



COUNCIL OF THE EUROPEAN UNION Brussels, 9 July 2009 (10.07) (OR. fr)

11948/09

AGRILEG 126 DENLEG 56

COVER NOTE	
from:	Secretary-General of the European Commission,
	signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	8 July 2009
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND TO THE COUNCIL on the application of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules

Delegations will find attached Commission document COM(2009) 334 final.

Encl.: COM(2009) 334 final

COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 8.7.2009 COM(2009) 334 final

#### REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND TO THE COUNCIL

on the application of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules

# TABLE OF CONTENTS

1.	Executive summary	3
2.	SCOPE OF REGULATION (EC) No 882/2004	4
2.1.	Sectoral legislation on official controls: residues of veterinary medicines and of pesticides	4
2.2.	Plant Health	5
3.	STATE OF PLAY OF IMPLEMENTATION	6
3.1.	Commission Guidelines	6
3.2.	Multiannual National Control Plans (MANCPs) and annual reports	6
3.3.	General Audits	7
3.4.	Official controls on imported feed and food	7
3.5.	Article 23 on approval of pre-export checks	9
3.6.	Better Training for Safer Food	10
3.7.	Community Reference Laboratories (CRLs)	10
3.8.	Technical updates	11
4.	FEES	12
4.1.	Context	12
4.2.	Scope of the evaluation	12
4.3.	Main conclusions resulting from the study	12
4.4.	Scenarios for change	13

#### **1. EXECUTIVE SUMMARY**

Article 65 of Regulation (EC) No 882/2004of the European Parliament and Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and welfare rules<sup>1</sup> (the "Official Controls Regulation", hereafter: the "OCR") requires the Commission to submit a report to the European Parliament and Council, in particular to review the experience gained from the application of the Regulation.

Such report should consider the following issues:

- "(a) re-evaluating the scope, in relation to animal health and animal welfare;
- (b) ensuring that other sectors contribute to the financing of official controls by extending the list of activities referred to in Annex IV, section A and in Annex V, section A, and taking into account in particular the impact of the Community feed and food hygiene legislation after its adoption;
- (c) setting updated minimum rates for fees referred to in Annex IV, section B and in Annex V, section B, taking into account in particular risk factors".

As regards the scope of the Regulation, in relation to animal health and animal welfare, experience gained so far does not call for a review of the scope of the Regulation as currently defined in Article 1. On the other hand, ongoing discussions in view of the modernisation and simplification of two significant sectors might help clarifying the relationship between the general framework established by the Regulation and existing sectoral legislation. This is particularly the case as regards the ongoing review activities carried out as a follow up to the Animal Health Strategy  $(2007-2013)^2$ , which aim, inter alia at establishing a single regulatory framework for animal health ("Animal Health Law"), and those activities that will result from the forthcoming review of the existing Plant Health acquis (Plant Health Strategy). In addition, consideration should be given to the need to ensure that existing sectoral Community provisions applicable to control activities in specific fields (on residues of veterinary medicines and of pesticides, for instance) are consistent with the principles and requirements of the Regulation. **Section 2** of the report deals with this issue.

**Section 3** of this report gives an account of the main actions and initiatives developed in implementing the Regulation, looking at the experience gained since 1 January 2006. Member States are progressively gaining hands-on experience in the preparation and implementation of their Multi-annual control plans (MANCPs), which are also being used by the Commission Food and Veterinary Office (FVO) in the framework of its regular General Audit missions. National Annual Reports are also an important feature of the new framework for official controls established by the OCR although the experience with such reports is too limited to allow an in-depth analysis to be carried out at this stage or conclusion to be drawn so far.

<sup>&</sup>lt;sup>1</sup> OJ L 165, 30.4.2004, p. 1.

A new Animal Health Strategy for the European Union (2007-2013) where "Prevention is better than cure". Communication from the Commission to the Council, the European Parliament, the European Economic and social committee and the Committee of the Regions. COM 539 (2007) final.

Article 65 requires that special attention be given to the issue of fees collected for the financing of official controls ("inspection fees"). Section 4 of the report gives account of the current state of play of discussions and reflections on this rather complex issue, on the basis of the results of a recent study carried out for the Commission by an external evaluator.

