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IMPACT ASSESSMENT

Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending Regulations (EC) No 999/2001, 1829/2003, 1831/2003, 1/2005, 396/2005, 834/2007, 1099/2009, 1069/2009, 1107/2009, Regulations (EU) No 1151/2012, [….]/2013 [Office of Publications, please insert number of Regulation laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material], and Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC, 2008/120/EC and 2009/128/EC (Official controls Regulation)

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Introduction

In order to afford European Union (EU) citizens a high level of human, animal and plant health, and guarantee the functioning of the internal market, Union legislation provides for a set of harmonised rules to prevent, eliminate or reduce the level of health risk to humans, animals and plants, which may arise along the agri-food chain. The risks addressed include health risks *sensu stricto* (risks to the integrity of humans, animals and plants from pests, diseases, microbial and chemical contaminants and other hazards) but also the preservation of inherent qualities required to ensure a safe start of plant production and regulated production methods (i.e. animal welfare, organic farming, geographical indications).

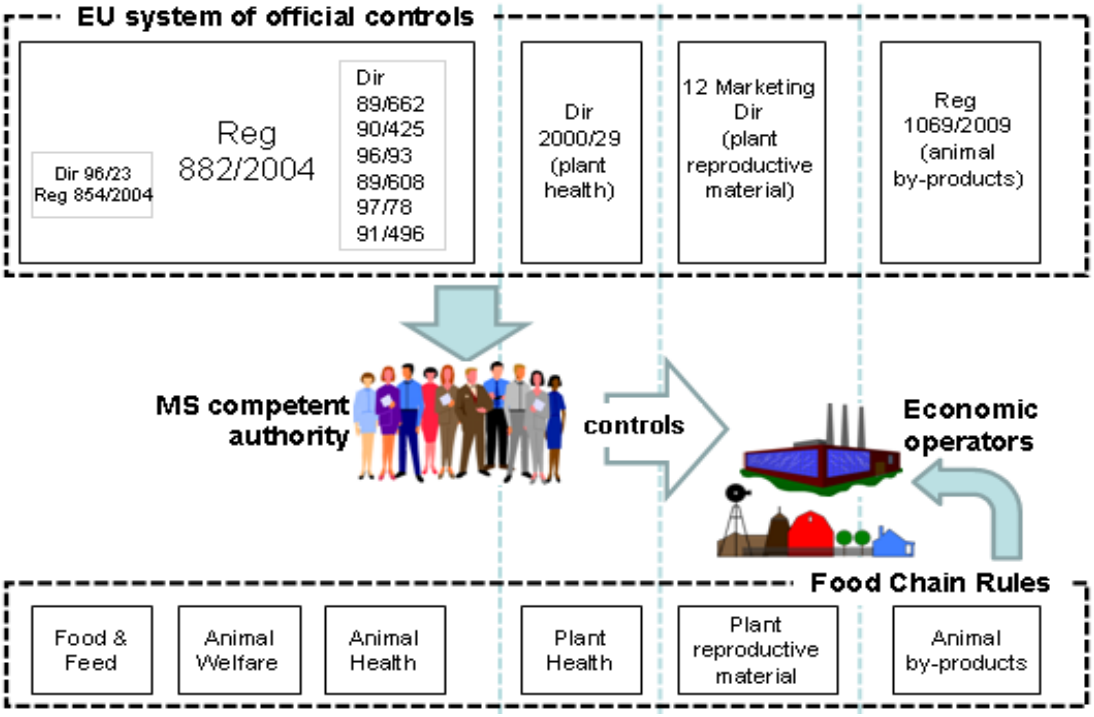
In particular, the EU has established rules governing all the activities, from primary production to retail and catering, which may affect:

- the health of animals and plants,
- the safety of food and feed for EU citizens,
- the welfare of animals,
- the quality of plant reproductive material and other quality aspects such as organic production and geographical indications.

In addition, rules have also been established to ensure the provision of information to consumers and to guarantee fair commercial practices in agri-food chain products' trade. This wide ranging set of rules is referred to in this Impact Assessment (*IA*) as "agri-food chain rules".

To ensure agri-food chain rules are enforced by Member States (*MS*) across the EU in a harmonised manner, a legislative framework for the organisation of official controls has been established. This IA considers the possible impacts of reviewing such a framework.

Figure 1 – application of EU rules across the agri-food chain



1. Procedural issues and consultation of interested parties

1.1. Ex-post analyses of the EU system of official controls

In July 2009 the Commission issued a report for the European Parliament and the Council[1] to review the experience gained throughout the first years of application of Regulation (EC) No 882/2004 (hereafter "the Regulation")[2]. The report showed that the new rules have introduced important changes to the way competent authorities ("*CA*") organise and carry out official controls, establishing a more integrated approach which ensures confidence in the agri-food chain across the EU. However, given the increasing integration of business operators along the agri-food chain, it indicated that improvements could be made to meet the Commission's Smart Regulation Agenda objective of simplifying regulation. This would also address issues of administrative burden reduction and fostering competitiveness.

The report also indicated that in order to rationalise and simplify the overall legislative framework, whilst simultaneously pursuing the objective of better regulation, consideration should be given to the possibility of integrating the rules currently applicable to official controls in specific areas (e.g. **residues of veterinary medicines** in live animals and animal products[3]; and **plant health**[4]) into the framework of the Regulation.

Additional research[5] carried out to evaluate the application of the Regulation outlined the existence of problems regarding the application of the rules (Articles 26 to 29) governing the **financing of official controls**. The report concluded that the overall objective of ensuring Member States allocate adequate financial resources to official controls is not being met throughout the EU. It recommended reviewing Articles 26 to 29 of the Regulation.

The Regulation also establishes the overall principles for MS' controls carried out on third country imports to the EU (**import controls**). In December 2010, the Commission adopted a report on the effectiveness and consistency of sanitary and phytosanitary controls on imports of food, feed, animals and plants[6]. Whilst concluding that the comprehensive body of legislation currently in place allows the EU to deal with emerging risks or emergency situations without causing distortions to trade, the report also found that import controls could be made more coherent by reviewing and consolidating existing acts[7]. It concluded that this

[1] COM/2009/334/Final.

[2] Regulation (EC) No 882/2004 of 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.

[3] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC.

[4] Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community.

[5] These conclusions were based on a 2009 study on "Fees or charges collected by Member States to cover the costs occasioned by official controls". The executive summary is available at Annex X.

[6] (COM (2010) 785 final); the report is published on: http://ec.europa.eu/food/animal/bips/guidelines_en.htm

[7] Article 15(5) of Regulation (EC) No 882/2004 establishing the framework for the performance of import controls on feed and food of non-animal origin; Directives 97/78 of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries, and 91/496 of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC; Directive 2000/29 on protective measures against the introduction into the Community of organisms harmful to plants or plant products; the latter governing, inter alia, border controls on plants and plant products.

improvement would bring benefits for MS and operators handling goods from third countries (importers). The review of the Regulation was considered a good opportunity to take account of the findings of the report and consolidate controls where possible.

Besides the above, DG Health and Consumers (DG SANCO) has conducted further analysis on the alignment of EU sectoral legislation on official controls[8] with the overarching principles established in the Regulation.

The review of the Regulation is part of a package which also includes three other major reviews to modernise the animal health, plant health and plant reproductive material (hereafter 'PRM') *acquis*[9]. Its aim is therefore to modernise and integrate the system of official controls in a manner that also consistently accompanies the upgrade of EU policies in these sectors. The package is scheduled for adoption in 2012.

All the information, data and evidence collected as part of the reviews above, including evaluations of the existing regimes, has been used throughout this IA to define problems, assess impacts and appraise options.

1.2. Data collection by or on behalf of the Commission

- *The Food and Veterinary Office (FVO)*

The Commission is responsible for ensuring that Union legislation is properly implemented and enforced by the competent authorities of the MS. The Food and Veterinary Office ("FVO") is a Commission's service which contributes to the fulfilment of this task, by in particular carrying out audits in the MS to verify the implementation of agri-food chain legislation and the functioning of national control systems, and to collect information on implementation practices.

The findings of each audit are set out in an audit report[10]. Information on the realities and difficulties of day-to-day implementation of agri-food chain legislation comes from such audit reports, in particular the ones assessing the functioning of national control systems along the agri-food chain. This IA draws on the findings of these reports and the data contained within them. Within a task force established by DG SANCO, feedback from national authorities and stakeholders gathered across all sectors (notably through the audit activities of the FVO) was studied to identify problems and shortcomings of the EU system of official controls.

- *Studies on the system of financing official controls*

In addition to the 2009 study on "Fees or charges collected by Member States to cover the costs occasioned by official controls" (see foot note 5), DG SANCO commissioned from another external contractor[11] a study to support the assessment of the options identified (2011)[12]. Whilst the contractor reported that there was difficulty in obtaining exact figures from MS to quantify the problem, the report did highlight the diverse spread of cost recovery within MS and certain problems with the application of EU rules which corresponded with previous studies and the Commission's own findings.

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[8] For an overview of the legislation on official controls co-existing with Regulation 882/2004 see figure 1 and Annex II.

[9] The IAs accompanying those initiatives are available at: http://ec.europa.eu/governance/impact/ia_carried_out/cia_2012_en.htm#sanco.

[10] The FVO audits reports since 2007 are listed in Annex VII.

[11] GHK Consulting Ltd working with ADAS UK Ltd.

[12] Annex XI provides for the executive summary of the study carried out by GHK to support the impact assessment on reviewing the rules on the financing of official controls.

- *Other data sources*

In addition to the data mentioned above, further information was collected on specific issues (i.e. official controls in the Plant Health area and official controls on residues of veterinary medicines) to contribute to the analysis[13].

1.3. Consultations[14]

1.3.1. Member States

The key issues to be addressed by the review of the system of official controls as well as the changes to be included in the legislative framework have been extensively discussed within the Working Group on the general application of the Regulation set up within the Standing Committee on the Food Chain and Animal Health (SCFCAH)[15].

The main problems identified and the provisional options were also presented and discussed at meetings of the Heads of Food Safety Agencies on 29 June-1 July 2011 and on 8 December 2011.

Moreover, MS were consulted in the context of the two studies contracted out by the Commission in the area of the financing of official controls.

Finally, MS have been consulted within other *fora* and frameworks on the following specific issues relating to official controls: accreditation of official laboratories, official controls on residues of veterinary medicines in live animals and animal products, veterinary border controls, animal health, plant health and plant reproductive material.

1.3.2. Stakeholders

Stakeholders (industry association representatives and NGOs) have been consulted during the evaluation studies and the preparation of the IA. Two *ad hoc* Working groups, on the review of the system of official controls and the review of the rules governing the financing of such controls respectively, were convened under the Advisory Group on the Food Chain and Animal Health and Plant Health. Progress was also presented and discussed in the plenaries of the aforementioned Advisory Group and on invitation at meetings of several industry representative bodies. In addition to discussions with MS, stakeholder consultation was a key element of the two studies contracted out to external consultants in the field of the financing of official controls.

1.3.3. Summary of consultation with interested parties

Annexes VIII, IX, XII and XIII give an overview of the positions expressed by MS and stakeholders at different stages of the review; Annex VI lists all the stakeholders that have been consulted during the process.

1.4. Inter-Service Steering Group (ISSG)

A Commission Inter-Service Steering Group on the IA for the review of the EU system of official controls along the agri-food chain was established. The group was led by DG Health and Consumers (SANCO) with the participation of the following Commission Directorates General and Services: Agriculture and Rural Development, Budget, Environment, Enterprise

[13] See Annex V.
[14] Details on the consultation process are available at Annex IV.
[15] http://ec.europa.eu/food/committees/regulatory/index_en.htm.

and Industry, Research and Innovation, Taxation and Customs Union, Trade, Development and Cooperation, Maritime Affairs and Fisheries, Legal Service, Justice and the Secretariat-General. The group met seven times. A final draft was sent to the group, whose members provided comments at a last meeting on 27 January 2012 which have been incorporated into the IA.

1.5. IAB opinion

The IA report was submitted to the IA board on 29 February 2012 and was formally presented on 28 March 2012. Following this meeting the board issued an opinion on 30 March 2012 emphasising four main points as well as some presentational issues to be addressed in the final version of the report. Following re-submission on 16 May, a revised opinion was issued on 8 June clarifying the points to be addressed:

1) **Improve presentation of the problem definition:**
   - section 2.2. presents now in a clearer and balanced manner the two main issues at stake: the deficiencies in the design of the official controls' framework (2.2.1.), and the uncertainties as regards the financing of such controls (2.2.2.); evidence as well as examples supporting both sets of issues are inserted;
   - a better distinction has been drawn between problems, underlying causes and consequences.
   - More thorough evidence on the design of the official controls and their efficiency across MS has been introduced by, where possible, quantifying the costs of inefficient controls to MS and operators. Where this is not possible, due to a lack of relevant data caused by short-comings in the current regime, this has been identified.
   - The problem definition is supported by clearer, referenced examples and is presented in table 1.
2) **Better define objectives and strengthen the intervention logic:**
   - the objectives in section 3.2. are now explained in light of the problem definition and the link between objectives and key problem issues is made explicit by a new table;
   - operational criteria in section 3.3 are reformulated in order to make them more appropriate and quantifiable;
   - the notion of safety has been reinforced in the intervention logic (problem definition, objectives, options, analysis of impacts), including by explaining why it is important that SMEs and micro-enterprises are subject to official controls without exceptions;
   - section 4.1. now explains how the policy options included in the analysis relate to the specific objectives.
3) **Reformulate the options and include options that address SME/micro enterprise issues**
   - options to address micro-enterprises issues are now included in sections 4.1. and 5 (under option 1B, exempting them from fees) and in section 4.2. (reducing controls on them);
   - The text better explains the effect of fees on micro-enterprises by integrating into section 2.2.2, additional relevant examples and findings from the referenced studies;

- options 2 to 4 include and assess a mechanism to alleviate the burden of fees on micro-enterprises while taking into account competition and sustainability concerns;
- the presentation of the logic flow in the assessment of impacts has been improved by separating the two steps of the assessment and explaining their sequence (section 4.1.);
- the earmarking element, presented in the original report, was eliminated from options 2 to 4 (and is no longer analysed in detail in the report) as the same objective could be achieved through less prescriptive tools (transparency, accountability) (section 5, under option 2).

4) Present a clear overview of costs and benefits and make comparison of options more transparent

- a new table 4 in section 6.2. provides an overview of costs and benefits that could be estimated through the assessment and which are referenced in boxes 6, 7 and 9. It presents figures as both benefits and costs to MS and industry, and calculations are explained in footnotes. An explaination of the table now makes it clearer to which sectors the costs and benefits apply under the different options.
- section 6.2. presents in a more transparent fashion the comparative advantages of the different options, with regard also to the views of stakeholders. The figures and results presented in the analysis of costs and benefits are explained, supported by verifiable evidence, and clearly referenced.
- With regards to MS which already apply full cost recovery, Box 6 in section 5, presents examples of practices which are currently undertaken.

5) Procedure and presentation:

- references to MS and stakeholders' opinions are now systematically made throughout the report. All examples and evidence are clearly referenced;
- Annex XI includes the executive summary of the GHK study only, and relevent findings are drawn out in a separate annex (XVII) so that it is clear that the Commission does not endorse the study as a whole;
- Annexes XXVII was removed because it is not relevant for the report.

2. Problem Definition

2.1. Background

2.1.1. The EU system of official controls along the agri-food chain

The responsibility to enforce EU agri-food chain legislation lies with the MS, whose authorities monitor and verify that the relevant requirements are effectively implemented, complied with and enforced across the Union. In doing that they verify that operators' activities and goods placed on the EU market (either EU produced or imported from third countries) are in compliance with the relevant EU agri-food chain standards and requirements.

Harmonised EU rules to govern control activities performed by MS are established in the Regulation with the aim of creating an integrated and uniform approach to official controls

along the agri-food chain. The Regulation provides for a general framework for official controls in the sectors of **feed and food law, animal health and animal welfare rules**, laying down rules governing both the **organisation** and the **financing** of such controls.

Despite the above integrated approach, for historical reasons controls for animal health purposes (both on domestic and imported goods) and controls on residues of veterinary medicines, remained regulated separately. Moreover, certain sectors pertaining to the agri-food chain were not included in the scope of the Regulation - i.e. **plant health, PRM, animal by-products (hereafter 'ABP')** - and specific sectoral regimes were developed for them.[16]

Competent authorities are required to perform official controls on all business operators active in the agri-food chain. Given that the emergence of food safety risks does not necessarily depend on the size of an operator, the current system is based on the principle that all should be subject to official controls, without exception, as this is the only way to ensure a risk-based prioritisation of controls, an efficient use of resources and the safety of the agri-food chain.

As regards the number of business operators concerned, figures suggest that they amount to approximately 25 million[17]. As highlighted in section 5 below, in a majority of Member States, micro-enterprises[18] represent more than half of the total number of business operators (at least in the four industries which are subject to the most intensive official control activities)[19]. In this context, the significance of controlling smaller businesses, including micro-enterprises, becomes apparent. This need is further reinforced by the fact that, notwithstanding their size, such enterprises are equally likely to conceal serious food safety risks/concerns. The **recent E.Coli crisis,** which spread across several Member States due to contaminated sprouted seeds, **originated in a micro-enterprise**. The crisis not only resulted in dramatic human losses with a death toll of 55 people and 4000 cases of serious human disease, but also caused huge economic damage which, in the first two weeks alone, amounted to approximately €812 million.

2.1.2. The international dimension

The efficient operation of the EU system of official controls is important for both EU exports and imports.

The EU is the world's largest exporter and importer of food and drink products. In 2010 EU27 food and beverages imports were worth €78 billion, and exports €73 billion. The EU27 imported 79.3 million tonnes of food and live animals and 3.4 million tonnes of beverages in 2010, with a trade deficit of 14 million tonnes for food and live animals, but a surplus of 6 million tonnes for beverages[20].

The EU's ability to export towards third countries relies on the reputation of the high production standards and added value that the EU goods can prove to have compared to the ones produced outside Europe. This can only be achieved by a reliable and trusted official controls system which ensures that the EU agri-food chain safety and quality standards are consistently enforced and corresponding expectations from trade partners met.

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[16] For a complete overview of the existing legislative framework applicable to official controls along the agri-food chain see Annex II.

[17] See Eurostat Pocketbooks, Food: From Farm to Fork Statistics 2008 Edition European Commission

[18] Enterprises with less than 10 employees and or a turnover or balance sheet equal to or less than €2 million.

[19] Micro-enterprises are also likely to be represented in large numbers in other industries subject to official controls.

[20] Source: Comext various years.

As regards imports, it is essential that all food on the EU market is safe. Controls perfomed by the MS CAs on goods arriving from third countries ensure that the latter offer adequate guarantees that they meet equivalent safety levels. The relevant import control rules must comply with the WTO Sanitary and Phytosanitary (SPS) Agreement, in particular with the provisions laid down in Annex C to the SPS Agreement.

2.2. Problem identification

MS ensure a good level of implementation of official controls across the agri-food chain, and progress can be recorded in the use of the enforcement tools established by Regulation 882/2004 (e.g. control planning and coordination, verification of effectiveness, auditing[21]). However, evidence gathered over the last five years of application (feedback from MS' CAs and FVO audits reports) has shown shortcomings stemming,

- on the one hand, from the design of the official controls framework (notably from the incomplete implementation of certain principles/objectives laid down in Regulation 882/2004, and from the fact that the integrated approach to official controls across the agri-food chain is consolidated only partly), and
- on the other hand, from uncertainties as to the availability of sufficient resources to adequately finance official controls.

2.2.1. Design of the official controls' framework

2.2.1.1. Inconsistencies, gaps in control requirements

Despite the increasingly integrated operation of activities along the agri-food chain, the integration of the EU system of official controls still suffers **inconsistencies** and **legal gaps,** in particular as regards controls carried out for **plant health**, **PRM** and **ABP** purposes. Controls in these areas are in fact not aligned fully with the framework laid down in the Regulation. On the other hand, **overlapping requirements** subsist also in the **animal health** area, already covered by the scope of the Regulation, because of the co-existence of sectoral legislation which survived the adoption of the general framework in 2004.

i) While certain differences in the design of official controls are justified because of the peculiarities of the concerned sectors (e.g. the certification procedure in the plant health area differs from that of the veterinary area), others appear to be arbitrary and result in inconsistencies in those cases where the same approach would be justified across sectors (e.g. the mechanism for delegating plant health control tasks differs from that regulated upon by the Regulation; also, laboratories performing official tasks are required to be accredited under ISO standards in all areas except plant health and PRM). Control authorities thus operate on the basis of different approaches and under different conditions depending on the specific agri-food chain rules they are called upon to enforce, without differences being justified.

ii) Some of the implementation tools or mechanisms established in Regulation 882/2004 are not available for the performance of official controls in the plant health, PRM and ABP areas (e.g. transparency requirements in relation to enforcement activities do not apply to controls on ABP rules; in the same area, no FVO audits are foreseen; EU rules on PRM do not provide for FVO audits on the functioning of national control systems, nor do they regulate upon

[21] For the most recent overview of the operation of controls activities in the Member States (years 2008-2009) and of the Commission's own control activities (2008-2010), see Commission Report on the overall operation of official controls on food safety, animal health and animal welfare and plant health COM(2012) 122.

competent authorities and their duties in this sector). As a result, CAs are not provided with the complete set of tools meant to ensure accountability, soundness and effectiveness of their enforcement activities.

iii) Certain requirements or procedures regulated upon by the Regulation in a horizontal manner are also present in sectoral legislation, in particular in pre-existing veterinary legislation. For example, the mechanism for administrative assistance and cooperation is regulated upon by the Regulation and by Directives 89/662[22] and 89/608[23]. This has resulted in different interpretations of similar procedures by MS who undertake different activities to verify compliance.

Inconsistencies and legal gaps are due to the fact that EU legislation on official controls has in the areas of plant health, PRM and ABP developed separately from the general framework established by the Regulation, and overlap in control requirements derived from the co-existence, for animal health related controls, of the Regulation with pre-existing sectoral legislation.

