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Focus

Revision of regulation (EC) No. 882/2004 on the organisation of official controls

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The European Commission recently adopted (6 May 2013) a set of four proposed regulations concerning animal health, plant health, plant reproductive material, and official controls[1]. This last text will replace Regulation (EC) No. 882/2004 on official controls, drawn up as a part of the "Hygiene Package" to cover a broader scope, especially concerning the plant sector. It will provide a basic text governing the organisation and quality of official controls, both as regards production in the various Member States and the importing of products and animals from outside the EU. The next stage is for the European legislative bodies, the Parliament and the Council, to examine the proposals and bring them into law in their final form.

Background

Although it was drawn up as part of the "Hygiene Package"[2], the current Regulation (EC) No. 882/2004, known as the "Official Controls" Regulation, already covers animal health and welfare as well as food legislation. The three other Regulations will replace a series of Directives, consisting of more than 60 texts on animal health, Directive (EC) No. 2000/29 on plant health and 12 directives concerning plant reproductive material, with provisions directly applicable to all Member States.
The revision of Regulation (EC) No. 882/2004 is a part of this process and addresses the need to adapt the rules governing official controls for all the sectors concerned. It also provides an opportunity to improve the current provisions and clarify certain points in light of acquired experience. The proposed Regulation is therefore broader in scope than the current version and has been drafted with a view to bringing greater legal consistency to all the texts covering the sector. Before adoption, it will be supplemented by about 40 delegated acts adopted by the European Commission (EC) and a similar number of implementing acts approved in technical committees.

Broader coverage and qualitative criteria for the control services

The proposal clarifies and broadens its field, which, beyond the areas of foodstuffs, plant health, animal health and welfare, and plant reproductive material, will cover fields closely related to the food chain such as animal by-products, GMOs, and plant protection products. Indications of quality and origin will now be mentioned explicitly.
In addition to official controls for verifying compliance with regulations, the proposal introduces the notion of "other official activities" to cover such activities as epidemiological surveillance, or combating animal diseases or pests.
The qualitative criteria, which will apply to the competent authorities and the organisation of controls, continue to follow the current principles embodied in Regulation (EC) No. 882/2004:

- among other requirements, the competent authorities, designated by each Member State, must be staffed by personnel with no conflicts of interest, qualified and of sufficient number, and have a sufficient number of laboratories and the legal power to carry out their missions. They must set up "internal" audits, their officials must have an obligation of discretion, etc.;
- controls must be carried out in accordance with risk, especially the risk of non-compliance, and depending on the nature of the hazard. The transparency of the results of controls is clarified and a programme for the verification and efficacy of controls and procedures must be set up.

One of the new items is the requirement for operators to grant control services access to IT units and systems, and to cooperate with them in carrying out the controls.

Coordination with control procedures in specific fields

In order to make the legislative package as consistent as possible, a series of ten articles provides a legal connection with the provisions to be adopted by delegated acts in different areas, in order to harmonise certain control procedures at European level and retain some of the existing provisions.
For example, the provisions concerning controls on residues of veterinary drugs and prohibited substances will be retained in a text based on the new "Official controls" Regulation, and Directive 96/23/EC will be repealed.

Delegation of activities adapted for better application in different sectors

Under the proposals, it will remain possible to delegate control activities or other official activities, as long as delegatees satisfy certain strict quality criteria, which may even include certification. To facilitate the protection of animal health, an individual, such as a veterinarian, can also be delegated to carry out missions on behalf of the competent authorities.

An entire chapter dedicated to analyses and laboratories

The choice of analytical methods to be used (Article 33)[3] favours harmonisation at European level and gives priority to the methods stipulated in European texts. If no clear choice

1. http://www.ansespro.fr/euroreference/Documents/ER10-Actu3.pdf
2. The "Hygiene Package" includes Regulations (EC) Nos. 178/2002, 882/2004, 852/2004, 853/2004, 854/2004, 183/2005 and several supplementary acts of application.
3. Article numbers are those of the provisional document of December 2013 but may differ in the final version.

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emerges, the method to be used must be selected according to a cascade approach: (i) internationally recognised methods, accepted by the European Committee for Standardization (CEN), or (ii) methods validated in terms of scientific protocols accepted internationally, developed or recommended by European Union Reference Laboratories (EURLs), or (iii) methods stipulated in national regulations, or (iv) methods validated, developed or recommended by National Reference Laboratories (NRLs), or lastly (v) validated *ad hoc* methods.
A section has been added to cover cases of analyses needing to be performed urgently, in the absence of available methods and satisfying the above criteria: NRLs or other competent laboratories are granted the possibility of using non-validated methods if necessary.
Article 34 maintains the right for operators whose animals or goods are subject to controls to benefit from a second expert opinion, but this process may be limited by application texts (implementing acts) in the future.
As regards sampling (Article 35), a new provision has been added enabling samples to be collected for controls via the Internet without identifying a "controller".
Regarding official laboratories responsible for analysis in the context of official controls (Articles 36 to 41), these are to be designated on the basis of the laboratory's certification, although temporary exemptions are possible to take account of new or changing methods and/or emergency situations, as well as the inspection of meat for *Trichinella*. Laboratories specialising in the analysis of seeds and plants are also exempt from the requirement to be certified. The text also makes it possible for the requirement to be certified to be relaxed at a later date in certain cases. The proposal adds the requirement, for official laboratories, to participate in inter-laboratory proficiency tests organised by the NRL or the EURL.
The competent authorities must ensure that the conditions for designating laboratories are satisfied, via audits and inspections.