The study in question provides the Commission with a valuable insight of the current functioning of the fees system, identifies some shortcomings in the current legislative framework applicable to inspection fees and in its implementation by Member States and discusses the possible need to review some of the features of that framework. According to the study, a number of possible options for change may be considered, to enable Member States to ensure delivery on the objective laid down in Article 26 of the OCR, according to which "*Member States shall ensure that adequate financial resources are available to provide the necessary staff and other resources for official controls*". For which it suggests possible future scenarios, ranging from full harmonisation of the features of the fees' system to increased flexibility for Member States in the implementation of the system, whilst ensuring transparency and clarity of the functioning of the system across Member States.

Further analyses on the issues raised by the study are needed, including a public discussion with stakeholders on the results of the evaluation carried out, and an impact assessment of available options for change. The Commission intends to launch such impact assessment in the course of 2009.

## 2. SCOPE OF REGULATION (EC) No 882/2004

# 2.1. Sectoral legislation on official controls: residues of veterinary medicines and of pesticides

Although official controls also include controls on residues of veterinary medicines and pesticides, the OCR makes reference to the necessity to maintain in force the more specific rules existing in the area of feed and food and animal health, and stipulates in particular to keep in place Council Directive 96/23/EC on measures to monitor certain substances and residues thereof<sup>3</sup> and Council Directive 86/362/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on cereals<sup>4</sup>, which was subsequently repealed by Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin<sup>5</sup> and amending Council Directive 91/414/EEC.

Directive 96/23/EC requires Member States to implement national residue control plans which are annually submitted to the Commission together with the results of the implementation in the previous year and the actions taken as follow-up of non-complaint results. It also establishes the minimum number of samples that shall be analysed for each food commodity according to the national production without taking into account other elements which may impact on the risk assessment (e.g. rearing

<sup>&</sup>lt;sup>3</sup> OJ L 125, 23.5.2006, p. 10.

OJ L 221, 7.8.1986, p. 37.

<sup>&</sup>lt;sup>5</sup> OJ L 70, 16.3.2005, p. 1.

practices, medicinal products authorised, etc). Apart from residues of veterinary medicines and pesticides, Annex I and II to Directive 96/23/EC also include environmental contaminants<sup>6</sup> among the group of substances to be controlled in the framework of residue control plans.

A Reflection Paper was published already in 2003 launching a broad consultation process on the technical aspects of the Directive<sup>7</sup>. During this process stakeholders expressed great interest in a review of this Directive and in the clarification of the line of demarcation between controls of veterinary medicines and contaminants in general in order to ensure alignment with the OCR.

Regulation (EC) No 396/2005 on pesticides contains a number of articles which relate directly to controls (Articles 26-30), aiming at verifying randomly compliance with maximum residue levels (MRLs) at Community level, complemented by targeted controls at Member State level. The Regulation (Articles 31-32) also contains annual reporting requirements. Some differences in the approach taken between Regulation (EC) No 396/2005 and the provisions of the OCR are the result of the separate, simultaneous interinstitutional negotiations that led to the adoption of the two acts.

With the objective of better regulation in mind, consideration should be given to the possibility of integrating through the necessary legislative changes the rules currently applicable to official controls on pesticides, contaminants and residues of pharmacologically active substances in food into the framework of the OCR, so as to rationalise and simplify the overall legislative framework whilst allowing the flexibility necessary to ensure the integration of both sectors into Member States' MANCPs.

#### 2.2. Plant Health

In the Plant Health sector, Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community<sup>8</sup> establishes sectoral control rules. Official controls in that area are therefore not governed by the OCR except for the provisions applicable to the establishment of, and annual reporting on, MANCPs and to Community inspections within the Member States and third countries (Articles 41 to 46).

<sup>&</sup>lt;sup>6</sup> Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food defines contaminant as any substance not intentionally added to food which is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food, or as a result of environmental contamination. Monitoring of other contaminants than those included in the annexes to Directive 96/23/CE is organised in the framework of contaminants legislation.

As result of this Regulation (EC) No 2377/90 has been amended by Regulation (EC) No xxx/2009 of the European Parliament and the Council laying down Community Procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (COD 2007/0064).
OJ L 169, 10.7.2000, p. 1.

As part of a more general exercise aimed at evaluating the existing acquis in the Plant Health area<sup>9</sup>, consideration will be given to the need to streamline the provisions on official controls of Directive 2000/29/EC and those of the OCR.

#### **3.** STATE OF PLAY OF IMPLEMENTATION

#### 3.1. Commission Guidelines

The OCR introduces a number of new obligations for the Member States regarding the planning, auditing and reporting of their official control activities. The Commission in accordance with Article 43 of the OCR has drawn up guidelines to assist Member States in meeting these requirements. The following Commission Decisions were adopted to this end:

- Commission Decision 2006/677/EC of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare<sup>10</sup>.
- Commission Decision 2007/363/EC of 21 May 2007 on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council.<sup>11</sup>
- Commission Decision 2008/654/EC of 24 July 2008 on guidelines to assist Member States in preparing the annual report on the single integrated multiannual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and the Council<sup>12</sup>.

The Commission organises regularly working groups to further develop the implementation of the guidelines and to provide assistance to the Member States in their preparation of the MANCPs, reports and audits.

## 3.2. Multiannual National Control Plans (MANCPs) and annual reports

According to Articles 41 and 42 of the OCR, Member States are required to prepare and implement a single integrated multi-annual national control plan (MANCP) not later than 1 January 2007 and to provide the Commission with an up-to-date copy upon request.

All Member States have provided the Commission with their MANCPs and they are being evaluated in the framework of the Commission Food and Veterinary Office (FVO) General Audits (see chapter 3.3).

<sup>&</sup>lt;sup>9</sup> The Council called on the Commission to evaluate the current plant health acquis and to consider possible modifications to it, and subsequently present a proposal for a Community plant health strategy. The Commission has launched the evaluation, and a study is to start by mid 2009.

<sup>&</sup>lt;sup>10</sup> OJ L 278, 10.10.2006, p. 15.

<sup>&</sup>lt;sup>11</sup> OJ L 138, 30.5.2007, p. 24.

<sup>&</sup>lt;sup>12</sup> OJ L 214, 9.8.2008, p. 56.

According to Article 44, one year after starting the implementation of MANCPs, and subsequently every year, Member States shall submit to the Commission a report indicating any amendment of the MANCPs, the results of controls and audits, the type and number of cases of non-compliance and the actions taking to ensure effective operation and enforcement. To date, the Commission has received the annual reports of 26 Member States (Portugal has not submitted an annual report because its first MANCP was not put in place until 2008 due to restructuring of its control services and therefore the first report will be made in the 2009 reporting cycle).

#### **3.3.** General Audits

Article 45 of the OCR requires that Commission experts shall carry out general and specific audits in Member States to verify that official controls take place in the Member States in accordance with the MANCPs and in conformity with Community law.

The Commission's FVO carries out the general audits of the Member States on a threeyear cycle. In 2007 general audits were conducted in Austria and the Netherlands and in 2008 in further six Member States (Germany, Estonia, Hungary, Ireland, Slovakia and Spain). Nine Member States will be subject to a General Audit in 2009 (Belgium, Cyprus, Finland, Greece, Latvia, Lithuania, Portugal, Slovenia and the United Kingdom). The 10 remaining Member States will be audited in 2010.

Final reports following a General Audit are being published and can be found at the following address: http://ec.europa.eu/food/fvo/ir\_search\_en.cfm

#### 3.4. Official controls on imported feed and food

Official controls to verify compliance with feed and food law and with animal welfare and animal health rules must be carried out on both Community-produced and imported food, feed and animals. The provisions laid down in Title II, Chapter V and Title VI, Chapter II of the OCR create the general framework and procedures applicable to official controls on feed and food imported from third countries into the territory of the Community.

Title II, Chapter V of Regulation (EC) No 882/2004 contains uniform rules applicable to:

- actions to be taken by the competent authorities following official controls on import of feed and food, as for instance, in case of suspicion or of established non-compliance (Articles 18 to 22);
- approval of pre-export checks carried out by third countries with a view to reducing frequency of controls at import (Article 23);
- required cooperation between competent sanitary authorities and custom services for the organisation of official controls (Article 24).

Article 25 empowers the Commission, through the procedure laid down in Council Decision 1999/468/EC (Comitology procedure)<sup>13</sup>, to adopt the measures necessary to ensure the uniform implementation of official controls on imported feed and food.

The OCR recognises the specificities of controls to be carried out on **feed and food of animal origin** (Article 14) as opposed to feed and food of non animal origin (Articles 15 to 17). As regards the former, the Regulation recognises the validity of the existing framework of harmonised import procedures established by Council Directive  $97/78/EC^{14}$  and performed by the network of Border Inspection Posts set up throughout the Community external borders. The Regulation requires the competent authority designated in accordance with Directive 97/78/EC to also carry out controls to verify compliance with aspects of the feed of food law not covered by this Directive.

The Commission, as part of its new Animal Health Strategy (2007 - 2013), is currently reviewing its veterinary import controls to deliver a better risk based approach to border inspections. The review will address how best to ensure the early warning and prompt detection of risks from animal products so that import measures can be applied to ensure the continued high level of protection of public and animal health within the EU.

Contrary to what happens at present for feed and food of animal origin, **feed and food of non-animal origin** are not subject to systematic EU-harmonised checks at the border prior to being imported into the Community (with the exception of those products for which emergency measures based on Article 53 (1) of Regulation EC No 178/2002<sup>15</sup> are in place). According to the provisions laid down in Article 15 of the OCR controls on imported feed and food of non-animal origin are to be carried out at an appropriate place, including the point of entry into the Community, the point of release for free circulation, warehouses, the premises of the importing feed and food business operator or other points of the feed and food chain. Member States decide, on the basis of their assessment of the risk, the most appropriate frequency and the modalities of official controls on imported products.

A deviation from the mentioned general rules is laid down in paragraph 5 of the same Article 15, which stipulates that a list shall be drawn up of feed and food of non-animal origin that is, on the basis of known or emerging risk, to be subject to an increased level of official controls at the point of entry into the Community. A draft Regulation aiming at establishing general provisions and such list for the first time has been adopted on x.x.2009 [to be updated before release].

The rules above are complemented by those of Title VI, Chapter I and II of the OCR which establish the procedures through which the Commission gathers relevant information as regards the level of compliance of third countries' systems with Community standards for feed and food (Articles 46 and 47), and decides what, if any,

<sup>&</sup>lt;sup>13</sup> Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, *OJ L 184, 17.7.1999, p. 23*.

<sup>&</sup>lt;sup>14</sup> Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries, *OJ L 24, 30.1.1998, p. 9.* 

<sup>&</sup>lt;sup>15</sup> Regulation (EC) N° 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general requirements and principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, *OJ L 31, 1.2.2002, p. 1.* 

specific import conditions are to be imposed for feed and food to be allowed into the Community (Article 48).

Relevant information is also gathered through FVO missions in third countries (Article 46) and through pre-mission questionnaires sent in advance of said missions, which provide in particular information about the countries' organisation and management of sanitary controls.

To the extent that the conditions and detailed procedures for import are not already provided for by Community legislation, (in particular by Regulation (EC) No 854/2004<sup>16</sup>), specific import conditions may be laid down in accordance with Comitology procedure. They may include the establishment of a list of third countries from which specific products may be imported into the Community, the establishment of models of certificates accompanying consignments and/or other special import conditions depending on the type of product or animal and the possible risks associated (Article 48).

Rules applicable to the conclusion of equivalence agreements with third countries are laid down in Article 49. These agreements may recognize that measures that third countries apply in specific areas offer guarantees equivalent to those applied in the Community, provided that the third countries supply objective proof in this respect.

## 3.5. Article 23 on approval of pre-export checks

Article 23 of the OCR gives the possibility to the Commission to approve, in accordance with the procedure referred to in Article 62 (3) of the Regulation, specific pre-export checks carried out by a third country prior to exporting a given product (feed and food) to the Community. As a consequence of the approval of pre-export checks, the frequency of import controls for feed or food may be reduced.

The approval of third country pre-export checks may be granted on condition that

- a Community audit has shown that feed or food exported to the Community meets the Community requirements or equivalent requirements
- the pre-export checks carried out in the third country are sufficiently effective and efficient as to replace or allow to reduce the documentary, identity and physical checks carried out on the basis of Community legislation.

In other words, approved pre-export checks guarantee that controls are carried out in conformity with the relevant requirements laid down in Community law.

The approval of pre-exports checks on the basis of Article 23 of the OCR does not affect the right of the Member States' competent authority to carry out official controls on imported feed and food. Nevertheless, the existence of an approved scheme of pre-export checks shall be considered by Member States' competent authorities when

<sup>&</sup>lt;sup>16</sup> Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption - *OJ L 139, 30.4.2004, p. 206 corrected and re-published in OJ L 226, 25.6.2004, p. 83.* 

deciding the frequency of physical checks to be carried out on food and feed. Such frequency is determined on the basis of the risks associated with the different types of feed and food, the guarantees offered by the exporting third country, the controls carried out by the feed or food business operator importing the product, the history of compliance with the requirements for the product concerned of the third country and the establishment of origin and of the food and feed business operators importing or exporting the product.

Commission Decision 2008/47/EC of 20 December 2007 approving the pre-export checks carried out by the United States of America on peanuts and derived products thereof as regards the presence of aflatoxins<sup>17</sup> is the only Commission Decision to grant the approval of such a scheme so far.

## **3.6.** Better Training for Safer Food

Article 51 of the OCR empowers the Commission to organise training for both the staff of the competent authorities of Member States and of third countries dealing with food and feed law, animal health, animal welfare and plant health rules. In accordance with this article, the Commission launched the Better Training for Safer Food initiative, now in its third year of activity. The second year's results were published in the initiative's annual report:

http://ec.europa.eu/food/training\_strategy/annual\_report2007/index\_en.htm.

At the end of 2008, approximately 7 500 participants had benefited directly from the training provided within the initiative, of which 52% came from Member States, 13% from Candidate Countries, Potential Candidate Countries, European Free Trade Association countries and European Neighbourhood Policy countries and 35% from other third countries. Participation levels are set to increase in the coming years, to reach an average of 6 000 participants per year.

In September 2006, the Commission adopted a Communication to the Council and the European Parliament on Better Training for Safer Food<sup>18</sup>, in which the scope and purpose of the initiative and its strategy for future development are outlined. In accordance with the conclusions of the Communication and the results of a cost-benefit analysis carried out by an independent consultant, the Commission decided to delegate implementation tasks of the programme to the "Executive Agency for Health and Consumers"<sup>19</sup>.

#### **3.7.** Community Reference Laboratories (CRLs)

Annex VII to the OCR established the consolidated list of Community reference laboratories (CRLs) for feed and food and animal health, which includes laboratories previously designated by various sectoral acts and new CRLs in areas not already

<sup>&</sup>lt;sup>17</sup> OJ L 11, 15.1.2008, p. 12.

<sup>&</sup>lt;sup>18</sup> COM (2006) 519, 20.09.2006, available online at:

http://ec.europa.eu/food/training/communication\_final\_report\_en.pdf

<sup>&</sup>lt;sup>19</sup> Commission Decision 2008/544/EC of 20 June 2008 amending Decision 2004/858/EC in order to transform the "Executive Agency for the Public Health Programme" into the "Executive Agency for Health and Consumers", *OJ L 173, 3.7.2008, p. 27.* 

covered. Since July 2005, the Commission has launched three calls for the selection and designation of new CRLs.

This has allowed the addition to the list in Annex VII of the following new CRLs:

- New CRLs in the sectors of: foot-and-mouth disease, Brucellosis, Listeria monocytogenes, Coagulase positive Staphylococci, Escherichia coli including Verotoxigenic E.coli (VTEC), Campylobacter, parasites ( in particular Trichinella, Echinococcus, Anisakis), antimicrobial resistance, animal proteins in feedingstuffs, pesticides residues, mycotoxins in food and feed, dioxins and PCBs and Polycyclic Aromatic Hydrocarbons (PAHs)<sup>20</sup>.
- CRL for equine diseases other than African horse sickness $^{21}$ .
- CRLs for crustacean diseases, rabies and bovine tuberculosis, laying down additional responsibilities and tasks for the CRL for rabies and bovine tuberculosis<sup>22</sup>

# **3.8.** Technical updates

# EN ISO/IEC 17020 standard replaces EN 45004

According to Article 5 of the OCR the competent authority may delegate specific tasks related to official controls to one or more control bodies in accordance with certain requirements. These control bodies must work and be accredited in accordance with European Standards, in particular with the EN standard on *«General criteria for the operation of various types of bodies performing inspection»*. The previous EN 45004 standards has been replaced by EN ISO/IEC 17020. The OCR should therefore be amended accordingly. The Commission is currently preparing and amendment, to be adopted by comitology procedure, of the OCR to reflect the changes to ISO standards.

## EN ISO/IEC 17011 standard replaces EN 45002 and EN 45003

According to Article 12 (1-2) of the OCR, the competent authority designates laboratories that may carry out the analysis of samples taken during official controls and these laboratories had to be accredited in accordance with certain European Standards. The previous EN 45002 on "General criteria for the assessment of testing laboratories" and EC 45003 on "Calibration and testing laboratory accreditation system – General requirements for operation and recognition» have been replaced by the same EN ISO/IEC 17011 on "General requirements for accreditation bodies accrediting conformity assessment bodies", and the OCR has been amended accordingly<sup>23</sup>.

<sup>&</sup>lt;sup>20</sup> Commission Regulation (EC) No 776/2006 of 23 May 2006, OJ L 136, 24.5.2006, p. 3.

<sup>&</sup>lt;sup>21</sup> Commission Regulation (EC) No 180/2008 of 28 February 2008, OJ L 56, 29.2.2008, p. 4.

<sup>&</sup>lt;sup>22</sup> Commission Regulation (EC) No 737/2008 of 28 July 2008, OJ L 201, 30.7.2008, p. 29.

<sup>&</sup>lt;sup>23</sup> Commission Regulation (EC) No 1029/2008 of 20 October 2008 amending Regulation (EC) No 882/2004 of the European Parliament and of the Council to update a reference to certain European standards, *OJ L 278, 21.10. 2008, p. 6.* 

## 4. FEES

# 4.1. Context

Article 65 of the OCR requires the present Report to address special attention to the issue of fees collected for the financing of official controls ("inspection fees").

In order to be able to report on this complex issue, the Commission called for an **external evaluation** aimed at providing a better understanding of the functioning of the inspections fees systems as currently implemented by the Member States on the basis of the relevant provisions of the OCR (Articles 26 to 29).

The evaluation ("the study") was carried out by a contractor in the period April-November 2008 through a survey addressed to competent authorities in all Member States, an in-depth analysis (case studies) in relation to six Member States representing a variety of fee regimes, interviews with key experts and stakeholders at EU level, extensive analysis of existing literature and data review (including relevant FVO reports and national legislation).

The results of the study were finalised and made available to the Commission in February 2009.

# 4.2. Scope of the evaluation

The objectives of the study were two-fold:

- (a) to evaluate the present situation as regards the application of the existing provisions on fees, in particular the way in which the system operates in practice;
- (b) to assess the advantages and disadvantages of a range of policy options (regarding the scope of current rules and the fee-setting mechanism).

The evaluators were also asked to identify the main strengths and weaknesses of the current system, as well as key problems and shortcomings that should be addressed in the future. They looked in particular at how Articles 26 to 29 of the OCR are currently implemented and how the fee system, as it is currently applied, contributes to achieving the objectives of the OCR.

## 4.3. Main conclusions resulting from the study

The study established that there is a significant degree of variation in the enforcement of the financing provisions of the OCR by the Member States and a significant lack of clarity and transparency of the various national fee systems as currently implemented. As a result, direct comparison of actual fee levels across the EU (and between sectors) is extremely difficult.

The study results also suggest that, due to the very broad definition of cost categories in Annex VI to the Regulation and to the reported lack of transparency of the calculation methods, it is quite unclear whether cost-based fees truly reflect actual costs incurred by the competent authorities of the Member States for the performance of the inspections for which the fees are collected. In more general terms, the study investigated whether the main objective of the inspection fees system as in place at the moment has been reached, i.e. ensuring that Member States have sufficient financial resources to carry out the official controls (Article 26 of the Regulation). The study suggests that this main objective has largely not been fulfilled at present for the EU as a whole.

#### 4.4. Scenarios for change

On the basis of the findings reported, the study assesses advantages and disadvantages of a range of policy options and compares possible alternatives to the current rules.

As working hypothesis, the study considers the two following extreme scenarios:

- "full subsidiarity", which would imply the repeal of most of the constraints laid down in the existing legal framework, as regards in particular the calculation of the fees and the scope of the mandatory fees; Member States would be free to decide on the best way to finance their official control services;
- "full harmonisation", with fees fixed at the same level across the whole European Union and for all the sectors concerned (identified by Community legislation).

The study then assesses advantages and disadvantages of intermediate scenarios, which result from the addition of mitigating elements to the two most radical options. The analysis is carried out in particular considering how the main components of a legislative framework on inspection fees would be characterised on a scale from "full subsidiarity" to "full harmonisation". Such main components are in particular:

- mandatory/non-mandatory nature of the fee
- harmonised/non-harmonised level of fee rates
- harmonised/non-harmonised fee calculation method
- harmonised /non-harmonised fee reductions and penalties for non-compliances
- list of activities covered by fees (scope of the system).

Consideration is also given to the possibility of maintaining the system as it stands but with some improvements to address, as far as possible, the reported shortcomings.

The Commission will now carry out an Impact Assessment to evaluate the options available and the need to prepare a legislative proposal. This will include a consultation of stakeholders and other interested parties.

Full details of the study results on fees are published at the following address: [to be completed].