Whilst it is not always possible to quantify the cost to MS CA and operators of such inconsistencies and gaps it stands to reason that the inefficiencies so caused will lead to official control enforcement regimes which are unnecessarily costly for CAs to operate and are overly burdensome on operators.

2.2.1.2. Inconsistent implementation of risk-based approach

Regulation 882/2004 is based on the principle that **official controls should be risk-based in order to maximise the efficiency of control activities directed at protecting health**.

Box 1: Risk based approach to official controls

The risk based approach to official controls

In a situation where resources are finite these are to be used selectively and the selection should be based on a series of criteria which include: the hazard and risks associated with the specific business activity, or product, the operator's record of compliance and reliability, indications of possible non-compliance.

Failure to do so would result in resources being allocated on the basis of non-risk related criteria and in situations where official controls which are more relevant for the protection of public health are not receiving appropriate attention.

The analysis focuses on the areas where the risk-based approach **is still not fully used (controls at the border and controls on residues of veterinary medicines)**.

i) EU border controls on certain goods from third countries

To ensure harmonised verification of compliance with EU agri-food chain rules, MS are required to carry out official controls on certain goods coming from third countries at the external borders of the EU (EU border controls). According to the risk-based approach, also EU border controls should be limited and proportionate to what is necessary to contain potential risks for humans, animals or plants.

[22] Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market.

[23] Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters.

However, the continuous and timely adjustment of the control effort at the EU border to the needs dictated by the actual risk is hampered by the rigidity and fragmentation of existing rules governing border checks in the different areas. E.g. current rules require MS to take samples and perform physical checks on 100% of consignments of animals, products of animal origin and plants intended to be introduced into the EU. Existing arrangements to reduce the frequency of costly and time consuming physical checks do not allow for the continuous adjustment necessary to take account of situations where the potential risk of the consignment spreading an animal disease or otherwise endangering public health is reduced.

In addition, the prioritarisation of the controls is carried out in a sectoral manner (animal health, public health, plant health) and not by comparing the levels of risk of all commodities of relevance for the agri-food chain across sectors: in other words, prioritarisation is carried out within sectors and not across sectors.

ii) Official controls on residues of veterinary medicines

MS are required by the provisions of Directive 96/23/EC to take samples of animals and foods for the presence of residues of veterinary medicines. Legal requirements are very strict, dictating the number of samples, which animals/tissues to analyse and for which substances. The result of such rigidity is that currently MS are demanded to carry out checks and laboratory analysis for substances for which over the past years there has been little or no evidence of actual risks.

Examples[24]

Stilbenes:

MS are required to take samples of all animals and animal products to check the presence of 'stilbenes'. The chart below shows that no non-compliance has been detected for several years now but, despite this, between 21000 and 24000 samples are analysed each year across the EU for stilbenes, their derivatives, salts and esters.

Year	Total number of samples analysed	Number of non compliances
2007	23 411	0
2008	21 664	0
2009	21 815	0
2010	23 455	0

Resorcylic acid lactones (including zeranol):

Samples taken on pigs to detect resorcylic acid lactones. More than 6000 samples continue to be analysed each year across the EU.

Year	Total number of samples analysed	Number of non compliances
2007	6234	0
2008	5594	0
2009	6237	0
2010	6166	0

The reason for official controls not being aligned to the risk-based approach in the areas above is that such controls are currently prescribed by EU rules[25], pre-existing the Regulation

[24] The data presented in these examples have been collected from Member States under Directive 96/23/EC and stored in DG SANCO application 'Residues: Monitoring Plants and Results version 4.1.1.

[25] EU border controls: Directives 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, and 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC; Directive 2000/29 on protective measures against the introduction into the Community of organisms harmful to plants or plant products; the latter governing, inter alia, border controls on plants and plant products. Official controls on

and not repealed by it, which do not establish appropriate mechanisms to take into account the actual risk a given good, business activity or third country might present. In addition, as regards the area of EU border controls, the lack of prioritarisation of controls across all sectors is due to the fact that existing legislation is highly fragmented, and different sets of rules apply to different sectors (food and feed of non animal origin, live animals and their products, plants)[26].

This results in resources being allocated – in all MS - to controls that are not justified by the risk and consequently are a significant waste of public resources (time and money) that could be better used where risks are higher. The inefficient use of resources also results in unnecessary burdens on operators (time, staff, equipment and facilities mobilised to allow controls). Indeed, it is estimated that the result of the current regime for residues of veterinary medicines may be the lost opportunity to save between €12.4 million and €98.5 million/year (see Box 4 in Section 5 below).

2.2.1.3. Administrative burden and disproportionate requirements

Unnecessary administrative burdens are placed on MS' CAs. It is the case for the obligation for annual updates to MS monitoring plans of residues of veterinary medicines that these be transmitted to and approved by the Commission. In the same area, also redundant are the specific reporting obligations, as they duplicate the general reporting requirement in the Regulation. These burdens result from obligations on MS laid down in Directive 96/23/EC.

In addition, while requiring official laboratories to be accredited in accordance with EN ISO/IEC 17025[27], the Regulation does not allow temporary arrangements for emergencies or cases where laboratories have to use a new method not yet included in the accreditation.

Example: no or nearly no official laboratory in the EU was accredited according to ISO 17025 for the detection of mineral oil in sunflower oil or for the detection of melamine in food when respectively the crisis on sunflower oil from Ukraine or the one on melamine in food from China broke out. This lack of ability to allow temporary arrangements for emergencies could have weakened the legitimacy of controls (and analyses) carried out during the emergency, and of any measure taken by MS on that basis.

Similarly, no flexibility is foreseen for small laboratories carrying out extremely basic types of tests).

Example: soon after the adoption of Regulation 882/2004 several MS brought to the attention of the Commission that accreditation is very burdensome and disproportionate in the case of smallest *Trichinella* laboratories, which are attached to a slaughterhouse or a game handling establishment and only perform a very simple type of test.

2.2.1.4. Uneven enforcement of cooperation and transparency requirements

The Regulation includes some important principles and mechanisms which are currently underused by MS' CAs or applied according to divergent practices among MS.

In particular, it calls for administrative cooperation i) between MS for cross-border enforcement action, and ii) between sanitary authorities and customs services. However, MS

residues of veterinary medicines: Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC.

[26] Ibid.

[27] A laboratory can only be accredited for the use of standardised and/or validated method.

are not making full use of this tool and/or they encounter difficulties in understanding the conditions for its application.

Examples:
- the Commission received a complaint against a MS from a business operator, alleging that the MS's CAs, although aware of a violation of agri-food chain rules perpetrated by the supplier of the complainant (from a second MS), failed to contact the MS of dispatch as requested by Article 38 of Regulation 882/2004 to request their cooperation, and held the complainant solely responsible and liable for the violation. The receiving MS's CAs were acting under the wrong assumption that the notification in the Rapid Alert system for food and feed (RASFF) had satisfied its obligation under Article 38.

- Another MS recently sent a complex interpretation query asking whether national customs authorities, in case of food and feed, can trigger the mechanisms foreseen in Articles 27/29 of Regulation 765/2008 (requirements for accreditation and market surveillance relating to the marketing of products) allowing them to suspend release of a product for free circulation on the Union market and inform the sanitary authority any time the product seems to present a serious risk to health, safety.

In both cases, uncertain interpretation of the rules has the potential to result in CAs not taking appropriate action (to pursue cross-border violations, to prevent the release of unsafe goods).

Another requirement laid down in the Regulation which is open to divergent practices in MS is the obligation for the MS' CAs to ensure a 'high level of transparency' of control activities with regards to operators and the public at large.

The uneven enforcement of the principles and mechanisms above is mainly due to the fact that the Regulation foresees no comprehensive guidance on how cooperation should take place (timing, information to be exchanged, etc.) and what information should be made available to the public. In addition, the Commission is not empowered to lay down further details and uniform implementation modalities.

Whilst it is not possible to quantify the shortcomings identified in financial terms, it is clear that the regime established by the legislation is not serving the public to its full potential.

2.2.2. Difficulties and inequities in financing official control activities

Another area in which the objective of the Regulation is not fully achieved by MS is the **financing** of official controls.

MS are requested to ensure that adequate financial resources are available for official controls.

However, information from MS and FVO audits indicates widespread difficulties in the MS to appropriately resource control services. Annex XV lists a number of significant cases where, during the last 4 years, EU inspectors have reported that the reason for identified shortcomings in control activities or for unsatisfactory or insufficient levels of controls is attributed to the lack or shortage of resources. In some cases the lack of resources leads to under-implementation of control plans or to a violation of established control requirements. For example an FVO audit in a MS, to evaluate controls on residues and contaminants in live animals and animal products and veterinary medicinal products, revealed that the CA could not afford to have samples, which had been taken from 'suspect' slaughterhouses, analysed urgently, so as to allow detention of the carcasses pending the result of the analysis. During a similar audit in another MS it was revealed that the insufficient provision of staff, equipment

and reagents was a significant obstacle to the proper functioning of the laboratory network meaning that the MS's CAs were not meeting their legal obligations) . All cases reported, point to serious difficulties faced by CAs in maintaining an appropriate level of controls (e.g. of veterinary checks on imported goods at the border inspection posts, of farm level controls on the use of veterinary medicines[28]). Further examples are presented in Annex XV.

Such difficulties are exacerbated by the ongoing economic and financial crisis and there is a risk that further pressure on public finances and on funds made available for official controls might increasingly adversely affect MS' capacity to deliver efficient official controls, and consequently the level of protection offered by EU law.

To reduce the dependency of the financing of controls on public finances, the Regulation identifies a number of control activities (mainly on meat, milk, fishery production, and on controls carried out at EU borders) for which MS shall collect a **fee from operators *(mandatory fee)* to recover control costs**[29]**.** For other control activities, MS can choose whether to charge a fee on operators or not.

However, mandatory fees as currently regulated do not enable CA to recover all their costs and thus to ensure a stable influx of resources to finance the performance of controls. On the one hand, fees are only collected for certain controls, whereas on the other hand, presently collected fees do not necessarily enable CA to recover their costs fully (MS typically recover between 20% and 80% of costs with respect to controls subject to mandatory fees resulting in the lost opportunity to mobilise an estimated €0.9bn – €3.4bn per year across the MS for official control activities[30]).

Limited scope of mandatory fees, lack of consistency/fairness

Current rules only require mandatory fees to be charged for official control activities on businesses handling meat, fishery products, and milk, for the approval of feed establishments and for most controls at the borders. With the new framework for official controls established by the Regulation, and the requirement that MS carry out such controls at all the stages of the agri-food chain, the current list of mandatory fees no longer appears justified and fair. Indeed, the Commission is consistently informed by those sectors currently subject to mandatory fees that they view the limitation of mandatory fees to particular sectors as being manifestly unfair. Additionally, by limiting the collection of mandatory fees to particular sectors, the opportunity is lost to mobilise a guaranteed flow of resources of official control activities the amount of which can be estimated to be between €2.3bn and €37bn/year across the MS (see table 4 below - these figures correspond to the two extreme hypothesis of all operators being charged at rates currently used for the smallest and largest scale businesses).

Box 2: Control activities covered/ not covered by mandatory fee under Regulation 882/2004

Control activities covered by a mandatory fee:

- controls on slaughter, cutting operations and cold storage of meat, production and placing on the market of fishery products, and milk production;
- controls carried out to grant feed establishments approval;
- controls carried out at a border on consignments of live animals and their products; certain food

[28] See also Impact Assessment report on "the proposal to revise the EU Plant Health Legislation", which highlights the same difficulties in that area and indicates that full cost recovery of control costs is essential for the good functioning of the relevant control systems.

[29] Separate fee provisions are also laid down in Directive 2000/29, covering certain aspects of official plant health control activities.

[30] Annex XI and Table 4 of this Impact Assessment Report

and feed of non animal origin.

Examples of control activities <u>not</u> covered by a mandatory fee:

- controls carried out in production of food other than meat, fishery products and milk; that is: eggs and egg products, honey and all foods of non animal origin.
- controls carried out in distribution (including wholesale, retail and restaurants) of all food;
- controls carried out in production and distribution (including wholesale and retail) of feed;
- controls carried out in production and distribution of animal by-products;
- controls carried out during import of products originating from third countries that need to be checked at the border other than those already covered by a mandatory fee (for example products subject to a safeguard measure).

<u>Failure to achieve sustainable funding in the sectors subject to mandatory fees</u>

Current rules are based on the principle of cost recovery <u>where fees are mandatory</u>. However, in most cases, full cost recovery is not achieved, due to the fact that, for most activities for which a fee is due, the current system gives the MS the choice between a cost based fee **and a standard, or minimum fee,** whose amount is fixed in the Regulation[31]: given the wide variations of control costs across MS, such EU fees may be higher or lower than the real costs of the activities they are meant to remunerate[32].

Furthermore, resources obtained through fees are not required to be earmarked for the needs of the control authorities which collect them. This, coupled with the fact that the modalities of calculation of the fees, and figures on the amounts collected through the system and on the use made of such revenues, contributes to the perceived unfairness of the fees system in the eyes of those currently charged as was repeatedly noted in consultation with stakeholders.

<u>Compliance / efficiency drivers are not being used / are not working</u>

A number of mechanism included in Articles 26 to 29, with the aim of promoting efficiency of the fees system and compliance by operators fail to deliver:

- despite the obligation laid down in Article 27(12), many MS fail to provide the public and the Commission with the **calculation method** they use to "cost" their controls and establish fee levels; when they do, cost categories, and other details that would ensure full transparency of the costing exercise are missing. Thus, on the one hand it is not clear whether fees do cover the actual costs of official controls (and if so in which areas / MS / regions) and, on the other hand, operators are not provided with the information and data that would allow them to fully appreciate the modalities of the calculation of fees and their fair implementation;
- the results of the external studies demonstrate that there is a widespread perception (in particular among operators) that the current system should (but does not) effectively reward compliant businesses by ensuring that they bear a reduced share of the cost of official controls compared to non-compliant businesses.

Acceptance of the system by business operators is undermined by the perceived unfairness of the system, notably by the lack of "penalising" mechanisms for the less compliant actors.

[31] Where standard / minimum fees are higher than the actual cost of the official control activities they are meant to remunerate, MS can apply lower fees.

[32] The EP recently received a petition from a MS veterinary department, concerned that the fees collected by that MS could not fully compensate costs incurred and thus finance controls.

Micro-enterprises

As noted in section 2.1.1, official controls are necessarily performed in accordance with the same principles regardless of the size of the operator concerned, and there is no evidence to-date to suggest that this results in a disproportionate burden being placed upon micro-enterprises in terms of time and staff being invested because of the controls.

On the other hand, where operators are required to pay mandatory fees for official controls carried out by competent authorities, stakeholders say that the impact of such fees may be greater on micro-enterprises by reason of their lower turnover/throughouput, in particular where standard/minimum fees are applied instead of cost based fees. Cost based fees are in fact proportional to the resources deployed during the performance of official controls and when levied on micro-enterprises, all other things being equal, they should be comparatively lower than those charged on larger operators. A risk based approach to the organisation of official controls means that costs on compliant operators, including micro-enterprises, are kept at a minimum.

This (the fact that cost based fees currently collected are comparatively lower for microbusinesses) is part of reason why the contractor studies performed on behalf of the Commission show that there is currently no evidence to suggest that the mandatory fees charged on the basis of Regulation 882/2004 have, in actual fact, given rise to adverse or disproportionate effects on micro-enterprises. This is supported by the fact that, with the exception of some small businesses' representatives, all stakeholders consulted (be they CAs or businesses) have not called for an exemption of micro-enterprises (or SME) from the fees system established by Regulation 882/2004.

Notwithstanding the above, the need to enable control authorities to recover costs so as to ensure sufficient resources for official controls should be balanced and weighed against the need to lower the burden on very small businesses, in line with the new Commission policy on *"Minimizing regulatory burden for SMEs – Adapting EU regulation to the needs of micro-enterprises"*[33]. According to this policy, micro-enterprises should in principle be excluded from regulatory burdens, unless the necessity and proportionality of their being covered can be demonstrated.

2.3. Parties affected

Rules on official controls are primarly addressed to national control authorities and impact on their activities. Thus, national CAs responsible for the implementation and enforcement of agri-food chain rules are mainly affected by the present review[34] (currently, there are over 100 000 FTE staff involved in the delivery of official controls within the 27 MS). **This initiative will indirectly impact on business operators** within the EU (the agri-food chain is a significant sector within the EU, generating €751 008 million of added value – 6% of the EU27's GDP, and employing over 48 million people) because of the time, staff, equipment and facilities being mobilised during controls. This burden is inversely proportional to the efficiency and effectiveness of controls carried out by the MS CAs.

[33] COM (2011)803

[34] A detailed description of the organisation of control authorities in each MS, prepared and constantly updated by the Commission in close cooperation with each MS can be found at: http://ec.europa.eu/food/fvo/country_profiles_en.cfm

Moreover, the **review of the rules applicable to the financing of official controls** (with the possibility to shift a larger share of the cost burden from the Member State CA to business) will also **affect business operators**.

The review will look not only at the extent to which operators participate in the financing of the control system but also at the mechanisms to ensure that operators (and citizens at large) are provided with information on how inspection fees are established and used and at the mechanism intended to reward compliance with agri-food chain rules by business operators.

The efficient operation of the EU system of official controls is of paramount importance both for EU exports and imports. Businesses (both in the EU and in third countries exporting to the EU) will also be affected by changes aimed at improving the efficency of the control system as a whole, and in particular of the import controls.

Consumers both in the EU and outside the EU, are not directly concerned by the review although they are the ultimate beneficiaries of measures to ensure the safety and quality of the agri-food chain. With the increased cost of controls for operators it is possible that some of the additional costs will be passed on to them through the price of final products, however by comparison with the overall cost of food production such an increase is expected to be small (see Box 6 and Box 8).

2.4. How would the problem evolve, all things being equal?

All identified shortcomings in the problem definition would remain. Potential under-enforcement of agri-food chain rules due to the suboptimal design of the legislative framework or to underperformances of the control system could result in a **loss of confidence** in the EU market in the long term. Inefficient use of control resources (including at the EU borders) could imply the perpetuation of avoidable administrative costs and burdens for operators.

As for the sectors pertaining to the agri-food chain but currently outside the scope of this Regulation (plant health, PRM and ABP), separate systems would continue to operate and develop according to sectoral logics and priorities; here again the opportunity for efficiency gains would be lost while existing gaps in the available range of enforcement tools in those areas and differences in national practices would persist.

As regards the financing of official controls, if the legislation is not revised the current regime would remain with its recognised limits and shortcomings[35]. None of the problems identified can evolve favourably and most could worsen without legislative change. In particular, **uncertainty would remain as regards the availability of sufficient resources to finance official control activities**.

The capacity of national control systems to prevent and counter risks which might arise along the agri-food chain (for humans, animals and plants) would inevitably be affected by the said shortcomings. This would represent potential obstacles to the objective of ensuring that national control systems are well equipped and capable of anticipating/preventing risks and may therefore adversely impact on the safety of the agri-food chain and its products. In particular, less efficient controls will increase the probability of health crises, and reduce the capacity of competent authoritires to remedy them, which may in turn lead to significant economic and human losses. Therefore, although cutbacks in relation to the financing of

[35] DG SANCO has developed an extensive baseline scenario (see Annex XVI) against which each of the options has been assessed.

official controls may seem justified in the short term, given relevant savings and reduced public expenditure, in the long term they may actually result in higher costs for citizens and industry where controls are unable to prevent large scale emergencies[36].

With **the current discriminatory treatment between those operators which must be charged (mandatory fees)** for official controls they receive and those which can be charged, depending on whether Member States decide to collect non-mandatory fees, failure to address the perceived unfairness of the financing system might also increase the reluctance of industry to remunerate official control activities.

2.5. Does the EU have the right to act (subsidiarity)?

2.5.1. Right of the EU to act **(legal basis)**

The Regulation was based on Articles 37, 95 and 152(4)(b) of the EC Treaty, now **Article 43, 114 and 168(4)(b)** respectively of the TFEU.

Article 43 is implementing the Common Agricultural Policy (CAP), policy qualified by the Lisbon Treaty as shared competence between the EU and its MS. It is obvious, however, that to a very large extent all fields of agricultural activity as well as ancillary activities upstream and downstream, have been regulated at the EU level. This means that legislation is predominantly a role for the institutions of the European Union.

Article 114 provides the legal basis for the establishment and functioning of the internal market for food products while ensuring a high level of protection of consumers and the approximation of provisions laid down by the law, regulation or administrative actions in this respect.

Article 168(4)(b) stipulates that in order to meet common safety concerns *'measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health*' should be adopted by the EU.

2.5.2. Necessity for the EU to act (**subsidiarity**)

Necessity – The existence of a harmonised EU legislative framework to govern the organisation and performance of official controls along the agri-food chain is necessary to ensure the uniform implementation of agri-food chain rules across the EU and the smooth functioning of the internal market. This rationale, which is still valid, underpins the existing rules on official controls. As the problems identified by this review are linked to the current design of the EU legislative framework, its reform cannot be achieved by MS acting alone. The intervention of the European legislator is required.

European added value test – The added value of a single, uniform set of EU rules to govern official controls lies in the fact that it offers national enforcers (and their operators) a framework within which CAs can rely on enforcement activities carried out in another MS, and on the reproducibility and scientific and technical soundness of control results. It also ensures that EU agri-food chain standards necessary for the functioning of the single market are applied uniformly and consistently in the different MS and sectors.

[36] See Impact Assessment report on "the proposal to revise the EU Plant Health Legislation" for an overview of the economic and environmental impacts which may result from an increase in the influx of harmful organisms into the EU.

As to the financing of controls, common EU rules ensure that CAs can count on a reliable flux of resources to maintain the control effort at a level justified by the risks and by enforcement needs (e.g. level of non-compliance). Provisions on fees in particular ensure that businesses, which benefit directly from efficiently performed controls, participate to the financing of the latter, so as to minimise the dependency of control funding on public finances. Common EU rules are necessary also to prevent discriminatory treatment between operators located in a MS where the user-pays rule (and thus fees) applies and those located in a MS where this is not the case. Only common EU rules can ensure a uniform approach to pursue this objective.

EU action should not go beyond what is necessary to achieve the objectives set. The present exercise has looked at a broad range of options, including that of harmonising fee levels across MS, and that of de-regulating the matter. The analysis sought to design the most proportionate solution to ensure a sufficient and steady flux of dedicated resources for official controls, whilst leaving MS the time and flexibility necessary to cater for their internal arrangements and the specificities of their business population.

3. Objectives

3.1. General objectives

The main purpose of this exercise is to reinforce the safety of the agri-food chain (in its broadest meaning) by strengthening the enforcement mechanisms of the relevant EU rules and enable a more efficient implementation of the harmonised framework which applies to food, feed, animals, seeds and plants . Thus the general objectives of this initiative broadly coincide with the Treaty objectives to safeguard the single market while ensuring delivery of a high level of health protection. They also reflect the Commission's objective of ensuring proper enforcement of EU law, as this is the original objective of the Regulation on official controls. In particular, the following general objectives are envisaged:

- contribute to promote the smooth functioning of internal market rules applicable to the agri-food chain;
- maintain a high level of human, animal and plant health protection and animal welfare throughout the length of the agri-food chain and prevent that this is undermined by potential non-implementation of EU legislation;
- ensure proper and uniform implementation of EU legislation.

3.2. Specific objectives

The specific objectives were set with the aim of eliminating the specific obstacles identified during the analysis which prevent or hamper the achievement of the general objectives in this area[37]. The specific objectives address the two sets of obstacles mentioned above, i.e. those resulting from shortcomings in the design of the official controls' framework and those resulting from the difficulties and inequities in financing of official controls.

[37] As the Treaty of Lisbon has made the Charter of Fundamental Rights of the EU legally binding, the results of this review shall be in full compliance with the Charter of Fundamental Rights of the EU, in particular the right to protection of personal data and the right to an effective remedy.

3.2.1. Objectives related to the design of the official controls' framework

- Ensure a comprehensive and consistent approach to official controls along the agri-food chain, by eliminating fragmentations and inconsistencies of the current legal framework:
  - the system of official controls should be consistent across all agri-food chain sectors avoiding differences which are not justified by the peculiarities of a given sector;
  - this system should provide for all tools necessary to ensure accountability, soundness and effectiveness of the enforcement activities performed in all agri-food chain sectors;
  - this system should avoid duplications and overlaps which result in divergent interpretations and implementation.
- Allow for a more efficient use of national control resources, by eliminating residual non risk based mechanisms for the allocation of control resources:
  - the system of official controls should require MS to allocate, in all agri-food chain sectors, finite control resources on the basis of the actual risk in order to achieve the most efficient use of such resources.
- Reduce administrative burden and remove unnecessary requirements:
  - unnecessary administrative burden, in particular on MS' CAs, should be eliminated;
  - the system should allow for the necessary flexibility so that important requirements (the accreditation of official laboratories) can be derogated where appropriate.
- Foster closer cooperation between MS to improve official control delivery:
  - the system of official controls should enable swift and effective cooperation, and synergies, among MS' competent authorities (including customs) which are tasked with controls over the agri-food chain.
- Improve transparency:
  - rules on official controls should provide MS with clear guidance on how a 'high level of transparency' should be ensured so that the European citizens can benefit from the same level of transparency across the EU.

3.2.2. Objectives related to the financing of official controls

- Ensure the availability of adequate resources:
  - The system of financing of official controls should ensure the availability of the resources necessary to maintain an adequate level of controls and, consequently, the level of protection offered by EU agri-food chain rules.
- Ensure equity and fairness in the financing of official controls
  - The system of financing of official controls should ensure that the burden on agri-food chain operators is distribuited in a fair and equitable manner to avoid distortions.
- Improve transparency
  - The fees system should be transparent and allow the public and, more specifically, the operators to understand how the fees are calculed and how revenue therefrom is employed; so that transparency can act as a driver to accountability and efficiency of the system of financing official controls.

3.3. Operational objectives

- Establish a single, simpler legislative framework for official controls along the agri-food chain;
- all controls, including border controls, to be risk based;
- increase the number of cases where cross-border enforcement cases are resolved through administrative assistance and cooperation;
- increase the number of formalised instruments between the CAs and customs (and/or other) authorities for the performance of official controls;
- reduce the occurrence of unsatisfactory enforcement results attributed to resources shortages.

Table 1: Link between the objectives and the problems

	Problem at stake	**Specific objectives**
Design of official controls' framework	Inconsistencies, gaps and overlaps in control requirements	Ensure a comprehensive and consistent approach to official controls along the agri-food chain
	Inconsistent implementation of risk based approach	Allow for an efficient use of national control resources
	Administrative burden and disproportionate requirements	Reduce administrative burden and remove unnecessary requirements
	Uneven enforcement of cooperation mechanisms	Improve transparency
		Foster cooperation between MS to improve official control delivery
Financing of official controls	**Difficulties** and **inequities** in financing official controls activities	- Ensure the availability of adequate resources - Ensure equity and fairness in the financing of official contrls - Improve transparency of the system of financing of official controls

3.4. Consistency with other EU policies and horizontal objectives

The review requires consistency with the reviews of the animal health law, the plant health law and the PRM legislation, the four proposals being adopted by the Commission together as a package (along with a fifth proposal establishing a multiannual programme for EU financing of actions aimed at ensuring a high level of health for humans, animals and plants along the agri-food chain). The review is also intended to ensure that the provisions of Regulation 882/2004 complement in a consistent manner those applicable to official controls in the field of veterinary medicines, also currently under review.

Moreover, the review preserves synergies between the current system and relevant aspects of agricultural legislation and creates the possibility for new ones by enabling environmental legislation on Invasive Alien Species (IAS) to be supported in its implementation through the control mechanisms established by the amended Regulation. In order to do so the present review will take into account the outcome of the ongoing work to develop the EU legislation on IAS.

The review also seeks to align the framework of official controls, in particular the terminology used, to the modernised customs code.

With a view to the Europe 2020 strategy, the provision of effective controls along the agri-food chain is to ensure safe food and feed while fostering competitiveness of business operators, rewarding complaint business operators and ensuring user-pays principles across all sectors.

This initiative pursues the objectives of the Communication on Smart Regulation in the European Union. One of the aims of the review is to simplify legislative burdens in light of comments made by MS and food business operators on the existing regime.

4. Policy options

4.1. Policy options included in the analysis[38]

The analysis of options available to address the problems and achieve the objectives above was carried out in two stages:

1. first, the potential impact of deregulating the matter of the financing of official controls and of exempting micro-enterprises from the fees system was considered;
2. the outcome of the analysis under 1 was then used to design options 2 to 4, which combine the following elements:

- expand the scope of the Regulation to agri-food chain sectors currently outside its scope (i.e. plant health, PRM and ABP);
- improve and simplify the legislative framework;
- ensure full cost recovery through fees;
- expand the list of control activities for which the collection of a fee from operators is obligatory.

Table 2: Summary of the options included in the analysis

	Scope of the Regulation	**Legislative framework**	**Cost recovery**	**Scope of mandatory fees**
Baseline	partial (plant health, PRM, ABP out)	deficiencies and shortcomings	partial	partial (meat, milk, fishery, imports)
Option 1A	status quo	status quo	No (deregulation)	/
Option 1B	status quo	status quo	status quo	exemption for micro-enterprises
Option 2	status quo	improved	full	status quo
Option 3	expand to plant health and PRM	improved	full	ADD plant health and PRM
Option 4	expand to plant health and PRM	improved	full	ALL registered food and feed operators

[38] For a description of the elements of each option and main changes implied see Annex XXIII.

Base line (status quo) The integration of the system of official controls along the food agri-chain is partial, some agri-food chain sectors being outside the scope of the Regulation. Official controls carried out at EU external borders on certain goods arriving from third countries, and official controls on residues of veterinary medicines are not aligned to the risk based approach. This will continue to generate avoidable costs (for rigidly prescribed, non risk-based controls). Inconsistency and inefficencies in the deployment of efforts by, and in cooperation between, national authorities will derive from the lack of uniform guidance on how to implement administrative cooperation and deliver a high level of transparency. No derogation is foreseen from the requirement of accrediting official laboratories.

The collection of fees is mandatory for a limited number of control activities (control activities on businesses handling meat, fishery products, and milk; for the approval of feed establishments; at EU borders on certain goods from third countries). MS can choose to charge a standard EU fee fixed in the Regulation, which does not correspond to the actual cost of the control. This results in potential under-resourcing of control authorities and in the risk that the capacity of the EU control system as whole to prevent and contain health risks along the agri-food chain is undermined.

Box 3: Financing of official controls: baseline[39]

Collection of mandatory fees: Twenty-one MS (AT, BE, BG, CY, CZ, DE, DK, EE, IE, EL, FI, FR, HU, IT, LT, NL, PL, PT, RO, SI, SK) collect fees for all official control activities for which mandatory fees apply[40]; however, five (ES, SE, LV, MT, UK) only partly collect such fees (in other words, in these MS, certain mandatory fees are not collected). Fees for milk production controls and fees for residue controls are the two types of control activities for which several of these MS do not collect fees. Data is not available for LU.

Twenty-two MS (AT, BE, BG, CY, CZ, DK, EE, EL, ES, FI, HU, IE, IT, LT, LV, NL, MT, PT, RO, SK, SI, UK) collect fees for activities for which fees are not mandatory[41]. On the other hand, two MS (FR, PL) do not collect fees for activities beyond those which are mandatory[42], and two MS (DE, ES i.e. countries with a decentralised management of fees) collect such fees in some regions but not in others.

Full cost recovery: Eight MS (NL, IT, AT, PL, LT, LV, PT, SI) currently achieve full or almost full cost recovery of mandatory fees for official control activities whilst eight MS (BG, CZ, EE, ES, FI, SE, EL, IE) achieve a low level of recovery. Eight MS (BE, DK, FR, HU, MT, RO, SK, UK) recover between 34 – 66% of the cost of official controls for which mandatory fees apply. Levels of cost recovery are unknown for three MS.

Fee rates: Across the EU fee rates vary considerably, not necessarily in relation with variances in costs. For example, fees paid for controls on the slaughter of adult bovine animals can vary from €2.3/head in some autonomous communities in Spain, to €8.2/head in Denmark and between €10-20/head in Sweden (against a minimum fee of €5/head in Annex IV). Even within MS the scale of the variation can be significant. For example, in Bavaria (Germany) fee rates for the slaughter inspection of adult bovine animals range from €9.4/head to €12.9/head depending on district.

Should the status quo be maintained, the shortcomings identified in Section 2.2 would remain.

[39] The baseline only describes the situation in MS as regards the collection of fees for the purposes of control activities currently falling within Regulation 882/2004.
[40] Article 27(2) of the Regulation.
[41] Article 27(1) of the Regulation.
[42] Article 27(2) of the Regulation.

Options 1A and 1B

A preliminary analysis focuses on two possible changes to the status quo which would specifically aim to A) repeal Union rules on control fees (thus leaving it to MS to decide how to ensure the appropriate funding of control activites), and B) maintain current EU rules on fees, exempting micro-enterprises therefrom.

The outcome of such analysis is then reflected in the design of subsequent options (2 to 4).

Although in theory both Options 1A and 1B could be combined with other elements of Options 2 to 4, they are presented and assessed individually given the significance of the changes they purport to introduce. Both would, in fact, substantially alter the current framework as regards the financing of national control systems and call into question established principles. Moreover, the combination of Options 1A and 1B with other elements of Options 2-4 would not result in significant trade-offs and would therefore not modify the cost/benefit analysis of the former to an appreciable extent.

Option 1A - Repeal Union rules on control fees

(Existing mandatory inspection fees are repealed; other provisions of the legislative framework remain unchanged)

Under this Option each MS is given the possibility to determine the approach it follows as regards the funding of official control activities, provided that it ensures a level of resources which allows the correct implementation of control requirements and the efficient enforcement of EU law. It would require **repeal** of **Articles 27-29** of the Regulation and in particular of the mandatory collection of fees in certain areas.

Option 1B - Mandatory exemption of micro-enterprises from the application of fees

(Existing mandatory inspection fees are maintained but not applied to micro-enterprises; other provisions of the legislative framework remain unchanged)

Option 1B was selected in view of the Commission's continued efforts to promote the competitiveness of micro-enterprises, as highlighted in the Commission policy on *"Minimizing regulatory burden for SMEs – Adapting EU regulation to the needs of micro-enterprises"*.

This Option would provide for the mandatory exemption of micro-enterprises from the application of mandatory fees and would require the breadth of operators upon which mandatory fees are levied to be appositely restricted.

Option 2 – Streamline

(The legislative framework is improved and streamlined, full cost recovery is ensured where mandatory fees are already provided, with the possibility for MS to refund fees paid by micro-enterprises)

Option 2 would aim to improve the legislative framework on official controls by clarifying, simplifying and streamlining existing provisions on controls in sectors currently covered by Regulation 882/2004, and by ensuring full cost recovery in the areas where mandatory fees are already provided. The main changes would be:

a) repeal redundant and obsolete pre-existing legislation in the area of **veterinary checks** in intra-EU trade so that **overlaps** in control requirments would be eliminated and the system would become more consistent because less open to divergent interpretation[43];

b) repeal existing sectoral provisions[44] in the area of **border controls** and establishing, in the Regulation, a single set of rules applicable to border controls on all goods requiring special attention at the external borders of the EU because of risks to human, animal, plant health. This system would be aligned to the risk based approach underpinnying Regulation 882/2004 so that the allocation of control resources would be made on this basis. In addition, the elimination of the legislative fragmentation in this area would allow MS to prioritise the controls across all sectors covered by the Regulation.

c) repeal Directive 96/23/EC applicable to **official controls on residues of veterinary medicines**, with additional rules established in line with the Regulation; as a consequence, these controls would be governed by Regulation 882/2004 only on the basis of the risk. In addition, the repeal of this Directive would eliminate the obligations identified as administrative burden.

d) clarify the obligation of **cooperation** between sanitary authorities and customs services, and include the possibility of setting control coordination mechanisms with other national authorities (at borders and elsewhere) so as to take advantage of all potential operational synergies at borders (including with customs and on controls on IAS).

e) clarify the rules applicable to the methods used by **official laboratories** and providing **derogations** from the obligation to accredit the laboratories in certain cases in order to avoid this requirement to be applied in a disproportionate manner;

f) introduce **new empowerments** to enable the Commission to i) specify the modalities of the administrative cooperation's mechanism so as to ensure its uniform application across MS; ii) provide guidance on how to deliver a 'high level of transparency';

g) require MS to calculate existing mandatory fees in manner which enables them to **fully recover the costs** of, and appropriately finance, official controls, and eliminate current obstacles to full recovery resulting from the provision of minimum fees;

h) improve **transparency** and introduce **incentives for compliant businesses;**

i) provide MS with the **possibility to refund fees to micro-enterprises** in accordance with State Aid rules[45] (current rules include the prohibition to refund, directly or

[43] Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market; Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market;; Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products; Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters.

[44] Article 15(5) of Regulation (EC) No 882/2004 establishing the framework for the performance of import controls on feed and food of non-animal origin; Directives 97/78 of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries, and 91/496 of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC; Directive 2000/29 on protective measures against the introduction into the Community of organisms harmful to plants or plant products; the latter governing, inter alia, border controls on plants and plant products.

[45] The option of requiring MS to exempt all micro-businesses from payment of mandatory fees is presented in Option 1B and analysed in section5 (Analysis of impacts). With regard to Plant Health, exemptions for micro-enterprises will not apply given that most operators under these health regimes could qualify as micro-businesses

indirectly, fees collected for the financing of official controls; Option 2 would repeal it insofar as micro-enterprises could benefit from the refund).

As the establishment and application of a full cost recovery system would require some adjustments in the Member States' current systems, **a transition period of 2 years would be provided**.

Option 3 – Streamline + Integrate

(The legislative framework is improved and streamlined, plant health and PRM, and ABP are included in its scope, full cost recovery is ensured where mandatory fees are already provided with the possibility for MS to refund fees paid by micro-enterprises)

In addition to the elements of option 2, option 3 would **widen the scope of the Regulation** to cover sectors of the agri-food chain *acquis* that are currently excluded (plant health law[46], PRM legislation, ABP rules) and complete the 'integration' of agri-food chain official controls. This would be done by repealing pre-existing provisions governing official controls in the sectors being integrated into the Regulation[47]. Appropriate **transitional periods** would be provided for new obligations (such as the laboratories' accreditation for plant health tests). The inclusion of the sectors above under Regulation 882/2004 would aim to ensure that, in principle, competent authorities operate on the basis of the same approach and under the same conditions no matter the agri-food chain rules they are called to enforce. Some adjustments would be introduced to account for specificities of those sectors, in particular as regards the certification procedure and the accreditation of official laboratories.

As regards the financing of official controls, the control activities covered by a mandatory fee would remain unchanged with the only exceptions being in the field of plant health, where mandatory fees will be introduced for official controls linked to plant passport obligations, and in the field of PRM, where it is envisaged that the principle of full cost recovery through fees would be established for certification.

Option 4 – Streamline + Integrate + broader cost recovery

(The legislative framework is improved and streamlined, plant health and PRM, and ABP are included in its scope, mandatory fees are extended to cover key areas of the agri-food chain with the possibility for MS to refund fees paid by micro-enterprises)

In addition to the elements of option 3, option 4 would **expand the list of mandatory inspection fees** to all controls carried out on feed and food business for which a registration requirement is established in accordance with food safety and feed safety rules, i.e. on all activities for which an obligation for operators to be registered exists in accordance with Regulation (EC) No 852/2004 (food hygiene) and/or Regulation (EC) No 183/2005 (feed hygiene). Although responsibility for the safety of food and feed on the EU market lies

(see Impact assessment report on "the proposal to revise the EU Plant Health Legislation"). The IA accompanying the proposal to review PRM acquis follows the approach presented here.

[46] At present only Articles 41-46 of Regulation 882/2004 apply to Plant health.

[47] Official controls provisions laid down in Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community; 12 Council Directives on the marketing of plant reproductive material; Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002.

primarily with food and feed business operators, in these areas an increased control effort is also required from CA to ensure that food and feed business operators comply with safety requirements, and, ultimately, that food and feed placed on the market is safe.

Compared to the baseline, fees would also become mandatory for the following activities:

- **production** of food other than meat, fishery products and milk (already subject to mandatory fees): **eggs and egg products, honey and all foods of non animal origin;**
- **distribution (including wholesale, retail and restaurants) of all food**;
- **production and distribution (including wholesale and retail) of feed**;
- **production and distribution of ABP** in so far as the concerned operators have to be registered under Regulation (EC) No 852/2004 or Regulation (EC) No 183/2005;
- **import of goods from third countries that need to be checked at the border** other than those already covered by a mandatory fee (e.g. goods subject to a safeguard measure).

As the establishment and application of cost based fees in all areas would require some adjustments in the MS current systems, a transition period of 3 years would be provided.

4.2. Discarded policy options

- *Reducing controls on micro-enterprises or SME's*

  Given the new Commission policy on *"Minimizing regulatory burden for SMEs – Adapting EU regulation to the needs of micro-enterprises"*, the possibility of exempting micro-enterprises or SME's from the performance of official controls was considered. This option was discarded as it ran counter to the basic principles underlying Regulation 882/2004 and would also not have addressed the problems identified in section 2.2.

  In particular, micro-enterprises represent a very high proportion of the business population subject to official control activities[48] and, given that food safety risks/concerns arise regardless of the size of an operator, their exemption from official controls would lead to the non-compliance of numerous goods placed on the EU market with relevant EU agri-food chain standards and requirements. The safety of the agri-food chain would be undermined and the number of food crises would increase. Furthermore, as highlighted with regards to the *E. Coli* crisis (see section 2.1.1), the gravity of food crises stemming from micro-enterprises/SME's should not be underestimated.

- *Non-legislative option (e.g. development and use of electronic systems, adoption of informal guidelines at EU level etc.)*

  A general option based on the development of "soft law instruments" to increase the clarity of the existing legal text. The option was discarded as the non-binding nature of soft law instruments was considered insufficient to address the interpretation and implementation difficulties linked to The Regulation and the shortcomings of the rules governing inspection fees.

Further options relating exclusively to the **availability of adequate resources for official controls** were also excluded:

[48] See section 2.1.1 and the analysis of Option 1B in section 5. The proportion mentioned is even higher if SME's are considered alongside micro-enterprises.

- *Imposing mandatory fees on all operators subject to official controls*

  The option of requiring MS to apply mandatory fees to all the operators subject to controls in accordance with the Regulation was discarded. Instead, the option of charging food and feed operators subject to a specific registration requirement laid down in Regulation 852/2004 (food hygiene) or in Regulation 183/2005 (feed hygiene) was retained (see option 4). The discarded all-inclusive option would have required the application of mandatory fees also on operators not directly concerned with the production of handling of food or feed (e.g. keepers of non food producing animals, plant nurseries) and on operators only marginally involved in the production of food for commercial purposes (e.g. farmers producing for domestic consumption, or for the direct supply of small quantities to final consumers or to local retailers supplying final consumers). These operators do not have to be registered under EU food/feed hygiene rules, and some of them would be subject to official controls organised in accordance with the Regulation only after the intended changes to its scope (options 3 and 4). Considering the absence of registration requirements for these operators, the great numbers and the fragmentation of the business population potentially concerned, which would further increase with the present review, it would have been very difficult to accurately assess the impact of this option (particularly in relation to those areas where Regulation (EC) No 882/2004 would become applicable only following the review).

- *Full harmonisation of fees*

  An option based on **full harmonisation** of fees across MS (i.e. the establishment of EU standard fees for each type of control carried out, irrespective of the actual cost in each MS). This option was discarded since it fails to achieve the objective of full cost recovery (harmonised fees would in most cases either 'under' or 'over' compensate costs). Furthermore, the development of EU-uniform cost models for each of the types of controls would be a very burdensome exercise. Monitoring and maintaining appropriate harmonised fee levels would also create a disproportionately heavy burden for Member States and the Commission.

  The option of **adjusting harmonised fees to the cost of living in each MS was also excluded**, as although adjusted fees could be somewhat closer to the actual costs, they would not be fully accounted by accurate and actual costing of control activities, and thus would not guarantee full cost recovery or the absence of overcompensation. Furthermore, they could only be obtained through a complex mechanism for the calculation of standard EU costs (and fees) for each type of control, for the update and application of the chosen adjustment index, and appropriate monitoring tools to constantly update the EU fees.

- *Harmonised fees for certain import controls*

  During the consultation phase, some respondents argued in favour of a specific, fully harmonised fee (i.e. not adjusted to cost-of-living or any other index) to be applied only for the performance of **border controls on goods arriving from third countries**. The argument for harmonised fees for import controls is that it would create a 'level playing field' across the EU-27 for such fees and remove the potential for trade distortions derived from importers seeking out border points with lower fees. Although several of those consulted through the 2011 Impact Assessment Study see this as an issue, evidence of such distortions has not been found in two successive contractor studies.

Section 5: Analysis of impacts

This IA analyses the likely social, economic and environmental impacts – be they direct or indirect – of the different policy options. Each option has been assessed against the theoretical baseline of 'do nothing' and therefore the impacts outlined are additional to the current status quo. Economic impacts are assessed through the following criteria: *competitiveness*, *innovation*, *sustainability, simplification*, and *administrative burden reduction.* Equally important for the analysis are social impacts (*safety* in particular, but also *accountability*). The assessment of each option in terms of environmental impacts and of impacts on employment rates has not identified significant impacts (either negative or positive).

To help comparisons between options the impacts have been rated (**0**: no impact; +, ++, +++: small, medium or large positive impact; -, --, ---: small, medium or large negative impact).

Option 1A – Repeal Union rules on control fees

The repeal of the existing EU framework on inspection fees is likely to result in an increased variance of national approaches, and possible cuts in resources allocated to controls.

Sustainability - Although the impact on the level of resources actually deployed will depend on the policy choices that each MS will make and so cannot be fully predicted and analysed, the problems identified in relation to the current fees regime, such as the failure to ensure proper cost recovery, and thus appropriate and stable resourcing of controls are unlikely to be solved. On the contrary, stakeholders and MS argue that, given the current economic crisis, the problems affecting the sustainability of controls could worsen if MS decisions result in fewer resources being allocated to the operation of national control systems.

Simplification - The repeal of the EU framework would result in a more complex legislative landscape as differences in national rules on the financing of controls are likely to increase. Under the current system MSs already exhibit significantly wide variance (see tables 1-4 in Annex XVII) in cost recovery levels, *bonus malus* arrangements and availability of information to the public. In the absence of a harmonised framework, national approaches to the financing of official controls are likely to vary even further over time as MS make different policy choices.

Competitiveness - Wider disparities amongst MSs might result in distortions of competition, if operators in one MS are charged for controls while competitors in another MS are not, with adverse impacts on the operation of the single market.

Accountability - This option would repeal the obligation for MSs to publish and communicate to the Commission the method of calculation of the fees, thus leaving MS free to decide the level of transparency (and of accountability) of their domestic regimes.

Safety – A decrease in the availability of resources would inevitably reduce the resources available to CAs to perform official controls potentially leading to fewer controls being carried out. CA may have difficulties maintaining an effective oversight of compliance by food business operators and, ultimately, the safety of the agri-food chain, especially when faced with large scale crises.

Summary of the key impacts under Option 1A

Criteria	Impacts
Competitiveness	-
Innovation	0
Sustainability	-
Simplification	-
Administrative Burden	0
Accountability	-
Safety	-

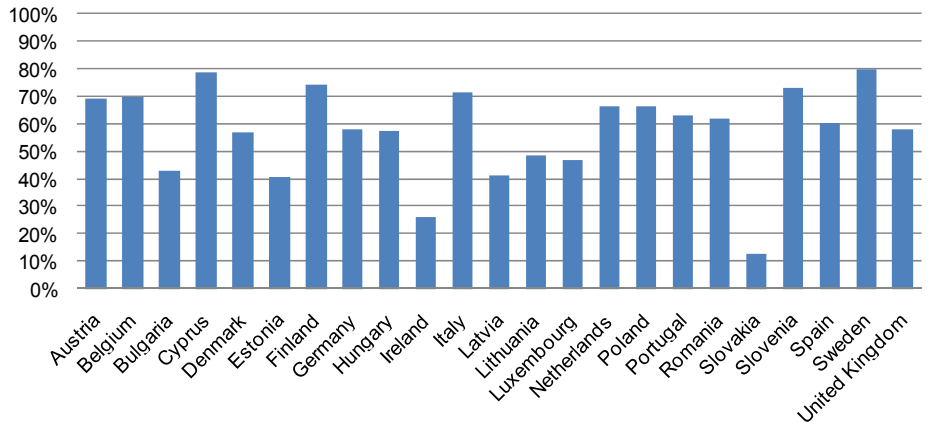
Based on the above analysis, the option to repeal current EU rules on fees as established in Regulation 882/2004 was not considered further.

Option 1B – Mandatory exemption of micro-enterprises from the application of fees

The mandatory exemption of micro-enterprises from the application of fees would reduce the financial burden on micro-enterprises However, the exemption would undermine the objective of ensuring the sustainability of the control system, and through it the safety of the agri-food chain.

Sustainability: Figure 3 gives an overview of the percentage of micro-enterprises on the total number of operators in the major industries subject to official controls (and to mandatory fees) under on Regulation 882/2004. In 16 of the 23 Member States for which data is available, micro-enterprises represent more than half of all businesses, and in 9 such States (AT, BE, CY, FI, IT, NL, PL, SE, SI) the percentage of micro-enterprises rises to two thirds (or more) of all business operators[49].

Figure 3 Share of Micro-enterprises in total number of business operators in the four major European industries affected by official control activity (2008)*



*Industry sectors include: processing and preserving of meat and production of meat products; processing and preserving of fish, crustaceans and molluscs; manufacture of dairy products; manufacture of prepared animal feeds. Greece and Malta are not included in Eurostat dataset. Data for the Czech Republic and France are not available.

[49] Also see Annex XXV.

In those MS where micro-enterprises represent an overwhelwing majority of businesses subject to fees, exempting them from the payment of the latter will have a severe negative impact on the proportion of costs recovered by CA. The objective of ensuring a sustainable financing of controls via full cost recovery would, in most (if not all) Member States, be undermined, as controls will still need to be carried out on all operators at a frequency dictated by the risk.

While the CAs' loss in revenue represented by the exemption could be compensated by transfers from the general budget, this would again create a strong dependency of the control action on public resources and thus create a situation – in particular in times of crisis and budget restrictions - of financial uncertainty which can not be reconciled with the objective of ensuring consistent, efficient and risk commensurate control activities across the agri-food chain.

Competitiveness - The mandatory exemption of micro-enterprises from the application of fees would reduce the financial burden upon them and help to encourage the development of small businesses, including artisanal establishments.

However, a mandatory exemption for micro-enterprises would result in the unfair treatment of larger operators who might be charged more to fill in the cost recovery 'void' left by the exemption of micro-enterprises. The impact on larger businesses would be particularly disproportionate in those Member States and those sectors with a large percentage of micro-enterprises.

Safety – Lower cost recovery by reason of the exemption of micro-enterprises would result in a lower revenue income for competent authorities. Over time, unless competent authorities were otherwise subsidised, this may lead to fewer official controls and result in a higher probability of food products not complying with EU agri-food chain legislation. The safety of the agri-food chain could ultimately be jeopardised and the risk of food crises would increase[50].

The analysis carried out above is fully in line with the views of competent authorities and industry. Throughout the consultation process both firmly opposed a mandatory exemption for micro-enterprises highlighting, amongst other things, that it would have a negative impact on the sustainable performance of official controls[51] and on competition. Similarly, stakeholders did not request that data on ways to support micro-enterprises be obtained.

Summary of the key impacts under Option 1B

Criteria	Impacts
Competitiveness	0/-
Innovation	0
Sustainability	--
Simplification	0
Administrative Burden	-
Accountability	0
Safety	--

[50] Given the huge economic losses and human suffering that may result from food crises (see e.g. the dioxins/E. Coli crises) any policy option should aim to avoid them, even when this implies imposing burdens on operators.
[51] See Annex XXV for a summary of stakeholder opinions.

Based on the above analysis, it is considered that an automatic exemption of micro-enterprises (or SME's in general) from the application of fees would, on the one hand, undermine the policy objective of ensuring the long term sustainability of national control systems and, on the other hand, create potential distortions of competition. This conclusion also holds true in cases where other possible changes to the status quo are considered and, in particular, if mandatory fees are imposed on all registered food and feed operators (as per Option 4) as the proportion of micro-enterprises in the different areas of the agri-food chain is very significant (data published in April 2012 by Fooddrinkeurope shows that 79% of operators in the food and drink industry are micro-enterprises).[52][53]

In the options considered below, the exemption of micro-enterprises from the application of fees is therfore replaced by a mechanism which aims to respond to both the abovementioned shortcomings (i.e. sustainability and competition).

Option 2 – Streamline

Increased efficiency of the risk based use of control resources and mobilisation of dedicated financial resources reducing pressure on national finances allow progress towards the primary objective of maintaining efficient controls and safety of the agri-food chain. MS may refund fees paid by micro-enterprises, conforming to State Aid rules.

Competitiveness - Option 2 would allow for the full implementation of the risk based approach to official controls in sectors where MS CAs are currently not allowed to adjust their control efforts to the actual risks (i.e. official controls carried out at EU border on certain goods from third counties, and official controls on residues of veterinary medicines). This would result in a better allocation of control resources and, thus, in a more efficient control system[54].

Box 4: Reduced costs for official controls on residues and other substances

A risk based approach to controls on residues of veterinary medicines would lead to a decrease of the number of samples ranging from 49 753 to 394 280, thus to a decrease of costs (for CA and ultimately for operators through the corresponding mandatory fee) ranging from € 12.4 million to € 98.5 million when considering the average total cost per sample for laboratory analysis (staff, consumables, overheads, etc.). MS in general expect the sampling capacity that will be freed to be used to increase the sampling of other substances/residues and/or on higher risk matrices.

Moreover, enabling national authorities to focus their control efforts where non compliances and risks are higher would minimise the burden of official controls on compliant businesses and have, therefore, a positive impact on their competitiveness.

However, the benefits in terms of increased efficiency and competitiveness would be only partial because plant health, PRM and ABP are not included within the scope of the Regulation according to option 2. In fact, the best allocation of control resources can only be achieved by ensuring that the risk prioritisation is carried out by MS CAs across all sectors of the agri-food chain, including those above. This is prevented by the current fragmentation of official controls legislation.

[52] http://www.fooddrinkeurope.eu/uploads/publications_documents/Final_Data__Trends_30.4.2012.pdf
[53] For plant health, see impact assessment report on "the proposal to revise the EU Plant Health Legislation"
[54] For a quantification of the costs reductios relating to the repeal of Directive 96/23/EC see Annex XXI; those data are also included in the table 4 (section 6.2.) providing an overview of the costs and benefits associated to each option.

Fees charged on the basis of actual costs would be (and be perceived as) fairer across the MS since at present the use of standard fees and the varying recovery rates applied across and within MS means that fees recovered by some MS may be either higher or lower than the cost incurred by the CA performing official controls. Under the current regime, where a MS is charging a standard fee which is higher than the actual cost whereas other MS do not, or where a MS recovers a higher percentage of fees than other MS, the operators in the territory of that MS will be at a competitive disadvantage in relation to operators in the other MS. Option 2 will create a level playing field for all operators charged with mandatory fees.

Importantly, the *bonus malus* principles which are already inherent in the current legislation (and which will be retained in the revised legislation), and new provisions (which will allow businesses currently charged a flat rate fee regardless of the level of enforcement activity to benefit from recognition of good performance), will ensure that costs on well-performing, low risk businesses are comparatively lower than those on non-compliant operators. Consultation results demonstrate that Industry is very keen to see this taken forward.

The possibility for MS to alleviate the impact of full cost recovery on micro-entreprises by refunding them the mandatory fees paid, on condition that this is in conformity with State aid rules (i.e. does not unduly affect competition), would ensure that the benefit for the recipients of the refund does not result in unfair competition for other businesses and does not deprive CA of the resources which are necessary to perform their control tasks. The 'refund' mechanism means that the benefit for micro-enterprises is not to be afforded at the expenses of full cost recovery by CA[55].

Innovation - By allowing in certain cases the use of methods not yet included in the scope of the accreditation of an official laboratory, Option 1 would remove legal obstacles to the introduction and development of new analytical methods.

Simplification - The repeal of pre-existing sectoral acts or provisions would streamline all rules dealing with official controls along the agri-food chain in a single legislative framework, eliminating duplications and overlaps with the Regulation[56].

Simplification gains would also come from the streamlining of border official controls on goods from third countries. CAs, instead of using different sets of rules depending on the type of goods to be controlled at the border, would refer to a single framework governing the mechanism of border controls for both live animals and their products, and food and feed of non animal origin. In practice, they will find the goods subject to such controls included in one consolidated list (based as much as possible on CN codes) and will be able to designate single border control posts where all such goods could be checked; a single and harmonised entry document will be used for all concerned goods. Economic operators would benefit from such simplification as they will us the same set of procedures and requirements, and a harmonised entry document independently of the goods they introduce into the Union.

Box 5: Simplification gains under option 2

Acts or provisions to be repealed under option 2

- Directive 89/662/EEC concerning veterinary checks in intra-Community trade
- Directive 90/425/EEC concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products (*except for the provisions concerning zootechnical controls*);

[55] Therefore, the refund could be replaced by an exemption from the payment of the fees only if an amount equivalent to the loss of cost recovery is transferred from the general budget to the CA.

[56] Simplification gains described in Annex XXIV.

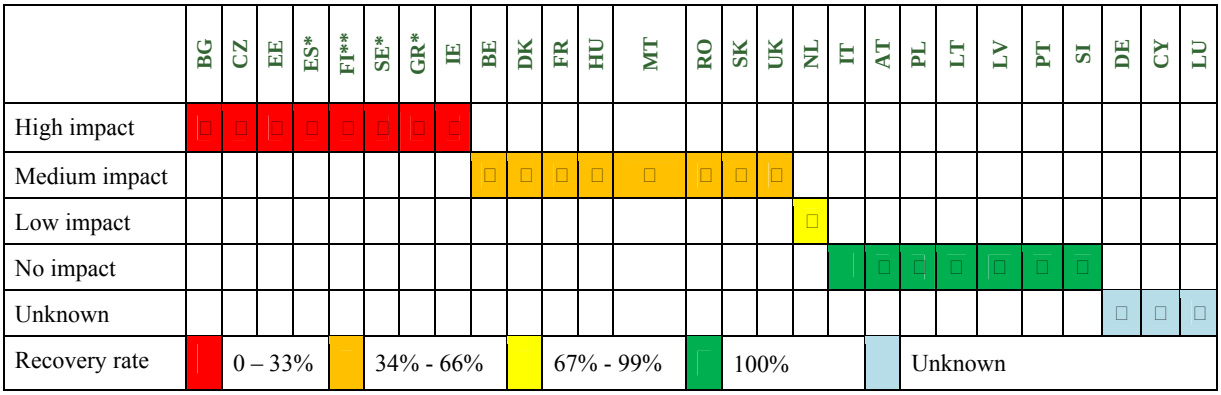
- Directive 89/608/EEC on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters (*except for the provisions concerning zootechnical controls*);
- Directive 96/93/EC on the certification of animals and animal products;
- Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products;
- Directive 97/78/EC laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries;
- Directive 91/496/EEC laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries.

The legislative framework for the financing of official controls will become simpler at EU level, as only cost based fees will be permitted as opposed to the current system which allows the possibility of choosing between actual costs and standard fees (see Table 5 of Annex XVII, which summarises data in the baseline scenario to illustrate the variety and combination of calculation methods employed across the MSs). Moreover by clarifying the list of activities for which fees are mandatory and the cost elements to factor in to calculations for each control activity, it is envisaged that implementation of EU provisions will become more uniform and transparent.[57]

Sustainability - Requiring MS to fully recover the costs of controls when mandatory fees are used would mobilise a steadier flux of financial resources collected through such fees, thus reducing the pressure on national budgets.

In the majority of MS, control costs are only partly recovered through fees, the recovery rate ranging from 20% to more than 80%, and 8 MS recovering all costs. Thus, introducing full cost recovery would see in some cases an additional part of the costs of controls being transferred to, and distributed amongst, agri-food chain operators. The increase in the level of mandatory fees would vary depending on the current recovery rate (see Figure 4 below).

Figure 4 Potential impact of requiring MS to achieve full cost recovery on controls for which fees are currently applied[58]



*The precise recovery rate is unknown.**Data about cost recovery rates in Finland is contradictory. The DG SANCO baseline states that it is 20 per cent, a previous evaluation (FCEC 2008) found that it was 99 per cent (for large FBOs) and an independent academic study (Lepostö et al. 2010) found that it is 38 per cent for municipal control authorities. The 2011 study has concluded that cost recovery rates are likely to be high for large FBOs (of which there are few) and low for small FBOs (of which there are many).

[57] Obviously in those areas in which no mandatory fees are required, variations, which are not accounted for by cost differences, will remain.

[58] The data used to construct this table is highly uncertain. It is intended to provide an indicative assessment of the distributional impact of requiring full cost recovery based on current rates of recovery. Actual impacts will be influenced by a range of factors in addition to current cost recovery rates.

Such level is expected not to represent a substantial additional burden for operators, even in those sectors where the cost of controls impacts most on the operators' overall production costs, which is meat inspection (see box 6 for some illustrative simulations).[59] Using the figures in box 6, we can estimate that, depending on the percentage of recovery of costs by Member States, additional fees corresponding to approximately 0.2% - 0.8% of the annual production value of a typical operator would be charged. In return, this would guarantee approximately €0.9bn – 3.4bn of new funds/year for official controls across the MS.[60]

Box 6: Economic impact of full cost recovery (meat inspection) – examples from the MS

The examples below refer to mandatory fees charged for **meat inspection** in 3 MS which apply cost based fees (as opposed to the standard EU fee). Meat inspection is the area of the agri-food chain where controls are most frequent and intensive (a regular and continuous presence of official inspectors is required in business operator's premises during operations). Thus the impact of fees on production costs is significantly higher in this field than in others.

In Belgium, meat inspections are funded via a mandatory fee ("retribution") calculated on the basis of a **half hourly rate of €23.13** and applied following specific criteria, such as the throughput of individual establishments[61] (volume and category of animals). According to available data, retributions allow Belgium to recover approximately 37% of the total costs they incur in organising official controls[62].

This allows one to postulate the level of fees in a full cost recovery scenario. Charges[63] on slaughterhouses with a single slaughter line for adult bovines currently vary from approximately €15.8/animal, where hourly throughput does not exceed 4 bovine units, to approximately €5.2/animal, where throughput exceeds 50 units per hour. Assuming that such charges represent 37% of the actual cost of controlling the slaughter line in each case[64], full-cost fees would vary between a maximum of approximately €42.7/animal (slow throughput) to a minimum of approximately €14.05/animal, for operators with a fast throughput. **In a representative average case ("*vache de reforme*")** with the price of a bovine carcass at approximately €1,580 (at slaughterhouse, i.e. before any further processing and net of any further profit margin)[65], charging slaughterhouses **a full cost fee would represent between 0.89% (fastest lines) and 2.7%**

[59] In certain MS the level of cost recovery for mandatory fees is unknown and may amount to 0%. Such MS are not compliant with existing EU legislation which requires recovery on the basis of actual costs or minimum/standard fees. While these MS will inevitably face a greater burden if Option 2 is adopted and the principle of full cost recovery is reinforced, part of that additional cost is the result of bringing the national practice into line with existing rules, and not the consequence of the option being considered here.

[60] Sector production value €400bn/year. No of enterprises 60,000 (Eurostat 2008). Average annual inspection charge per operator at full cost recover approximately €80,000/year (Industry data).

[61] See Article 3(1) Arrête Royal du 10 Novembre 2005 relatif aux rétributions visées à l'article 5 de la loi du 9 Décembre 2004 portant financement de l'Agence fédérale pour la Sécurité de la Chaine alimentaire.

[62] See SANCO validated baseline, Annex XVI.

[63] See Arrête Royal du 10 Novembre 2005 relatif aux rétributions, cited above.

[64] It should be noted that Option 2 does not prescribe how Member States should achieve full cost recovery. The latter are therefore free to choose the type and manner of cost recovery, which does not necessarily imply it will be spread evenly across all fees.

[65] In other words, this figure does not include further processing costs (e.g. cutting, de-boning, packaging, etc.), nor profit margins down the processing and distribution line. Taking such elements into account would result in a significant increase of the total value of meat per kilogram (at least 25% on average).

[66] Such percentages would be even lower if compared to the final value of the carcass noted in the footnote above.

[67] See SANCO validated baseline, Annex XVI.

[68] http://www.food.gov.uk/foodindustry/meat/mhservice/chargesguide.

(slowest) of the total value of the carcass.[66]

The UK presently recovers 43% of mandatory fees[67]. Official controls at approved meat premises are currently charged on a time-basis. The presence of an auxiliary during normal working hours is charged at **£29.20 (approximately €35) per hour** and the presence of an official veterinarian is charged at **£37.60 (approximately €45.50)** per hour[68]. Achieving full cost recovery would increase these rates to approximately £68 (€82) and £87 (€105) respectively.

Data submitted by the UK Food Standards Agency suggests that the overall cost of delivering official controls is €65.77m per year. Full cost recovery would thus shift a further €37.49m on industry per year. **This additional cost represents 0.5% of the total value of the UK meat industry** which is thought to be worth €7.65bn per year.

Unlike BE and UK, **Italy** claims to fully recover the costs of meat inspection from fees. An hourly rate of **€50/hour** has been used to determine minimum fees for certain operators, depending on the throughput of their establishments. **Fees vary from €5/animal** in slaughterhouses with a yearly throughput of 10,000 units **to €3/animal** in faster lines (more than 70,000 units/year). Although such fees represent minimum levels and may therefore fluctuate, the fact that Italian authorities claim to fully recover costs would suggest that **a move to Option 2 is unlikely to have significant effects on business operators in Italy.**

Reduction of administrative burden - Information obligations in the area of official controls of residues of veterinary medicinal products (see Annex XXII) and the corresponding administrative burden will be eliminated.

Current rules require MSs to publish and communicate to the Commission fees' calculation methods. Strengthening such a requirement by requesting more details on cost elements and calculation assumptions is not expected to create substantial additional costs. Analysis has shown that once the move to full cost recovery has been made, reporting information regarding fees to the Commission and the public is likely to require little additional administrative cost for most MS, particularly where such information is already provided through CA websites (See Figure 5 below).

Figure 5: Transparency and reporting to the public on fees for official controls by EU Member State

	BE	IE	UK	ES	FL	NL	SE	DE	EE	FR	IT	LT	PL	SK	MT	AT	BG	CY	CZ	DK	GR	HU	LU	LV	PT	RO	SI
All information available online	□	□	□	□	□	□	□																				
Legislation published in the official journal				□	□	□	□	□	□	□	□	□	□	□													
Information recorded but not available / published															□												
No information available / identified																□	□	□	□	□	□	□	□	□	□	□	□
				High transparency					Medium transparency							Low transparency				No information available / identified							

With regards to the requirement within Option 2 to calculate all fees (including those for which a standard EU fee is established by the Regulation) on the basis of costs it is expected that no substantial additional administrative burdens will fall upon MS which already

calculate fees in such a manner. Additional efforts will be necessary in those MS which do not currently establish fees on the basis of costs incurred as changes to their administrative structures may be required so as to ensure that costs are reflected in fees and to implement/monitor cost recovery. Additional costs are expected to be affordable by public budgets (see box 7 below for estimations provided by 2 MS). Option 2 takes account of this adjustment by giving MS 2 years to ready their administrative systems to the new costing/charging model.

Box 7 – Examples of the costs of establishing a fees regime based on actual costs for the UK and Finland

The UK Food Standards Agency (FSA) has estimated that collating information on total control resources in a centralised manner (i.e. for the country as a whole) would require two days of a middle manager's time and three days of a junior manager's time. Therefore the cost of reporting on the financial resources devoted to official controls would be around €1655 per annum[69]. Given the decentralised nature of the UK, the FSA calculated that a more detailed reporting requirement providing figures for total resources at a sub-national level would require an additional 6 working days by an analyst, at a cost of €1815.

A move to a system requiring the collection of precise data on costs, based on actual time spent on each operator, would have a more significant financial impact on MS. The Finnish Food Safety Authority (EVIRA) has estimated that setting up such a system in Finland (where the operation of controls is decentralised) would cost approximately €500,000 for appropriate IT tools. Such an expense would be a "one off" and ongoing costs would result from the need to maintain 4 full time equivalent staff (FTE)[70] to collect and submit information about the resources used by CAs in the execution of official control activities.

The **possibility** for Member States to refund fees to micro-enterprises is also likely to result in increased administrative burdens in those MS which would chose to use it. Setting up a refund system implies the need to determine the eligibility criteria, to collect fees from micro-enterprises and to re-imburse them on the basis of the aforementioned criteria. Although there is currently no data available, such a system would add to the costs resulting from the management of a costing/charging system applicable to all operators (with no refunds or exemptions fro certain categories).

A refund system would also be more complex and more costly than the direct exemption of micro-enterprises from the payment of fees, as it adds the costs of the refund mechanism to the basic costs of managing the aid scheme. Nonetheless, a refund system allows for full cost recovery and ensures that competent authorities have sufficient resources to guarantee the effective organisation of official controls (as opposed to the exemption mechanisms, which would deprive the CA from the fees revenue, unless appropriate compensation is granted).

Accountability - Option 2 would contribute to increasing the accountability of control activities in light of the effect of the stronger and certain link between costs and fees. This would be underpinned by the increased transparency of the mechanisms through which fees are calculated as operators would be able to see clearly what they are being charged for and how these charges are derived in light of costs to CAs. This improved clarity would be a

[69] This calculation is carried out on the basis of hourly rates applicable to middle and junior managers in the UK. See http://www.statistics.gov.uk/statbase/product.asp?vlnk=13101.

[70] Costs of an FTE within a particular MS will depend on the applicable salary levels. See Table 6, Annex XVII for a breakdown of hourly salary rates for the food safety agencies of several MS.

driver for improved efficiency of official control systems and also allow better supervision of implementation by the Commission.

Furthermore, increased transparency would contribute to the objective of ensuring that fees revenues are not unduly distracted from their intended use (compensate control costs). The option of requiring the establishment of a specific ring-fencing mechanism to ensure that fee revenues are recycled back in to the CAs' budget would require legislative changes in a number of MS and could be difficult to implement. The same result, however, could be obtained by ensuring a clear definition of eligible costs, transparency of full cost recovery requirements and thus the accountability of the fees system as a whole, which would enable the public and operators in particular to appreciate how costs are identified and charged and how fees are calculated and used. During the consultation, a number of MS (IT, DE, NL, FR and UK) noted that a fees system that has a clear definition of eligible costs, transparency of reporting and full cost recovery requirements, would effectively operate as a ring-fencing mechanism without a formal requirement to do so.

Safety – Increased efficiency of the risk based use of resources would ensure a better enforcement of agri-food chain rules covered by the Regulation (food and feed law, including rules on residues of veterinary medicines[71], FCM and GMOs, and animal health and welfare rules) and thus a higher level of protection of the safety of the agri-food chain.

A stable mobilisation of resources coupled with the other elements mentioned above (e.g. accountability, *bonus malus* etc.) allows progress towards the primary objective of maintaining efficient controls and ensuring the continued safety of the agri-food chain.

Summary of the key impacts under Option 2

Criteria	Impacts
Competitiveness	+
Innovation	+
Sustainability	+ +
Simplification	+
Administrative Burden	+
Accountability	+
Safety	+

Option 3 – Streamline + Integrate

As in 2; plus, a fully integrated system of controls along the agri-food chain would maximise efficiency of enforcement through simplification and synergy gains, facilitating the fulfilment of the objectives of agri-food chain legislation.

In addition to the impacts highlighted for Option 2, the following impacts would be produced by expanding the scope of the Regulation to the plant health, PRM and ABP sectors.

Competitiveness - As a consequence of including the new areas under the scope of the Regulation, MS CAs would be able to carry out the risk prioritisation taking into account all agri-food chain sectors, better allocate control resources and increase the efficiency of the

[71] See Section 5 of Annex XX.

control system as a whole. In turn, economic operators would benefit from a more focused, and fully risk based system of controls.

Simplification - Option 3 would ensure a harmonised approach to official controls along the entire agri-food chain, while taking into account the specificities of every sector where necessary. The overall system would become more consistent and reliable as the same mechanisms and tasks would be being used by all sectors[72].

Box 8: Simplification gains under option 3

Acts or provisions to be repealed under option 3

- Acts referred to in Box 6.
- 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 (*official controls provisions to be replaced by revised Regulation 882/2004; other provisions to be replaced by the new Plant Health Law*);
- 12 Council Directives on the marketing of plant reproductive material (*official controls provisions to be replaced by revised Regulation 882/2004; other provisions to be replaced by the new plant reproductive legislation*);
- Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption (*only official controls provisions to be repealed by revised Regulation 882/2004*).

Safety – A fully integrated system of controls along the agri-food chain would maximise efficiency of enforcement through simplification and synergy gains, thus allowing optimal fulfilment of the objectives of the agri-food chain.

As regards official laboratories, Option 3 would imply a new obligation for laboratories carrying out plant health tests to be accredited. This would generate additional costs (for the initial accreditation and for the annual audits): the costs for the initial accreditation would be borne by the EU, the annual audits costs would be for the laboratories themselves[73]. A tailor-made simplified set of requirements and a transitional period of 5 years are foreseen to facilitate the smooth introduction of such an obligation. Option 3 also foresees the possibility to create a network of reference laboratories to improve methods and protocols used. This would ensure the soundness and reliability of laboratory results and would improve safety.

Summary of the key impacts under Option 3

Criteria	Impacts
Competitiveness	+ +
Innovation	+
Sustainability	+ +
Simplification	+ +
Administrative Burden	+
Accountability	+ +
Safety	+ +

Option 4 – Streamline + Integrate + Broader cost recovery

[72] Simplification gains described in Annex XXIV.

[73] For a quantification of these costs see Annex XIX; these data are also included in table 4 (section 6.2.) providing an overview of the costs and benefits associated to each option.

As in 3; plus, by broadening the collection of mandatory fees to key activities of the agri-food chain, this option would improve the sustainability of the control system as a whole and reduce its overall dependency on budgetary decisions. It also ensures a more equitable approach to inspection fees, by eliminating the perceived unfairness of the current system, which only requires certain categories of operators to be charged.

In addition to each of the changes identified under Option 3, operators who are registered in accordance with Regulation (EC) No 852/2004 and/or Regulation (EC) No 183/2005 would be charged fees for official control activities.

All of the benefits applicable to Option 3 also apply to Option 4. Moreover, by expanding the scope of the list of mandatory fees, this option also addresses other issues, giving rise to the further effects detailed below.

Sustainability - Option 4, as compared to Option 3, would improve mobilisation of CA resources for official controls as a stable flux of resources would be available not only for controls on operators for which mandatory fees apply under the current regime, but also for other controls carried out on operators registered in accordance with Regulations (EC) No 852/2004 and Regulation (EC) No 183/2005.

The economic impact on each MS and on operators would depend on whether (and to what extent) MS charge sectors which are not subject to mandatory fees but which would become so under Option 4. For those MS that already collect such fees, effects are likely to be minimal for CAs and business operators alike. On the contrary, effects are likely to be more significant in those MS which do not. Box 9 illustrates the potential impact on business operators of the extension of mandatory fees.[74]. Data available from MS currently charging such fees shows that when these are levied upon all operators subject to controls (irrespective of whether an inspection is actually carried out during a reference period) the amounts are modulated according to the size or the throughput of the business and represent **a rather negligible fraction of production costs**. For instance, fees applied annually irrespective of whether an inspection is actually carried out during the year may **range from small (€84.5 for the smallest scale restaurants in Belgium) to higher, yet still not significant, sums (€1,500 for the largest scale industrial bakeries in Italy).** On the other hand, in MS where the actual cost of each inspection is charged, amounts vary in relation to the hourly cost of control activities (see box 9 below for examples). Evidence suggests that the increase in costs for those individual operators in sectors which would be covered by the extended scope of mandatory fees is likely to be of little significance for the overall production costs.

It is impossible to quantify the precise economic impact that the extension of mandatory fees would have on business operators as this is closely linked to, and depends upon, national features such as the hourly cost and/or intensity of controls (i.e. frequency, length, tools employed, training etc.). Nonetheless, some idea as to the scale of the impact that Option 4 may have can be deduced by analysing the charges applied by those Member States which already charge non-mandatory fees. In particular, this can give **an indication of the charges which may result from the expansion of the scope of mandatory fees (**assuming that MS

[74] Annex XVII, Tables 7-8 present an analysis of the number of enterprises in each Member State that could be affected by an extension of the scope of mandatory fees to cover operators registered in accordance with Regulations (EC) No 852/2004 and No 183/2005. In summary, the assessment of expanding the scope of mandatory fees indicates that high impact will be felt in a relatively small number of countries, but where a large number of businesses may be affected. In the majority of MS, operators would see moderate impact from this extension. See also Annex XI.

generally devote similar levels of effort to official controls, guaranteeing equivalent levels of efficiency).

It is also very important to note that in areas currently not covered by mandatory fees (e.g. inspections in restaurants, in establishments producing non animal foodstuffs) official controls are not carried out at intensities comparable with that of meat inspection; thus, costs per year and per operator are a fraction of little significance of the costs incurred for the latter. The control frequency in those areas depends on the risk, on the record of compliance of the operator, on the reliability of its own checks, on indications of possible non compliance. It varies therefore from one sector and from one category of business to the other. However, **for illustration purposes** a typical example would be the case of a small food retailer, controlled on a yearly basis, by 1 inspector who spends 1.5 hours to perform the checks and 1.5 hours of desk work to prepare for and to report from it. **Such a hypothetical control would cost, if** charged on the basis of control time used, around **€50/year** in Poland and **€150/year** in a MS using Italy's hourly rate. Inspection visits in a restaurant would have a similar frequency but would take on average longer (2-3 hours if arrangements facilitate the visit) and would cost between 30-40% more (from €65/year in Poland up to €210/year in Italy). On a global scale, this could guarantee between €2.3bn - €37bn/year of new funds for official controls across the Member States.[75]

Box 9: Impact on business operators of the extension of mandatory fees

As noted above (see Box 3), in **Italy** Legislative Decree No. 194 of 19 November 2008[76] calculates fees for official controls across the entire food production chain (such fees include those presently not mandatory under Regulation 882/2004)[77]. Calculations are made on the basis of actual costs in line with the criteria set out in Annex VI of Regulation 882/2004[78]. Moreover full cost recovery is

[75] Combined new fees for sectors currently subject to mandatory fees (i.e. top up fees in meat sector under Option 2) and those to be charged for the first time under Option 4. No. of enterprises 25m (Eurostat 2008). Typical range of fees charged under Option 4 - €85-€1500 (see Box 6).

[76] See Italian Official Journal No. 289 of 11 December 2008.

[77] Ibid, Annex A.

[78] The hourly charge for official control activities in Italy has been calculated as being €50/hour and this forms the basis for all subsequent determination of fees. See Italian Official Journal No. 289 of 11 December 2008, Annex C.

[79] See DG SANCO's validated baseline, Annex XVI.

[80] Feed producers are charged €11,984.70 where production is more than 200,000 tonnes per year. See Avis relative a l'indexation des montants fixes a l'arrête royal du 10 Novembre 2005 fixant les contributions visees a l'article 4 de la loi du 9 decembre 2004 relative au financement de l'Agence Federale pour la securite de la chaine alimentaire.

ensured .

Amongst the non-mandatory fees currently collected by Italy is a yearly charge imposed on **wholesale bakeries and manufacturers producing oven baked products**. Such a charge, which is meant to cover official control activities, increases progressively in line with operators' yearly production and ranges from **€400/year** where production is less than 500 tonnes to a maximum of **€1,500/year where production exceeds 1,000 tonnes**.

In **Belgium**, non-mandatory fees ("contributions") are charged to all relevant operators at the beginning of the year and are meant to cover routine inspections regardless of whether these actually take place throughout the year. "Contributions" appear to fully recover costs incurred by Belgium in carrying out official controls in the relevant areas[79]. Depending upon the size and sector of establishments, "contributions" may range from approximately €20 - €12,000.[80] Restaurants, for example, are charged as little as €87.68 when they employ 0-4 people and up to €1,719.58 when the employ 100 or more people.

In **Germany**, although charging practices vary across Länder an indicative hourly rate for certain non-animal health controls (i.e. those to which the scope of mandatory fees may be extended) is approximately €44/hour plus transport costs[81] calculated on an actual-cost basis.

In **Poland**, non-mandatory fees for official controls are charged at €13 per control activity with an additional €4 per hour for sampling and testing. Such fees include transport costs, document control and verification procedures and are claimed to represent full cost recovery.[82]

Competitiveness - Option 4 addresses the perceived unfairness of the current system, which only requires certain categories of operators to participate in the financing of controls, by ensuring that mandatory fees are applicable to a wider array of operators within the food production chain.

Administrative burden - As with Option 2, Option 4 would result in limited additional administrative burdens for CAs to record the cost of controls and calculating, setting, and collecting fees. The scale of such costs is likely to be comparable to those to be expected from Option 2, only marginally increased by the broader scope of the calculations. A transitional period of 3 years would be provided to MS to organise the new costing/charging system with the expanded scope. Such costs would in any event decrease over time and, eventually, only the costs of collecting fees would remain. The latter would also gradually decrease as fee collecting mechanisms become more streamlined and effective.

Summary of key impacts under Option 4

Criteria	Impacts
Competitiveness	+ + +
Innovation	+
Sustainability	+ + +
Simplification	+ +
Administrative Burden	+
Accountability	+ +
Safety	+ +

[81] See Annex XVI.
[82] Ibid.

Section 6: Comparing the options

6.1. Comparing the options in light of the objectives

Table 3: Options compared against the objectives

General objectives	Option 1A	Option 1B	Option 2	Option 3	Option 4
Contribute to promote the smooth functioning of the internal market	**(--)** Divergences among MS likely to increase and affect competition	**(0)**	**(+)** Distortions due to divergent practices (fees) are eliminated (where mandatory fees apply currently)	**(++)** As in 2, plus streamlined rules on official controls would apply across all agri-food chain areas	**(+++)** As in 3, plus distortions linked to fees are eliminated also in the new areas covered by mandatory fees
Maintain a high level of human, animal and plant health protection and animal welfare and prevent that this is undermined by potential non-implmentation of EU legislation	**(-)** Possible reduction of controls and of ability to respond to risks	**(0)**	**(+)** More risk-based controls would increase the efficiency and capability to respond to risks	**(++)** Efficiency of controls is maximised and risks of suboptimal protection reduced	**(++)** As in 3
Ensure proper and uniform implementation of EU legislation	**(-)** Possible suboptimal enforcement of law if resources decrease	**(0)**	**(+)** Clearer list of activities to be charged and list of costs; only cost based fees	**(++)** Same requirements and tasks across all agri-food chain sectors	**(++)** As in 3

Specific objectives	Option 1A	Option 1B	Option 2	Option 3	Option 4
Ensure a comprehensive and consistent approach to official controls along the agri-food chain	**(0)**	**(0)**	**(+)** Consistent use of risk based principle	**(++)** Same tasks & mechanisms used by all sectors	**(++)** As in 3
Allow for a more efficient use of national control resources	**(0)**	**(0)**	**(+)** Full risk based approach	**(++)** The inclusion of all agri-food chain areas in would allow cross-sectors risk prioritisation	**(++)** As in 3
Reduce administrative burden and remove uneccesary requirements	**(0)** Removes AB linked to EU fee rules, but MS would administer their own regimes	**(0)**	**(+)** Redundant plans & reports eliminated	**(+)** As in 2	**(+)** As in 2
Foster closer cooperation between MS to improve official control delivery	**(0)**	**(0)**	**(+)** Rules on admin. cooperation can be adopted, synergies developed (IAS)	**(++)** Synergies possible also with plant health, PRM sectors	**(++)** As in 3
Ensure the availability of adequate resources	**(-)** Sufficient funding would depend on budgetary choices –failure to ensure cost recovery likely to worsen in times of crisis	**(- -) ins**ufficient funds, as no fees charged on micro-enterprises	**(++)** As cost would be recovered through fees, dependency from and pressure on national budgets decreases	**(++)** As in 2	**(+++)** As in 2, on a broader scale

Ensure equity and fairness in the financing of official controls	**(-)** No level playing field guaranteed as approaches to fee likely to vary	**(-)** No level playing field as micro-enterprises advantaged	**(+)** All operators charged with mandatory fees would pay the actual cost of controls	**(+)** As in 2	**(++)** As in 2, plus all operators benefiting most from controls would all be charged
Improve transparency, including of the system of financing official controls	**(0)**		**(++)** 'High transparency' requirements can be detailed; transparency of fee mechanism would increase	**(++)** As in 2	**(++)** As in 2

6.2. Costs-benefits analysis

Table 4: Policy Options - Significant Costs / Benefits

		Option 1.A deregulate fees	Option 1.B exempt micro-entreprises	Option 2. Streamline		Option 3. Streamline + integrate[83]		Option 4. Streamline + integrate + broader cost recovery	
		Action	**€**	**Action**	**€**	**Action**	**€**	**Action**	**€**
Member State CA	**Cost**	Will depend on choices made by each MS on whether to charge or not for official controls (1A) and on whether to recover costs of controls on micro-enterprises from other businesses and % of the latter (1B)		Estalishing and operating reporting regime for calculation and charging of fees	**€0.5m one off** + **€2000/year** (per MS). **€13.5m one off + €54,000/year** (across EU MS)[84]	Same (as Option 2 + Plant Health and Plant Reproductive Materials)	Same	Same as Options 2&3	Same
	Benefit			Stable funding in areas already charged i.e. meat sector **(top up from the % of costs already charged to reach full cost recovery)**	Depends on % recovery of costs by MS. Approx. **€0.9bn –3.4bn** new funds per year across EU MS[85,86]	Same	Same	Full cost recovery for all OC on registered operators + 'top-up' as per Option 2	Approx. total of new fees **€2.3bn –37bn/year** across EU MS[87] + €0.9 – 3.4bn per year
Business Oper.	**Cost**	Will depend on choices made by each MS on whether to charge or not for official controls (1A) and on whether to recover costs of controls on micro-enterprises from other		Top up to existing fees (meat sector) to reach full cost recovery	Depends on % recovery of costs by MS. Approx. **€0.9bn –3.4bn** new fees (across EU MS) (approx	Same (as Option 2 + Plant Health and Plant Reproductive Materials)	Same	New costs for operators currently not charged (non meat sector) + 'top-	Approx. total of new charges €2.3bn – 37bn/year across EU MS[89] + €0.9 – 3.4bn per

[83] For Option 3, costs/benefits would relate to inclusion of plant health, PRM and ABP into the scope, impacts of which have been assessed within the relevant Impact Assessments for these sectors and which are not included here.
[84] Based on FI / UK data. See Box 6.
[85] Sector production value €400bn/year (DG Enterprise). No. of enterprises 60,000 (Eurostat 2008). Average annual inspection charge per operator at full cost recovery approximately €80,000/year (Annex XI).
[86] , The majority of operators, in individual MS, are currently being charged between 30% and 80% of inspection charges, with some paying 100% (see figure 4)
[87] New fees for those sectors to be charged for the first time under option 4. Average cost to operators not currently subject to fees - €85 – 1500/yr (See Box 6). No. of operators who are not currently subject to fees – 25m (Eurosat 2008).

	businesses and % of the latter (1B)		**0.2 – 0.8**% of annual product. value in the **meat sector**[88])			up' as per Option 2	year
	Benefit		Risk based approach to vet. med. controls	EU-wide saving of **€12.4m – 98.5m/year** (covered by fee)	Same	Same	Same as Options 2&3	Same

[88] Based on UK industry estimates (see Box 6)
[89] See footnotes 85-87 above

6.3. Preferred option

In light of the assessment above, it is considered that **Option 4** (i.e. the legislative framework is improved and streamlined, plant health and PRM are included in its scope, and mandatory fees are extended to cover key areas of the agri-food chain) provides the best way to achieve the objectives. It offers the best approach to simplification, clarity, coherence and reduction of administrative burden without losing the capacity of the legislative framework to account for the specificities of every concerned sector.

Insofar as the financing of official controls is concerned, **Option 4** preserves the long term sustainability of national control systems[90]. The conclusion of this IA is that the rationale for the current system is still valid, i.e. agri-food chain business operators should bear the costs incurred by competent authorities when performing official controls. While they are primarily responsibile for preventing that unsafe products enter the agri-food chain, the system of own controls that they are required to establish could not deliver fully if it was not complemented by a dedicated, complex and costly system of official controls maintained by each MS, requiring from CAs an effort which goes beyond "normal" market surveillance duties.

In this respect, CAs assessment of the changes proposed through option 4 is overall positive as improvements to the control system as a whole are expected to result from the extension of the range of mandatory fees and from the full cost recovery rule. Industry stakeholders worry about costs of such changes, while recognising the positive impact to be expected from the increased transparency and comparability of systems across the EU, and stress the need to eliminate the unfairness of the current system of charging only some sectors for control costs.

As to such costs, while the move to full cost recovery without expanding the scope of mandatory fees (Option 2) would impact essentially on the sectors already charged (meat inspection in particular), generating between €0.9bn and €3.4bn new revenue for CAs, with an impact on individual operators which remains marginal when rapported to their turnover, the proposed option of also expanding the scope of mandatory fees to cover all the sectors which "use" most intensely the official control capacity of national CAs would impact on all such sectors and generate yearly an extra revenue estimated to be beteween €2.3bn and several times this figure (up to €37bn/year in the hypothetical case of all operators being charged at rates currently applied to the largest food businesses, i.e. around €1.500).

Furthermore, Option 4 ensures the most effective achievement of the objective of providing an **improved legal framework** for official controls across all sectors of the agri-food chain.

Options 2 and 3 achieve the set objectives partly, only in the areas specifically covered by each of them, thus failing to cover the whole agri-food chain in an integrated approach, and to promote synergies and cost savings. They also fail to address the unfairness and discriminatory character of the current financing system and the resulting lack of legitimacy.

As to **Options 1A and 1B**, they cannot ensure the sustainability of the system of official controls due to their potential consequences on the availability of sufficient resources for the performance of such controls.

The **cost/benefit comparison** of the different options must take into account quantifiable and non quantifiable elements (an approximation of the former being included in Table 4 above).

[90] This is in line with the conclusions of the abovementioned impact assessment reports on plant health and plant reproductive material where full cost recovery is also foreseen.

In terms of costs, **options 2 to 4** all imply additional costs for the setting up of a full cost recovery system in those MS which do not have one (one-off cost for the setting up of the system and subsequent operating costs). The estimates available suggest that such costs will be affordable and that they will decrease with time as the system stabilises and staff and organisations familiarize themselves with it. These options also alleviate the competent authority from the burden of some non risk-based controls (and operators from the corresponding fees).

When it comes to the impact on operators, **Option 4** ensures that costs are spread in a more equitable manner across all operators which are responsible for the safety of the agri-food chain. This is expected to result in a positive increase of the legitimacy of the financing system.

Also a net benefit of **Option 4** is the increased accountability of competent authorities towards the operators they control and charge, which is the result, on the one hand, of the direct link between costs and charges and, on the other hand, of the increased transparency of the financing system, which gives operators direct access to the details of the costing mechanisms. Operators will thus be able to see and scrutinise how the cost of controls (and the fees) are established, and thus – albeit indirectly – the efficient use of fees revenue.

Indeed, the improved transparency of the system is instrumental in ensuring that the increased financial security of CAs corresponds to an increased accountability of the control system as such towards business operators and the public in general.

Section 7: Monitoring and evaluation

The review of the EU legislative framework applicable to official controls along the agri-food chain aims at improving the efficiency and consistency of the system, and ensuring its long term sustainability. It is considered that whichever option is taken forward would clarify the existing rules and make them easier to apply by MS CAs.

To assess the success of the measures introduced, the following core progress indicators have been identified in line with the operational objectives of the policy action:

Establish a single and simpler legislative framework for official controls

→ Indicator - Number of requests for legal interpretation received by the Commission

→ Indicator - Number of pieces of EU level legislation applying to official controls per sector/product

→ Indicator - The reported change in the declared average administrative burden on industry and MS

All controls, including border controls, risk based

→Indicator – Surveying MS on whether resources freed by this review are being used to perform controls in areas of higher risk

Increase the number of cases where cross-border enforcement cases are resolved through administrative assistance and cooperation

→ Indicator - Number of contacts through administrative cooperation contact points foreseen by Article 35 of the Regulation

→ *Indicator - Number of complaints from economic operators pointing to MS having failed to coordinate investigations in case of cross border non-compliances*

Increase the number of formalised instruments between the CAs and customs authorities for the performance of official controls

→ *Indicator - Number of service level agreements formalised between CAs and other authorities including customs*

Reduce occurrence of unsatisfactory enforcement results in FVO reports attributed to resources shortages

→ *Indicator – Trends in the number of FVO reports which point to a lack of resources in MS.*

The monitoring of the correct implementation of the legislation on official controls along the agri-food chain is ensured by the audits carried out by the FVO on the functioning of national systems of controls. This will provide the Commission on a regular basis with data and information about the indicators listed above and more generally about the fulfilment by MS of the objectives pursued by the legislation.

Annex I: Glossary

EU: European Union

FVO: Food and Veterinary Office

MS: Member States

CA: Competent authority

EURLs: EU Reference Laboratories

NRLs: National Reference Laboratories

MANCP: Multi Annual National Control Plan

CVO: Chief veterinary offices

FCM: Food Contact Material

PH: Plant Health

AH: Animal Health

AW: Animal Welfare

PRM: Plant Reproductive Material

ABP: Animal by-products

FCM: Food contact material

TRACES: TRAde Control and Expert System

BIP: Border inspection post

DPE: Designated point of entry

SCFCAH: Standing Committee on the Food Chain and Animal Health

Annex II: Overview of the legislative framework applicable to official controls along the food chain

1. Official controls to enforce feed and food law, animal health and welfare rules

The EU system of official controls consists of a general framework established by Regulation 882/2004 of 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** and of a complex constellation of sectoral acts laying down official controls provisions (for the implementation of **feed and food law, animal health and welfare rules**). This is due to the fact that when Regulation 882/2004 was adopted a plethora of pre-existing acts (characterised by a sectoral approach) were kept in force.

Regulation 882/2004 also provides for a set of rules aimed at ensuring that CAs tasked with control duties are appropriately resourced, including through the levying of **inspection fees** from business subject to official controls.

1.1. Regulation 882/2004 on official controls

Regulation 882/2004 was adopted to complement a wider initiative of modernisation, recast and simplification of EU legislation in the areas of food and feed safety, animal health, animal welfare and in part, plant health, carried out between 2000 and 2004, with a coherent legal framework for official control activities in those areas, to ensure the smooth functioning of the Single Market through the effective implementation of food and feed standards and of public, animal and (only partially) plant health rules. This new legal framework has been in application since 1st January 2006.

The Regulation applies to control activities performed to ensure the verification of compliance with feed and food law, animal health and welfare rules across the EU. To a limited extent, it also applies to Plant Health related controls, in particular as far as the provisions on the multiannual control plans and Union audits are concerned.

Regulation 882/2004 provides CAs in the MS with a solid and comprehensive set of rules which affords them the necessary powers and tools to deliver their enforcement duties in an efficient and reliable fashion. In particular, the Regulation includes:

- the obligation for MS to designate the authorities responsible for the performance of official controls in the areas covered by the Regulation;
- the all-important principle according to which **official controls must be risk based**, so that the deployment of control/enforcement resources is prioritised on the basis of the risk,
- the obligation to plan official controls through a multiannual programming instrument (the multiannual control plan – MANCP) and to report on their implementation and outcomes;
- provisions intended to ensure that
    - **competent authorities are transparent and fully accountable** with regard to the performance of their duties and the effectiveness of their work; the outcomes of **official controls are sound and reliable** and remain so also in case of delegation to other control bodies;

- **competent authorities possess the powers necessary** to control compliance with the rules and to enforce them, and the powers necessary to supervise and monitor situations where risks for the health of humans or animals may arise;
- **official laboratories perform to the highest standards**;

The Regulation also provides for:

- the general framework and procedures applicable to official controls on feed and food imported from third countries into the territory of the Union and specific rules on the establishment of increased controls at the point of entry into the Union for certain products[91]); and
- procedures for establishing import conditions (i.e. the requirements that imports into the Unions must satisfy in order to ensure that they do not pose a risk to human or animal or health) for such commodities and to the extent that those conditions are not provided for by other EU law.

The Regulation also lays down the rules governing the audits carried out by Commission experts (the Directorate F, Food and Veterinary Office [FVO] of DG SANCO) in Member States and third countries to verify the implementation of EU law and the functioning of the systems of official controls in MS.

Finally, a key section of the Regulation is Chapter VI, which provides for a set of rules aimed at ensuring that CAs tasked with control duties are appropriately resourced, including through the levying of **inspection fees** from business subject to official controls. In particular, the Regulation provides for:

- the general principle according to which MS shall ensure that adequate financial resources are available for official controls by whatever means considered appropriate, including through general taxation or by establishing fees or charges;
- an obligation for MS to use fees (*mandatory fees*) for financing control activities when it comes to certain sectors:
  - controls on slaughter, cutting operations and cold storage of meat, production and placing on the market of fishery products, and milk production;
  - controls carried out to grand feed establishments approval;
  - controls carried out at a border on consignments of live animals, products of animal origin, animal products, animal by products; certain food and feed of non animal origin.
- a set of standard fees applicable in some cases where mandatory fees are required: where standard fees exist, they offer the CAs a statutory fee in cases where the MS has not calculated the costs of the activity in question for the purposes of charging a cost based fee;
- a set of common principles applicable to mandatory and non-mandatory fees among which the all-important one according to which fees are meant to cover the costs incurred and cannot exceed such costs;
- the obligation for MS to make public the method of calculation of fees and communicate it to the Commission;

[91] Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC (OJ L 194, 25.7.2009, p. 1).

- the obligation for the MS competent authorities to charge the operators for the expenses arising from additional official controls carried out when non compliances are detected.

1.2. Official controls on residues of veterinary medicines in live animals and animal products (Directive 96/23/EC)

Regulation 882/2004 stipulates to keep in place Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.

Directive 96/23/EC requires MS to implement national residues monitoring plans which are not included in the MANCP and 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 mandatory minimum number of samples that shall be analysed for each combination sub-group of substances / animal or animal product according to the national production without taking into account other elements which may impact on the risk assessment (e.g. rearing practices, veterinary medicinal products authorised, etc). The requirements for third countries are essentially the same as for MS. Apart from residues of veterinary medicines, Annex I to Directive 96/23/EC also includes several residues of pesticides[92] and several environmental contaminants[93] among the group of substances to be controlled within the framework of the national residues monitoring plans.

1.3. Official controls on products of animal origin intended for human consumption

Regulation (EC) No 854/2004[94] of the European Parliament and of the Council lays down specific rules for official controls on products of animal origin intended for human consumption. The Regulation addresses specific aspects of official controls associated with such products, including meat, live bivalve molluscs, fishery products and milk. In particular, the Regulation lays down specific rules on approval of establishments, specific official control activities in EU establishments and specific rules for controls of products imported to the EU.

1.4. Veterinary border controls

As mentioned above, Regulation 882/2004 sets out the general framework and the procedures applicable to official controls on feed and food imported from third countries into the territory of the Union. Moreover, it establishes a legal basis for the introduction of an increased level

[92] Regulation (EC) N°396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC requires MS to carry out official controls on pesticides residues in accordance with relevant provisions of Regulation (EC) N° 882/2004 and to establish risk based multi-annual national control programmes. It requires also the Commission to prepare a coordinated multi-annual Union control programme with a view to assessing consumer exposure and the application of current legislation.

[93] 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. Regulation (EEC) 315/93 and Regulation (EC) N° 1881/2006 require MS to carry out official controls on contaminants on the basis of their own risk assessment.

[94] 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).

of official controls at the point of entry of the Union for certain feed and food of non-animal origin on the basis of known or emerging risk.

Specific rules for veterinary border controls on animal origin products and on live animals, , are laid down in Directives 91/496/EEC[95] and 97/78/EC[96]. These specify that veterinary checks have to be carried out in approved border inspection posts (BIPs) which are listed in Decision 2009/821/EC[97] on such consignments and how these veterinary checks need to be carried out. Additional details are laid down in secondary legislation, such as the minimum requirements for BIP facilities and their technical equipment, the frequency of physical checks, the list of animals and animal origin products to be checked in BIPs and details for checks and follow up on specific consignments, e.g. transit and transhipment.

1.5. Official controls in the animal health sector

The rules of Regulation 882/2004 already apply to official controls carried out to verify compliance with the requirements of animal health rules. However its wording in certain cases is more focused on food and feed products and, as a result, not always consistent when it comes to its applicability to animal health issues.

In parallel, two Directives dealing with official controls carried out to verify compliance with animal health requirements in intra-Community trade (Directives 89/662/EEC[98] and 90/425[99]) have also remained in force. Those rules are complemented by a Directive dealing with official certification in the veterinary area[100], and a Directive on mutual cooperation of competent authorities and administrative assistance between them[101].

2. Official controls in sectors not (or only partially) covered by Regulation 882/2004

There are a number of provisions governing the food chain whose enforcement is not (or only partially) governed by Regulation 882/2004.

2.1. Official controls in the animal by-products sector

Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption[102] establishes *inter alia* its own system

[95] Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC.

[96] 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.

[97] Commission Decision 2009/821/EC of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces.

[98] Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra- Community trade with a view to the completion of the internal market.

[99] Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market.

[100] Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products.

[101] Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters

[102] Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1).

of official controls, excluding thus the applicability of Regulation 882/2004 except for those provisions explicitly recalled thereof.

2.2 Official controls in the plant health sector plant propagating material sector

Regulation 882/2004 does not concern, with the exception of some specific Articles (dealing with the multiannual controls plan and Union audits in MS and third countries), official controls in the field of **plant health**. Official controls in this area are governed by Council Directive 2000/29/EC[103], which rules and measures concerning certification, import and intra-EU movements of plants and plant products, with regards to eradication and containment of outbreaks and in relation to Union co-financing of measures taken.

In parallel with Regulation 882/2004, it imposes *inter alia* obligations on the MS to carry out controls to verify compliance with the requirements thereof and defines what legal persons may be charged with official tasks in this respect. It also foresees a system of fees that may (plant passport) or shall (import) be levied by the MS to finance official controls.

2.3. Official controls on plant reproductive material

The plant reproductive material legislation is fully outside the scope of Regulation 882/2004. The limited number of official controls is currently regulated by a set of 12 Council Directives on the marketing of plant reproductive material[104]. These Directives too impose obligations on the MS to carry out controls to verify compliance with the requirements thereof and define what legal persons may be charged with official tasks in this respect. They do not foresee a system of inspection fees.

[103] Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community (OJ L 169, 10.7.2000).

[104] Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed; Council Directive 66/402/EEC on the marketing of cereal seed; Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine; Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants; Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material; Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species; Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed; Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed; Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes; Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants; Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed; Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit propagating material and fruit plants intended for fruit production.

Annex III: Details of the problem identification

- ***Inconsistencies, gaps and overlap in control requirements***

The EU legislative framework for official controls on the food chain is an incomplete patchwork. **Inconsistencies** and **gaps** have been identified. In particular,

- differences (e.g. the definitions of CAs and the mechanism for delegation of official tasks, including laboratory tasks, the logic of risk based controls, the system of border controls) are apparent between Regulation 882/2004 and the legislation concerning official controls in the **plant health** sector; while some of these differences are justified because of the peculiarities of that sector (i.e. certification procedures), others appear to be arbitrary insofar as they result in different rules where the activities regulated upon call for the same set of guarantees to be applied;
- current EU rules on **plant reproductive material** do not include provisions on official controls;
- Regulation 882/2004 only partly applies to controls on **animal by-products and derived products not intended for human consumption (ABP)**; as a result, some important provisions (e.g. on transparency of enforcement activities, on accreditation of official laboratories, on FVO audits in MS) are currently not applicable to such controls.
- On the other hand, certain requirements and procedures laid down in Regulation 882/2004 are also present in pre-existing sectoral legislation, either with an identical formulation or with a slightly different wording which however does not change the substance of the provisions, calling however for different interpretations. For example, the mechanism for administrative assistance and cooperation are regulated upon by Regulation 882/2004, Directives 89/662[105] and 89/608[106]); registration and approval requirements for operators are laid down in Regulation 882/2004, and Regulations 183/2005[107], 852/2004[108], 854/2004[109].

[105] Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra- Community trade with a view to the completion of the internal market

[106] Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters

[107] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene

[108] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

[109] 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

- ***Inconsistent implementation of risk-based approach resulting in insufficient / differing / inefficient prioritisation of official controls***

Regulation 882/2004 requires official controls to be risk based, and MS to prioritise their control efforts and allocate resources giving priority to situations/areas where the risk is higher. Existing harmonised rules in certain areas prevent however this principle to fully deploy its benefits in terms of more efficient use of resources and of reduction of unnecessary burden on business operators subjected to controls (time, staff, equipment and facilities being mobilised to allow controls).

As regards **import controls**, MS are currently required to carry out official controls on certain commodities arriving from third countries at the outer borders of the EU (border controls).

In fact, safety of goods from third countries is ensured not only through risk based controls carried out by national authorities at any stage of the food chain, but, most importantly, by sanitary checks carried out at the outer borders of the EU on goods which present an intrinsic risk for human, animal or plant health. Border Inspection Posts (*"BIPs"*) exist for the performance of veterinary checks on animals and products of animal origin, Designated Points of Entry (*"DPEs"*) carry out border checks on certain foods and feed of non animal origin, and entry points are designated by each MS for the performance of phytosanitary controls[110] on imported plants and plant products.

The rationale and the underpinning principles of such controls across the range of food chain products (from plants to animals and animal products, to food and feed, animal by-products, food contact materials) are the same and they conform to the overarching principle according to which border controls shall be limited and proportionate to what is necessary to contain the potential risks for humans, animals or plants. The possibility to fully adjust the control effort to the level of risk is however limited by two different factors: on the one hand by the rigidity of current rules, which in some areas do not allow the continuous adjustment of the frequencies of physical checks as established in legislation to take into account of situations where the risk is reduced. On the other hand, as the different control systems at the borders are operated in accordance with different sets of rules (and by different authorities in some cases) depending on the sectors/products to be controlled, there is no integrated mechanisms to allow the prioritisation of checks by comparing the levels of risk of all the commodities of relevance for the food chain; in other words, risk prioritisation is carried out within sectors and not across sectors.

This results in burdens (above) and costs (most border controls result in a fee levied on the business operator responsible for the consignment) not always justified by the risk posed by the product being introduced into the EU. Similarly, the lack of integration of the different control structures operating at the border also prevents efficiency gains and savings in administrative costs to be reflected in lower fees being charged on operators.

Example

A number of Member States asked the Commission whether Designated Points of Entry can be located within the same facilities of EU approved Border Inspection Posts.

Under Directive 96/23/EC on official controls of **residues of veterinary medicines**, MS are required to include in their national residues monitoring plans a minimum number of samples for each combination of animal (or animal product) and (sub)group of substances, and to test

[110] Official controls carried out in the area of plant health.

for certain substances and substance groups also in cases where there has been little or no evidence of a risk that would justify that intensity of checks.

Examples

Stilbenes - All animals and animal products

Although absolutely no non compliance has been detected for several years now, between 21000 and 24000 samples are analysed each year across the EU for stilbenes, their derivatives, salts and esters.

Year	Total number of samples analysed	Number of non compliances
2007	23 411	0
2008	21 664	0
2009	21 815	0
2010	23 455	0

Resorcylic acid lactones (including zeranol) in pigs.

Although absolutely no non compliance has been detected for several years now, more than 6000 samples continue to be analysed each year across the EU.

Year	Total number of samples analysed	Number of non compliances
2007	6234	0
2008	5594	0
2009	6237	0
2010	6166	0

The Directive also prescribes in a detailed fashion what enforcement action Member State' authorities must take in relation to the different possible violation of EU rules (illegal treatment, use of unauthorised substances, presence of residues of veterinary medicines at levels exceeding the maximum residues limits (MRLs), repeated infringements of MRLs, etc). No flexibility is left to CAs in view of ensuring that enforcement action is proportionate to the situation at hand and to their specific enforcement needs. The rigidities in the system created by the Directive clearly result in an inefficient allocation of control resources, unnecessary burdens on operators, and inefficient enforcement action.

- ***Administrative burden and disproportionate control requirements***

Rules governing official controls on residues of veterinary medicines result in avoidable administrative burdens for both the MS CAs and the Commission, in several respects. Directive 96/23/EC requires that annual updates to MS' monitoring plan of residues of veterinary medicines be transmitted to and approved by Commission. There is no such requirement for any of the other control planning instruments or for the MANCP as such and the long and heavy administrative procedure laid down in the Directive of residues is not justified by any specificity of the controls to be carried out.
A similar requirement exists in relation to the residues monitoring plans of third countries exporting animals or animal products to the EU. While of course appropriate guarantees must

be provided by exporting third countries that their produce offer a level of safety which is equivalent to the one offered by EU products, less bureaucratic mechanisms can be designed to replace the current formal approval.
Also redundant with the general reporting requirement set by Regulation 882/2004 for all control activities are the specific reporting obligations laid down in the Directive.

Article 12 of Regulation 882/2004 provides for the mandatory accreditation of official laboratories in accordance with EN ISO/IEC 17025[111]. No flexibility is allowed for cases where the official laboratories might have to use a specific method which is not yet included in the scope of the accreditation because of an emergency or because the method is new.

Example

No or nearly no official laboratory in the EU was accredited according to ISO 17025 for the detection of mineral oil in sunflower oil or for the detection of melamine in food when respectively the crisis on sunflower oil from Ukraine or the one on melamine in food from China broke out.

Nor there is flexibility for the very specific case of small laboratories attached to operators' establishments, where extremely basic tests are carried out.

Example

A concrete example of the latter situation is the small laboratories performing *Trichinella* tests. Soon after the adoption of Regulation 882/2004 several Member States brought to the attention of the Commission that accreditation is very burdensome for very small *Trichinella* laboratories, attached to slaughterhouses or game meat handling establishments which only perform that type of test (the test is not complex and easy to carry out) and covering only the needs of the one establishment. Therefore, besides a transitional period for the accreditation of all laboratories granted for 4 years, ending in 2009, the Commission extended such a transitional period until 31 December 2013 for the accreditation of laboratories tasked with *Trichinella* testing and located in a slaughterhouse or a game handling establishment.

- ***Unclear rules and insufficient implementation details***

Regulation 882/2004 includes some unclear rules, which may generate divergent interpretation and application, and thus legal uncertainty.

a) The Regulation lays down a general obligation for MS CAs to ensure a "high level of transparency" when performing their control activities. The provisions on transparency are unclear as regards both the types of information to be disclosed and the degree of such disclosure.

b) Doubts exist about whether all methods used by a laboratory when operating as an official laboratory must be included in the accreditation. Furthermore, divergent interpretation are reported of Article 12(3) of Regulation 882/2004, according to which the accreditation of testing laboratories in accordance with EN ISO/IEC 17025 may relate *"to individual tests or groups of tests"*(depending on the practice followed by the different national accreditation bodies, the scope of accreditation can comprise one method, several methods or even groups of methods).

[111] A laboratory can only be accredited for the use of standardised and/or validated method

The scope of accreditation according to EN ISO/IEC 17025 of a laboratory can be fixed or flexible. A flexible scope accreditation is in general more difficult to obtain as it allows the laboratory not only to carry out the methods specified in the scope of accreditation, but also to add methods within the defined limits to the scope on the basis that the competence of the laboratory to develop and validate methods has been positively evaluated.
For both types of accreditation scopes, the interpretation of Article 12.3 differs greatly from one MS to another.
In some Member States, a fixed scope accreditation can only cover the use of a specific method (to be followed very precisely by the laboratory) on a specific matrix in order to detect a specific substance, virus, bacteria, etc (e.g. HPLC analysis of aflatoxins in pistachios). The consequence is for instance that for each new use of the method (e.g. on another very similar matrix like peanuts or almonds), the laboratory has to undergo a new accreditation procedure. In other Member States, fixed scope accreditations are given for the use of a method on several similar matrices making it for instance possible for the laboratory to use the method on another similar matrix without undergoing a new accreditation procedure.
Also, for some accreditation bodies but not for others, a flexible scope accreditation can cover the use of all methods using a same analytical technique (like for instance all methods using the ELISA technique).

c) In some cases, identical terms are used to define different concepts; for instance, while the terms 'surveillance' and 'monitoring' indicate in Regulation 882/2004 specific forms of official controls to verify compliance with the law, in the animal health and plant health legislation, such terms refer to activities carried out by CAs but also by stakeholders, with the objective of detecting, eradicating or containing diseases or harmful organisms.

d) While the scope of Regulation 882/2004 covers the enforcement of feed and food law, and of animal health and animal welfare rules, the wording of many provisions is specifically focused on feed and food. This results in uncertainties and divergent interpretations as to whether such provisions apply to controls on compliance with animal health and animal welfare rules, or with specific legislation governing the materials and articles intended to come into contact with food (FCM)[112] or the deliberate release into the environment of genetically modified organisms[113].

Example

Recently, Sweden enquired whether the mandate of the FVO as defined in article 45 of Regulation 882/2004 extends to Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. In particular, it asked whether controls of field trials, including the authorisation process and the cultivation of the Amflora potato fall within the mandate of the FVO.

- ***Insufficient administrative cooperation amongst public authorities***

CAs rarely make use of the rules of Regulation 882/2004 on administrative cooperation, which require them to liaise with their counterparts in another MS to ensure that serious non-

[112] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC.
[113] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

compliances are also pursued in the MS where the violation originates. The reason for that is to be found in the fact that no implementing tools exist to allow the cooperation mechanisms to function (i.e. CAs are not provided with any rule on how to trigger cooperation requests, on what the request content could be and what can be expected as a result of it etc., nor on the technicalities of the cooperation mechanisms).

Example

The Commission received a complaint against Germany from a food business operator. The complainant indicated that Germany, although aware of the fact that a violation of food chain rules was also to be attributed to the supplier of the complainant located in Poland, failed to contact the MS of dispatch (Poland) as requested by Article 38 of Regulation 882/2004, and held the complainant solely responsible and liable for the violation. Germany maintained instead wrongly that the notification in the Rapid Alert system for food and feed (RASFF) satisfied its obligation under Article 38.

For import controls, Regulation 882/2004 requires customs and sanitary authorities to cooperate during controls they carry out on imported products. However, feedback from CAs indicates that some important efficiency gains could be made if the operation of the two parallel systems of customs and sanitary checks on imported products could be "synchronised" better so as to eliminate all unnecessary duplications in the two parallel processes, e.g. in the collection of pre-arrival information and in the processing of it, or in the processing of information necessary for the final clearance of products (also from a sanitary point of view) before they are released for free circulation. Such duplications are a burden and have a cost for all concerned (customs authorities and sanitary authorities and, inevitably, importers). This is again the result of the lack of detailed indications on what modalities the cooperation obligation laid down in Regulation 882/2004 must take for it to fully deploy its potential in terms of efficiency gains and reduced burden on operators subject to import checks.

Example

France asked the Commission whether the national customs authorities, in case of food and feed, can trigger the mechanisms foreseen in Articles 27 to 29 of Regulation 765/2008 (on setting out the requirements for accreditation and market surveillance relating to the marketing of products) allowing them to suspend release of a product for free circulation on the Union market and inform the sanitary authority any time the product seems to present a serious risk to health, safety.

Moreover, potential synergies of action across different competent authorities are hampered as no provision of Regulation 882/2004 allows the delegation of specific controls tasks to the sanitary authority present at border. One important example is the present inability of the competent authority responsible for biodiversity rules to delegate border control tasks to the sanitary authority at the border to verify the presence of Invasive Alien Species (IAS), which would lead to important efficiency gains.[114]

[114] On the ongoing initiative on Invasive Alie Species, see Annex XXVI.

Annex IV: PROCEDURE - Details of the consultation

1) Consultation of Member States

- Meetings of the Working Group on the general Application of Regulation 882/2004 set up within the Standing Committee on the Food Chain and Animal Health (SCFCAH) were held on:

  - 7 September 2009,

  - 3 May, 27 September 2010,

  - 1 March, 11 April, 23 May, 27 June, 7 October, 10 November and 5 December 2011.

In addition, Member States were consulted on the following specific issues:

- Financing of official controls

The Commission contracted out to an external contractor[115] a study on the state of the application of the rules on inspection fees imposed by MS on operators to finance official controls (Inspection Fees). In this context, a survey of the Member States' competent authorities was carried out by means of a *questionnaire* to collect both information on the state of the implementation of the rules on the financing of official controls and views about a series of possible options for addressing existing difficulties. The final results of this study were made available to the Commission in February 2009[116] and presented at the meeting of the Heads of Food Safety Agencies organised by the Swedish Presidency in Stockholm on 25-26 September 2009. The Commission started a second consultation of MS through an *ad hoc* MS experts working group which met on 7 September 2009.

In preparation of the impact assessment (IA), a second study was contracted out to an external contractor[117] to assess the impact of the options identified to address the weaknesses of the system. The options on inspection fees were discussed with Member States by the external contractor to gather evidence and data to inform a decision on the recommended option. The final results were made available to the Commission on 20th September 2011 and presented to the Member States at the meeting of the Working Group on the general application of Regulation (EC) No 882/2004 on 10th November 2011[118].

- Accreditation of official laboratories (Article 12 of Regulation (EC) No 882/2004)

Accreditation of official food, feed and animal health laboratories according to Article 12 of Regulation (EC) No 882/2004 was discussed at two meetings of the Working Group on the general application of Regulation (EC) No 882/2004 (3 May and 27 September 2010) with the participation of Directorate General Enterprise and Industry and European co-operation for

[115] Food Chain Evaluation Consortium (FCEC), consisting of Civic Consulting, Agra CEAS Consulting (project leader), Van Dijk Management Consultants and Arcadia International.

[116] http://ec.europa.eu/food/food/controls/inspection_fees/docs/external_study_en.pdf; Annex X to this document provides for the executive summary of this study.

[117] GHK

[118] Annex XI to this document provides for the study carried out by GHK to support the impact assessment on reviewing the rules on the financing of official controls.

Accreditation (EA). As a follow-up to these meetings, a discussion paper[119] was drafted with the purpose of summarising the main issues identified during the discussions as well as the corresponding suggestions for improvement from the MS. The aim of the paper was to reflect on available options to improve the enforcement of Article 12 of Regulation (EC) No 882/2004. This paper was sent in January 2011 to the members of the Working Group on the general application of Regulation (EC) No 882/2004. In June 2011, the discussion paper was also sent to the Chief Veterinary Officers (CVOs) in order to identify any specific issues concerning in particular animal health laboratories. These results of the discussions as well as the answers to the consultations received from the Member States have been presented to the Working Group on the general application of Regulation (EC) No 882/2004 (meeting on 5 December 2011) as well as to the members of EA (meeting on 8 December 2011) and fed into this Impact Assessment Report.

The possible introduction of a mandatory accreditation for plant health laboratories and the possibility to establish EU reference laboratories in the plant health sector were discussed with the chief officers for plant health (COPHs) of the Member States as well as during the specific task force with MS experts and the Commission on 26 May 2011 (see "Plant Health and Seed and plant propagating material related controls" hereafter). After these meetings, the COPHs and the task force members were consulted in writing on the costs of the introduction of a mandatory accreditation for plant laboratories.

Similar consultations were organised during the evaluation and review of the EU regime for the marketing of seed & plant propagating material (Task force with MS experts and the Commission – see "Plant Health and Seed and plant propagating material related controls" hereafter).

- Official controls on residues of veterinary medicines in live animals and animal products (Directive 96/23/EC)

In 2003 the Commission launched a broad consultation process to review the whole legislation on residues of pharmacologically active substances used for the treatment of animals including Directive 96/23/EC which was finally not modified nor repealed as its revision was put on hold.

At the beginning of 2011, the extensive material collected at that time was considered, insofar as it was still relevant, and a new consultation of the MS on the impacts of the different options available was carried out. The objective of this consultation was to update and complement the relevant information gathered in 2003 with fresher input and to collect additional data to be used to assess the impact of the available options. A *questionnaire*[120] was addressed to the Working Group on the general application of Regulation (EC) No 882/2004, to the Chief Veterinary Officers (CVOs) of the MS as well as to officials in the MS in particular responsible for the management of residues of veterinary medicinal products control plans in the MS (the "residues experts working group" set up within the SCFCAH). The outcome of the consultation[121] was then presented to and discussed with the Working Group on the general application of Regulation (EC) No 882/2004 (meeting on 27 June 2011), the CVOs (meeting on 29 September 2011) and the "residues experts working group" (meeting on 5 September 2011).

[119] See Annex XVIII.
[120] See Annex XX.
[121] See annex XX of this document

- Veterinary border controls

In 2007 the Commission launched a questionnaire to all Member States to investigate in which areas there are difficulties with the implementation of the veterinary checks in BIPs. All Member States provided detailed replies favouring the review of the veterinary border control legislation and highlighting the need for more effective physical checks including a risk based approach. In addition several problematic areas, such as implementation of pre-notification, re-enforced physical checks, procedures for specific consignments such as for transit, for transhipment, channelled and rejected consignments, re-imports and approval and supervision of specific free and customs warehouses were raised. These problematic areas were discussed in the Working Group on veterinary check legislation with Member States' representatives.

Two Steering Group meetings were hold (27.05.2010 and 03.03.2011) to inform the members (including stakeholders), during which the Commission explained how the work concerning the Review of the import control legislation started and how it is planned to continue. Participants in the Steering Groups did raise several questions for clarification but no major comments in relation to the review were raised.

In addition two task forces with a limited number of Member States representatives were held (25.01.2011, 23.06.2011) to discuss the review of Regulation (EC) No 882/2004 to integrate principles of import controls for live animals and products of animal origin and repealing and replacing Council Directives 91/496/EEC and 97/78/EC. The results of the discussions in the Taskforces were presented to the Working Group for veterinary checks and the review of Regulation (EC) No 882/2004 was discussed on 02.12.2010, 11.03.2011 and 06.07.2011.

- Animal Health related controls

The Animal Health Law, including related controls aspects, was discussed at numerous Chief Veterinary Officers' working group meeting since early 2009. On some elements two public consultations also took place in 2009 and 2010 respectively and in particular at the meeting on 22 March 2011. In addition, a dedicated meeting of the Working group on the Animal Health Law, with representatives of the MS was organised on 30 May 2011 to discuss certain aspects relating to animal health controls.

- Plant Health and plant reproductive material related controls

Repeated consultations were organised for the review of the EU plant health regime, during the evaluation phase, for the preparation of options for the future and for assessing the potential impacts of certain measures. The consultations included the organisation of meetings and conferences as well as written consultations.

The relationship between the plant health regime and Regulation (EC) No 882/2004 and the possible full inclusion of the former in the scope of that Regulation was discussed repeatedly with the Chief Officers for Plant Health of the Member States. On their request, a specific task force with MS experts and the Commission and reporting to the said Chief Officers was convened on 26 May 2011 to discuss the feasibility of the inclusion of plant health related controls in the horizontal framework for official controls.

Repeated consultations were similarly organised during the evaluation and review of the EU regime for the marketing of seed & plant propagating material. Also in this area, a task force with MS experts and the Commission was set up to discuss the feasibility of the inclusion of

seeds and propagating material within the scope of the general framework for official controls. This task force was convened on 24 May and 19 July 2011.

2) Consultation of stakeholders

- Under the Advisory Group on the Food Chain and Animal Health and Plant Health, two *ad hoc* Working Groups were established:

  - the one on the review of the inspection fees rules took place on19 October 2009,

  - the one on the review of the system of official controls took place on 19 September 2011.

- The Advisory Group on the Food Chain and Animal Health and Plant Health took place on:

  - 14 March 2011,

  - 14 November 2011.

3) Inter Service Steering Group

- The Commission Inter-Service Steering Group on the IA for the review of the EU system of official controls along the food chain met six times on:
  - 5 May 2011 (planned approach and problem analysis were discussed),
  - 24th June 2011 (collection of data and a first draft of the IA were discussed),
  - 19 July 2011 (outcome of the results of the consultation on Directive 96/23, problem definition, objectives and policy options),
  - 7 September 2011 (problem definition and objectives),
  - 18 October 2011 (policy options),
  - 25 November 2011 (policy options and analysis of impacts),
  - 20 December 2011 (analysis of impacts and preferred options).

Annex V: PROCEDURE – Specific data collection activities

- **Directive 96/23 on official controls on residues of veterinary medicines in live animals and animal products**

Information collected in the context of the 2003-2009 evaluation in order to review the whole legislation on residues of pharmacologically active substances used for the treatment of animals (including Directive 96/23/EC[122]) has been considered for this review insofar as it was still relevant. It has been updated and complemented by information and data received from the MS through the consultation carried out at the beginning of 2011.

A significant amount of information was also available in the Commission's "Residues Application", which records the number of samples of animals or animal products analysed for residues and the corresponding results. Data on the cost of the residues controls was collected through a questionnaire sent to the MS at the beginning 2011[123].

Data from the "Residues Application" and from the consultations carried out have been used in particular to assess the potential impacts of the options available[124].

- **Plant Health**

The general evaluation of the EU plant health regime was carried out in 2009-2011[125] and included elements of the EU regime on official controls in the Plant Health sector.

A data gathering exercise was also conducted with regard to additional burdens to MS authorities and operators that could result from 1) a possible link of plant and plant products imports to the TRACES system, 2) the cost of mandatory accreditation of laboratories for methods related to plant health and 3) the cost of setting up EU reference laboratories for plant health.

[122] Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC.
[123] The questionnaire and the results of this consultation are presented in Annex XX.
[124] See Annex XXI.
[125] http://ec.europa.eu/food/plant/strategy/index_en.htm

Annex VI[126]: PROCEDURE – List of consulted stakeholders

Acronym	*Organisation*
AESGP	European Self-Medication Industry
AIPCE-CEP	European Fish Processors Association European Federation of National Organisations of Importers and Exporters of Fish
AVEC	Association of Poultry Processors and Poultry Trade in the EU countries
CEFIC	European Chemical Industry Council
CELCAA	European Liaison Committee for the Agricultural and Agri-Food Trade
FOODDRINK EUROPE (former CIAA)	European food and drink industry (recent Confederation of the food and drink industries of the EU)
CLITRAVI	Center for the Meat Processing Industry in the European Union
COCERAL	*Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures*
COPA-COGECA	Committee of Professional Agricultural Organisations-General Confederation of Agricultural Cooperatives
EDA	European Dairy Association
EHPM	European Federation of Associations of Health Product Manufacturers
ESA	European Seed Association
ESA	European Snacks Association
EUROCHAMBERS	European Association of Chambers of Commerce and Industry
EUROCOMMERCE	The retail, wholesale and international trade representation to the EU
EUROGROUP FOR ANIMALS	Eurogroup for animal welfare at European Union level
EUROPABIO	European Association for Bioindustries
FEFAC	European Feed Manufacturers' Federation
FEFANA	EU Association of Specialty Feed Ingredients and their Mixtures
FESASS	European Federation for Animal Health and Sanitary Security
FRESHFEL EUROPE	European Fresh Produce Association
FVE	Federation of Veterinarian of Europe
HOTREC	Trade association of hotels, restaurants and cafés in the European
IFOAM-EU GROUP	International Federation of Organic Agriculture Movements
UEAPME	European Association of craft, small and medium-sized enterprises
UECBV	European Livestock And Meat Trading Union

[126] Stakeholders active in the fields of Plant Health and Plant reproductive material were also consulted in the context of the related reviews.

FRUCOM	Representation of European Importers of Dried Fruit, Edible Nut, Processed Fruit & Vegetable, Processed Fishery Product, Spices, Honey and Similar Foodstuffs
	Breiz Europe
UGAL	Union of Groups of Independent Retailers of Europe

Annex VII: PROCEDURE – List of FVO audits since 2007

GENERAL AUDITS				
MEMBER STATE	GENERAL AUDIT YEAR	CLOSING DATE	REFERENCE	DATE OF PUBLICATION
FR	2011	ongoing	2011-6092	Not yet published
AT	2011	ongoing	2011-6084	Not yet published
CZ	2010	Feb 2011	2010-8710	Not yet published
RO	2010	Feb 2011	2010-8730	Not yet published
FR	2010	March 2011	2010-8627	Not yet published
IT	2010	March 2011	2010-8741	Not yet published
SE	2010	April 2011	2010-8723	Not yet published
BG	2010	May 2011	2010-8713	Not yet published
UK	2010	March 2010	2010-8371	Not yet published
CY	2010	March 2010	2010-8372	Not yet published
EL	2009	May 2010	2009-8315	Not yet published
PT	2009	March 2010	2009-8378	Not yet published
CY	2009	Nov 2009	2009-8783	30/03/2011
FI	2009	Mar 2010	2009-8316	01/12/2010
LV	2009	Jan 2010	2009-8821	16/03/2011
LT	2009	Jan2009	2009-8774	31/03/2011
SI	2010	Jan2010	2010-8779	17/08/2011
EE	2008	Apr 2009	8600-2009	11/05/2010
HU	2008	Feb 2009	2009-8346	05/02/2010
IE	2008	Nov 2008	2008-8724	18/08/2010
AT	2007	Jan 2008	2007-7995	10/12/2008
SK	2008	Apr 2009	2008-8380	03/02/2011
GENERAL FOLLOW UP MISSIONS and AUDITS				
LV	2010	Sep 2010	2010-8373	Not yet published
SK	2010	May 2010	2010-8365	Not yet published
NL	2010	May 2010	2010-8363	Not yet published
IE	2010	May 2010	2010-8364	Not yet published
FI	2010	Nov 2010	2010-8375	Not yet published
LT	2010	Dec 2010	2010-8374	Not yet published
SI	2011	March 2011	2011-6076	Not yet published
PT	2011	April 2011	2011-6077	Not yet published
RO	2011	Sept 2011	2011-6085	Not yet published
DE	2011	Nov 2011	2011-6075	Not yet published
SE	2011	Nov 2011	2011-6090	Not yet published
IT	2011	Oct 2011	2011-6088	Not yet published
ES	2011	Jan 2011	2011-6074	Not yet published
HU	2009	Oct 2009	2009-8120	Not yet published

HU	2011	Jul 2011	2011-6078	Not yet published
CZ	2011	May 2011	2011-6079	Not yet published
CY	2010	ongoing	2010-8372	Not yet published
BG	2009	Oct 2009	2009-8100	Not yet published
GR	2010	Dec 2010	2010-8368	Not yet published
LU	2011	Oct 2011	2011-6083	Not yet published

SPECIFIC AUDITS

MEMBER STATE	SPECIFIC AUDIT YEAR	DATES	TITLE	REFERENCE
AT	2007	29/01 – 02/02	Food, feed and seed consisting of or produced from genetically modified organisms	2007-7177
AT	2007	05/11 – 09/11	Import controls on food and feed of non-animal origin	2007-7224
AT	2007	25/06 – 06/06	Intra-Community trade in live animals	2007-7350
AT	2007	04/06 – 11/06	Intra-Community trade in semen and embryos of domestic animals of the bovine species	2007-7370
AT	2007	04/09 – 12/09	Official controls on feed and compliance with requirements for feed hygiene	2007-7500
AT	2007	22/05 – 30/05	Health rules on animal by-products	2007-7518
AT	2007	04/09 – 12/09	Plant passport system, the current situation of Erwinia amylovora (Burr) and the system of import controls for plant health	2007-7602
CY	2009	19/01 – 28/01	Poultry meat and poultry meat products	2009-8064
CY	2009	02/02 – 10/02	General Food Hygiene, bottled water, pesticide residues (food of plant origin)	2009-8143
CY	2009	02/03 – 06/03	Bovine Spongiform Encephalopathy (BSE)	2009-8304
CY	2009	17/03 – 24/03	Residues and contaminants and the use of veterinary medicinal products in food producing animals	2009-8130

CY	2009	18/05 – 22/05	Import/transit control system and border inspection posts	2009-8076
CY	2009	21/09 – 25/09	Feed hygiene	2009-8086
CY	2009	19/10 – 23/10	Animal welfare	2009-8244
CY	2009	16/11 – 24/11	Contingency plans for epizootic diseases Eradication programme for Brucella melitensis	2009-8253
FI	2009	23/02 - 27/02	Evaluate the implementation of controls for animal welfare on farms, during transport and at the time of slaughter	2009-8262
FI	2009	23/03 - 01/04	Evaluate the official controls systems in place for import controls, food additives and food contact materials	2009-8149
FI	2009	30/03 - 03/04	Evaluate import/transit control system and border inspection posts	2009-8081
FI	2009	04/05 - 11/05	Evaluate the control of residues and contaminants and the use of veterinary medicinal products in food producing animals	2009-8125
FI	2009	02/06 - 11/06	Evaluate the food safety control systems in place governing the production and placing on the market of poultry meat and poultry meat products	2009-8065
FI	2009	30/06 - 09/07	Evaluate the implementation of measures concerning official controls on feed legislation	2009-8088
FI	2009	07/09 - 18/09	Evaluate the follow-up action taken by the Competent Authorities with regard to official controls related to the safety of food of animal origin, in particular meat, milk and their products	2009-8229

FI	2009	05/10 - 09/10	Evaluate the system of import controls for plant health and the internal market controls of wood products of relevance for Bursaphelenchus xylophilus	2009-8150
LV	2009	19/01	Public Health (Hygiene Package) – red meat and milk	2009-8207
LV	2009	2/02	Animal welfare	2009-8271
LV	2009	9/03	Import / transit controls on live animals and products of animal origin	2009-8078
LV	2009	16/03	Public Health (Hygiene Package) poultry meat and poultry meat products	2009-8068
LV	2009	5/05	Residues and contaminants in live animals and animal products, veterinary medicinal products	2009-8126
LV	2009	25/05	Plant Health – protected zones and import controls	2009-8166
LV	2009	15/06	Animal Health – contingency plans and rabies control	2009-8259
LV	2009	2/11	Food hygiene, additives and food contact materials	2009-8174
LV	2009	30/11	Animal By-Products	2009-8431
LT	2009	2/03	Import / transit controls and border inspection posts (BIPs)	2009-8079
LT	2009	16/03	Feed and compliance with requirements for feed hygiene	2009-8089
LT	2009	20/04	Salmonella risk in the table egg sector	2009-8069
LT	2009	12/05	Plant Passport/Protected Zones+ Import controls	2009-8169
LT	2009	25/05	General Food Hygiene, Food additives (FA) & Food Contact Materials (FCM)	2009-8159
LT	2009	9/06	Residues and contaminants in live animals and animal	2009-8131

			products, veterinary medicinal products	
LT	2009	20/07	Contingency plans & Rabies	2009-8265
LT	2009	19/10	Traceability and beef products	2009-8234
LT	2009	23/11	Animal Welfare	2009-8252
SI	2010	07/09-11/09	contingency plans and eradication programmes for epizootic diseases	2009-8267
SI	2010	26/01-30/01	measures concerning Bovine Spongiform Encephalopathy (BSE)	2009-8114
SI	2010	20/04-30/04	systems in place to control the Salmonella risk in the table egg sector	2009-8071
SI	2010	04/05-08/05	Veterinary import/transit control system and border inspection posts	2009-8203
SI	2010	19/01-23/01	control of residues and contaminants and the use of veterinary medicinal products in food producing animals	2009-8132
SI	2010	16/06-24/06	implementation of controls for animal welfare on farms, during transport and at the time of slaughter	2009-8241
SI	2010	03/03-13/03	follow-up action taken with regard to official controls related to the safety of food of animal origin, in particular meat, milk and their products	2009-8223
SI	2010	05/10-13/10	official control systems in place for food hygiene, traceability, labelling and bottled water and the official control system in place for food additives and food contact materials	2009-8168
SI	2010	23/03-30/03	import controls for plant health, the implementation of the protected zone for Erwinia amylovora and the internal market	2009-8157

			controls of wood products of relevance for Bursaphelenchus xylophilus	
EE	2008	16/06-20/06	veterinary import/transit control system and border inspection posts	2008-7756
EE	2008	20/05-29/05	control systems in place in relation to disease contingency plans for epizootic diseases (in particular foot and mouth disease and classical swine fever) and surveillance activities for bluetongue	2008-7785
EE	2008	14/04-18/04	implementation of health rules on animal by-products	2008-7739
EE	2008	15/09-19/09	implementation of controls for animal welfare on farms, during transport and at the time of slaughter	2008-7765
EE	2008	22/04-30/04	control systems in place governing the production and placing on the market of fishery products	2008-7640
EE	2008	10/03-14/03	official control systems in place for food of non-animal origin	2008-7842
EE	2008	16/09-26/09	plant health controls for imports, the plant passport system and the protected zone for Erwinia amylovora	2008-7898
HU	2008	19/5-29/5	Evaluate the food safety control systems in place governing the production and placing on the market of poultry meat and poultry meat products	2008-7629
HU	2008	1/9-5/9	Evaluate the implementation of measures concerning official controls on feed and compliance with requirements for feed hygiene	2008-7720

HU	2008	13/5-23/5	Carry out a specific audit to assess import/transit controls and border inspection posts	2008-7754
HU	2008	20/5-30/5	Carry out a specific audit to evaluate the implementation of controls for animal welfare on farms, during transport and at the time of slaughter	2008-7767
HU	2008	8/9-12/9	Evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products	2008-7774
HU	2008	2/9-11/9	Evaluate the Classical Swine Fever eradication control programme	2008-7798
HU	2008	15/4-25/4	Carry out a specific audit to evaluate the follow-up action taken by the competent authorities with regard to official controls related to the safety of food (meat, milk and babyfood)	2008-7817
HU	2008	6/10-10/10	Evaluate controls of pesticide residues in food of plant origin	2008-7849
HU	2008	16/6-20/6	Assess the official control systems in place for food hygiene (within the meaning of Regulation (EC) No 852/2004), traceability and labeling	2008-7866
HU	2008	14/10-15/10	Evaluate the food safety control systems in place governing the production and placing on the market of poultry meat and poultry meat products (follow up to mission 2008/7629)	2008-8009
IE	2008	04/02 – 15/02	To evaluate the system of import controls for plant health	2008-7891

IE	2008	04/02 – 15/02	To evaluate the implementation of the plant passport system, the situation of Erwinia amylovora (Burr) and its protected zone and the control of Ralstonia solanacearum	2008-7893
IE	2008	27/02 – 07/03	To evaluate the food safety control systems in place governing the production and placing on the market of poultry meat and poultry meat products	2008-7631
IE	2008	31/03 – 04/04	To assess controls on food of non-animal origin	2008-7843
IE	2008	07/04 – 11/04	To carry out a specific audit to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products	2008-7780
IE	2008	21/04 – 25/04	To evaluate import/transit controls and border inspection posts	2008-7750
IE	2008	19/05 – 23/05	To carry out a specific audit to evaluate the implementation of measures concerning official controls on feed and compliance with requirements for feed hygiene	2008-7721
IE	2008	03/09 – 12/09	To evaluate the control systems in place governing the production and placing on the market of fishery products	2008-7641
IE	2008	07/09 – 12/09	To carry out a specific audit to evaluate the implementation of controls for animal welfare on farms, during transport and at the time of slaughter.	2008-7768

IE	2008	03/11 – 10/11	To evaluate the implementation of EU animal health requirements for intra-community trade in semen and embryos of domestic animals of the bovine species, as part of the general audit in Ireland	2008-7802
SK	2008	22/10	Public Health (Hygiene Package) - Meat/Milk	2008-7815
SK	2008	12/05	Salmonella risk in the table egg sector	2008-7634
SK	2008	22/09	Poultry meat and poultry meat products	2008-7635
SK	2008	9/06	Food additives (FA) and food contact materials (FCM)	2008-7850
SK	2008	3/11	Food hygiene and other issues related to food production and distribution3	2008-7861
SK	2008	14/04	Residues and contaminants in live animals and animal products, veterinary medicinal products	2008-7776
SK	2008	16/06	Feed and compliance with requirements for feed hygiene	2008-7722
SK	2008	1/04	Import / transit controls and border inspections posts (BIPs)	2008-7751
SK	2008	13/10	Animal Welfare	2008-7769

Annex VIII: Member States' Opinions

This Annex presents an overview of the positions taken by the Member States in reply to the consultations about the review of Regulation (EC) No 882/2004 held within:

1) the Working Group on the general application of Regulation (EC) No 882/2004;
2) the Working Group of Chief Officers for Plant Health and its Task Force on the inclusion of plant health in regulation (EC) No 882/2004;
3) the Task Force on " Plant reproductive material" under Regulation (EC) No 882/2004

The Commission has attempted to correctly summarise and refer to those positions, which however had to be re-arranged and interpreted for the purposes of this Annex.

Scope

1. ***Issue**: clarifying the scope of Regulation (EC) No 882/2004*

   Member States: general support. MS would welcome some clarifications on the extent to which the Regulation applies to AW and AH sectors. Some MS stated it must be clear that the Regulation does not apply to food itself, but also to packaging and food contact materials.

2. ***Specific measures:** clarify the definitions of the terms "monitoring", "survey" and "surveillance" in order to align them to those included in the sectoral legislation and clarify to which extent Regulation (EC) No 882/2004 applies to these activities.*

   Member States: general support. Many MS suggest aligning these definitions to those of the OIE or other international organizations. One MS claim it should be clarified if the "surveys" carried out in the PH sector (in its opinion a crucial part of the control activities carried in this sector) are to be considered as an official control and, thus, included within the scope of Regulation (EC) No 882/2004.

3. ***Issue**: extending the scope of Regulation (EC) No 882/2004 to ABP, PH and Plant Reproductive material legislation.*

   Member States: diverging views. Some MS (4) are in favour of this measure, as it would permit to build a more coherent and exhaustive framework of official controls. Other MS (4) opposed the proposal to extend the scope to PH and Plant reproductive material legislation: since the aims and the functioning of control activities in these sectors differ profoundly, such an extension would be a complex and possibly costly exercise.

Language and terminology

4. ***Issue**: Adjust the language and the terminology used throughout Regulation (EC) No 882/2004 in order to avoid divergent interpretations and take fully account of all sectors already covered by the Regulation as well as, in case of an extension to PH, Plant reproductive material and ABP sectors, will fall under its scope.*

Member States: general support. All MS recognise the need to reformulate the language and terminology, in particular if the scope of Regulation (EC) No 882/2004 is to be expanded.

5. ***Issue**: clarify the definitions of "official controls", "competent authority", "control body", "official certification", "import" provided for by article 2, in particular when inconsistencies exist with the respective definitions provided for by AH and PH legislation.*

   Member States: general support. Many MS proposed to align these definitions to those of the OIE, IPPC, EPPO, ISTA or other international relevant organizations. Regarding the definition of "official control" one MS suggested including, under the definition of "official controls", the follow-up activities carried out in case of non compliance under article 54. Some MS also stated that the definition of "official certification" should be amended in order to take into account the specificities of the Plant reproductive material sector.

Transparency

6. ***Issue**: amendment to the provision on transparency (article 7), in order to set the minimum level of information to be disclosed by the Competent Authorities as well as the degree of such disclosure. The possibility of establishing a common format for providing this information was also considered.*

   Member States: general support except for one MS, according to which the extension of this provision to the Plant Health and to the Plant reproductive material sectors (if included in the scope of the Regulation) would de disproportionately onerous for MS control services. Another MS considers that information should only be disclosed in summary format, and that, in any case, CA should be left free to decide the format to adopt for the report.

7. ***Issue**: introduction of an obligation for MS to make the MANCPs and the ARs available to the public.*

   Member States: one MS opposed this measure, affirming that the decision on the disclosure should pertain to MS.

Border controls

8. ***Issue**: establishing a common set of rules governing border controls in relation to all commodities requiring controls prior to their entry into the EU. A list of the abovementioned commodities would be adopted. The type and frequency of the border controls, as well as their frequency, would be harmonised and risk-based.*

   Member States: general support. MS believe this measure would enhance the transparency and efficiency of border controls. However, two MS affirm that EU action should be limited to establish the general principles and requirements governing border controls, while the more specific issues would be regulated under sectoral legislation. As concerns the Plant Health sector, some MS opposed the adoption of a risk-based approach, insisting that the rule should be 100% frequency checks.

Information management and handling system for official controls (TRACES+)

9. ***Issue**: establishment of a computerised information system for the management and exchange of data and information concerning official controls. TRACES+ should be interoperable and integrated with other European and national systems.*

   Member States: general support except for one MS according to which the establishment of TRACES+ would result in additional administrative burdens and costs. Interface problems between national IT systems and the current TRACES were reported by MS, which affirmed that attention is required on this point in the development of IT tools in the implementation phase.

Official certification

10. ***Issue**: clarify and harmonise the principles governing official certification and the conditions under which it is issued. Amendment of the definition of "official certification in order to include the official certification issued by operators under the supervision of the Competent authority.*

    Member States: general support. MS suggest aligning the provisions concerning official certification to the existing internationally recognised rules. Some MS affirm the peculiarities of the Plant Health and of the Plant reproductive material sectors should be taken into account when establishing the rules governing official certification. As regards the Plant reproductive material sector, MS welcome the possibility of amending the definition of "official certification", as this would allow to take into account the peculiarities of this sector.

Planning and reporting

11. ***Issue:** extension of planning and reporting requirements to the sectors newly introduced within the scope of Regulation (EC) No 882/2004.*

    Member States: MS are against this measure, in particular as regards the extension of planning and reporting requirements to the Plant reproductive material sector (note that the obligation already covers the plant health sector). In their opinion, this obligation would represent an unnecessary and excessive burden.

12. ***Issue:** empowerment to the EC to provide MS with standard templates for the drafting of the MANCPs and of the ARs.*

    Member States: general support except for one MS, according to which there is no need for such a template.

13. ***Issue:** empowerment to introduce a minimum level of controls for certain illegal substances in the MANCPs*

    Member States: Ms were sceptical about this measure, as it is incoherent with the risk-based approach of official controls and might lead to an ineffective use of financial resources by MS. In any case, MS stated further discussions on this point were needed.

In addition, overviews of the positions expressed by MS in relation to specific issues can be found in the following Annexes:

- Annex XVIII – Laboratories - MS' consultations on the accreditation of official laboratories (discussion paper and results).
- Annex XX – Directive 96/23 - MS' consultations on the available options (questionnaire and results).
- Annex XXI – Directive 96/23 - costs reductions relating to the repeal of the Directive.

Annex IX: REVISION OF REGULATION 882/2004 – Summary of stakeholders' opinions in 2011

This Annex presents an overview of the positions taken by the stakeholders in reply to the consultations, either at conferences and consultation meetings or in writing about general issues relating to the review of Regulation 882/2004. The Commission has attempted to accurately summarise and refer to those positions, which however had to be re-arranged for the purposes of this Annex[127].

I. Issues specifically addressed during the Working Group held on the 19/09/2011

1. Transparency

1.1 High level of transparency

The issue of transparency was addressed by the majority of the stakeholders as one of the priority of the review.

Eurogroup provided the Commission with a detailed proposition on how to improve the level of transparency throughout the Regulation. Firstly they underlined that in Article 7 the meaning "a high level of transparency", "relevant information" or "information on the control activities and their effectiveness" is unclear. Consequently they suggest that the text specifies which information the member states must make publicly available and what they need to do to inform the public that this information is available. Secondly they suggest that the following documents are made available on the Commission website:

- Above mentioned documents, with links to each of the national reports, plans and other documents of each member state,

- Reports including following controls on-farm and in slaughterhouses,

- Multi Annual Control Plans (MANCP), of the Annual reports and of reports of controls conducted by third countries administrations on food and feed products and live animals to be imported,

- Measures taken by the member States take in case of infringements to the European Commission (eg. the amount in case of a fine)

The European Snack Association and **Fooddrink** strongly believe that the primary objective of the revision of Regulation (EC) No 882/2004 is to ensure a greater level of transparency and clarity at all levels among stakeholders. Furthermore practices and interpretation by authorities should be more transparent to food operators throughout the supply chain. Another key concern for them is transparency in the listing and delisting process. They suggest creating a more transparent process regarding how decisions on testing frequencies are reached. In addition ESA affirms that greater cooperation and information exchange would enable food operators and their suppliers to more quickly and directly respond to food safety concerns, resolving them expeditiously and thus would benefit the

[127] Stakeholders active in the fields of Plant Health and Plant reproductive material were also consulted in the context of the related reviews, *inter alia* as regards the inclusion of those sectors under Regulation 882 and consequent implications.

entire food supply chain. Finally they warn that the existent lack of transparency adds to the fear among food operators and suppliers that it will continue to be easier to add things to the list than take them off, leading to a gradual lengthening of the Annex I list (and associated increase in costs to importers).

UECBV is in favour of full transparency between Food Business Operators and Competent Authorities in both directions. It is important for FBOs to know what criteria are applied when inspections are carried out and the reasons behind the decisions taken. Similarly, it must also be clear to CAs what is done at company level, in particular with regard to the framework of their HACCP-based systems or certification schemes. With regards transparency towards the public, they believe the most important and relevant information is whether a plant is EU approved. Such approval ensures that the FBO is producing safe food. They are concerned that providing more complex and detailed information would lead to misunderstandings by consumers and possible distortions of competition.

CELCAA emphasises that the authorities need to provide a complete picture of the risk involved to the public.

- Transparency of official controls on feed and food on non-animal origin

The **European Snack Association** claims that there is a lack of transparency about how foodstuffs that are subject to increased levels of control have been defined, the criteria used to make such decisions and also regarding the basis used for adding or deleting foodstuffs from the high risk list. They would welcome an explanatory note with the background for each of the commodities/origins included in the Annex as well as for any deletions to the list, as this would enable origins/suppliers to better understand where any deficiencies exist, and how they can be addressed. Since there appears to be no formal notification of 3rd countries or of the commodities regarding the imposition of mandatory import controls (where commodities are added to the list), they request stakeholders/interested parties to be informed as early as possible and that appropriate transitional arrangements are put in place to allow industry to ensure compliance. In addition they would consider the publication of a consolidation of the quarterly reports provided by the Member States to the Commission to be of great value to stakeholders since it would not only help them to understand better how the Annex review process works but also add credibility to the actions taken. Finally they emphasise that not all Member States adhere to the established timeframe of 15 days for control and that given improvements in analytical methods and costs associated with demurrage, a shorter period should be established when dealing with food products (especially perishable items).

1.2. Publication of MANCP and Annual reports

While five stakeholders claim that these documents should be made available to the public, one is opposed to this measure.

The **European Snack Association, Fooddrink and UECBV** believe that these two documents should be made publicly available in order to increase transparency and confidence among stakeholders. In their view Member States should also be obliged to report their focus for the coming year, where they are going to be doing surveillance, etc. In the same line of thought, they believe that Member States should be obliged to include how they deal with retesting, ability to move goods to bonded warehouse pending testing/release/reshipment, fees, etc. **FEFAC** is of the opinion that the MANCP and the Annual reports should be made available to the public, as this would help operators and national authorities from other Member States to review and adapt their own risk analyses. **UECBV** claims that these documents should be made available on the Commission web-site.

CELCAA notices that the publication of these documents should be well reflected and submitted to clear criteria in view of the damage some information may cause to FBOs. Nevertheless CELCAA would welcome to have access to information (on at least the parts relevant to them) via the CIRCA system.

1.3. Performance rating ('system of smileys')

While one stakeholder fully supports of the introduction of a 'smileys system', and another one is clearly opposed to it, three believe this issue deserves more investigation.

According to **Eurogroup** system of rating (smileys) could be a good way to inform the public of the level of compliance found for specific food business operators. However more information is needed on how it is applied, what level of information it represents and what is the perception of the public.

UECBV is not in favour of performance ratings such as smileys, since where such ratings exist, they differ very much from one Member State to another, can be misleading and may not be comparable at an EU level. HORTEC also considers that Member States should remain free to implement or not such systems. They argue that the experience has shown that the divergences between the countries where the system is already in place and other ones, have no impact on the single market.

Fooddrink'view is that the suggested system based on ