports are also sent to the relevant competent authorities in the Member States and to the European Parliament.

## **Sanctions & Fees**

### ***Why are sanctions being introduced?***

Administrative sanctions are already to some extent provided for in EU legislation. Veterinary legislation in particular requires for example the withdrawal of the approval number if establishments fail to comply with the food hygiene rules. Experience has shown however that the existing system of sanctions has not always been sufficient to ensure compliance. In many cases, the possibility of criminal sanctions in addition to administrative sanctions is necessary.

### ***What form will these sanctions take?***

Two levels of sanctions are provided for 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, restriction of the scope or scale of activities.
- Member States are required to impose criminal sanctions where serious offences against EU food and feed law are committed intentionally or through gross negligence.

In the case of Member States, where the Commission has proof that a control system is inadequate, it can, together with the other Member States within the Standing Committee or in serious cases on its own initiative, take special measures. These may include suspending the placing of a certain food or feed on the market as well as laying down special conditions or other interim measures to protect human, animal or plant health, animal welfare or the environment. This procedure supplements the emergency measure laid down in Article 53 of Regulation 178/2002 which can only be applied if feed or food that is likely to constitute a serious risk to human health, animal health or the environment is placed on the market.

### ***Who will apply the sanctions?***

Competent authorities in Member States will apply the administrative and criminal sanctions. The Commission will intervene with interim measures against Member States, when required, together with the Member States within the Standing Committee or in serious cases on its own initiative.

### ***Will fees be increased to pay for the additional controls?***

The proposal lays down that Member States must ensure that adequate financial resources are available for official controls. The means by which this requirement must be fulfilled is, as a matter of subsidiarity, left to the Member States.

If Member States impose inspection fees on food and feed business operators, they will have to respect a number of criteria so as to avoid for example excessive fees for small businesses. The proposal also lays down that if the competent authority displays non-compliance, and if such non-compliance leads to expenses that exceed the normal expenses for routine monitoring, these extra expenses can be charged to the food or feed business operator responsible for the non-compliance.

## **Current control system for the implementation of EU food and feed law**

The Commission has three main instruments at its disposal to ensure that EU legislation is properly implemented and enforced. It verifies the transposition by Member States of EU legislation into national laws and analyses reports received from Member States and third countries on the application of aspects of EU legislation, such as national residue programmes and animal feed controls. Significantly, it also carries out inspections in Member States and third countries to check the implementation and enforcement of EU legislation by national competent authorities.

The control function at EU level is mainly the responsibility of the Commission's Food and Veterinary Office (FVO), a directorate of DG Health and Consumer Protection established in 1997. Its main task is to carry out on-the-spot inspections to evaluate national control systems, to report on its findings and to follow up the action taken by national competent authorities in response to its reports. Inspection missions are organised on a sectoral or thematic basis concentrating on a specific area of EU law, e.g. specific aspects of meat or dairy production, residues, fishery products, BSE controls, specific aspects of plant health, animal health or welfare or general food hygiene. Inspections involve verifying the transposition and implementation of the relevant legislation and the effectiveness of its application.

Over recent years, the FVO has developed its working methods and procedures in several important respects. It has moved away from the focus on standards in individual production establishments towards evaluating the performance of the relevant competent authority in the overall operation of national control systems, especially its ability to transpose, implement and enforce EU legislative standards effectively. This approach will be reinforced as national control programmes are developed within the new EU framework described in the proposed Regulation on food and feed controls.