Controls on imported animals and goods

With a view to simplifying and harmonising procedures between sectors, the proposal modifies the provisions of Regulation (EC) No. 882/2004 and the procedures for controlling products and animals entering the EU. It contributes to the prioritising of controls in accordance with risk. A new title, "border inspection post", replaces the various titles specific to each sector concerning the mandatory controls required for customs clearance. Different instruments, such as the Common Health Entry Document, will be created. Control procedures and the measures to be taken are defined on the basis of a common foundation, and cooperation with the other authorities such as the Customs Services will be strengthened. There is no question of inspecting a living animal in the same way as one would a can of food, but of using the same procedures and a common vocabulary.

Funding for controls and other official activities

The Member States remain entirely responsible for funding controls and "other activities" but the issue of the financial participation of operators is considerably modified compared to the current rules, under which fees are mandatory for certain sectors and allow those Member States who so wish to impose fees in the other sectors.
The basic principle that the entire cost of controls should be covered by the operators via "fees" charged by the competent authorities is considerably moderated by an exemption for micro-enterprises (those with turnover below €2 million and employing fewer than 10 people). This means that only a very small number of operators would be involved in financing controls via a system of fees, which would therefore apply only to companies above a certain size.
This is no doubt the section which will give rise to the most discussions and debates when the text comes up for examination.

Official certification

The Commission has taken on a considerable challenge, as different sectors use the terms "certification" and "certificate" with different meanings. For example, "certification" can cover both official signed certificates, such as health certificates for exports or certificates for the trade of living animals between Member States, and official declarations by professionals, as is the case in the seed and plant sector, with express authorisation from the control authorities.

Laboratories and reference centres

Reference activities are not limited to laboratory analyses, and the new provisions (Articles 91 to 97) enable the European Commission to designate EU reference centres in the plant reproductive material sector and for animal welfare.
The European Union Reference Laboratories (EURLs) are of course retained, and the conditions for their designation remain essentially unchanged.
The missions of the EURLs are clarified and extended, in coordination with those of the national reference laboratories (NRLs) designated by each Member State. Their principal mission is to improve and harmonise methods for analysis, testing and diagnosis, as well as to contribute to the quality and uniformity of the analytical data generated. This mission was not quite so explicitly defined in the current regulations and the proposed text confirms it as one of the core missions of an EURL. Other missions are added: (i) to collaborate with EFSA and the ECDC, (ii) to provide active support in the diagnosis of outbreaks of foodborne, zoonotic or animal diseases or plant pests, by examining pathogens sent to them for confirmation, characterisation and taxonomic or epizootic studies, and (iii) to set up and maintain reference collections of pathogens or plant pests, as relevant to their field of competence.
EURLs must publish lists of NRLs.
With the extended scope of the Regulation, the field of plant health is set to benefit the most from the EURL/NRL system across the EU, which already operates in the food and animal health sectors.
The conditions governing the designation and missions of NRLs (Articles 98 to 99) are essentially retained, with a few minor changes.

General responsibilities incumbent upon the competent authorities

The proposed text clarifies the relationship between the competent authorities of the different Member States and with the European Commission, with a view to improving application of the regulations. The procedures for exchanging information and for cooperation are an extension of the procedures for emergencies, such as those covered by the Rapid Alert System for Feed and Food (RSAFF).

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Member States are still required to prepare a multiannual control plan and to furnish an annual report. One new feature should be noted however: the European Commission has retained the option of using delegated acts to determine such elements as criteria for categorising risks according to the activities of operators, control priorities, and performance indicators, which the Member States will be obliged to incorporate in their control programmes. Emergency plans concerning foodstuffs and animal feed must be drawn up. In animal and plant health, these emergency plans are governed by the regulations for each sector.
A specific section is dedicated to "coercive" measures and sanctions that must be set up by the competent authorities.

The Commission retains an important role with several new initiatives

Commission controls are maintained with the principal objective of inspecting the control system implemented by the competent authorities of the Member States. These inspections also concern non-member countries regarding the procedure governing the conditions for entry into the EU of animals and goods covered by the text.
The European training program for the officials of the competent authorities (entitled Better Training for Safer Food – BTSF) is extended to cover the entire field of the Regulation.
An overall system for information management is planned, incorporating the current TRACES information system on imports and trade and enabling data to be transmitted to the Commission.

Phasing in

The new regulation will be phased in between one and three (or even five) years after the final version passing into law comes into force, and its timing will be coordinated with the entry into force of the three other sector-based texts.

The legislative procedure

The European Parliament and Council of Ministers began examining the text and the three other proposals at the end of the first half of 2013. It is important that the "legislative package" remain internally consistent and the work can be expected to take several months. The French positions have been prepared by all the departments concerned, coordinated by the Secretary-General for European Affairs.

Conclusion

The proposed Commission Regulation for "official controls and other official activities" retains most of the principles of Regulation (EC) No. 882/2004 as regards the "technical" organisation of controls, while attempting to harmonise the way they are applied in the different sectors. Harmonised procedures for import controls will be common to all types of products and animals. Reference activities will be given greater importance by the creation of reference centres for animal welfare and in the area of seeds and plants. Concerning analytical laboratories, European Union Reference Laboratories and National Reference Laboratories will continue to contribute to the quality of the system, with clearly-defined and broadened missions. The issue of financing, however, will considerably modify the current system.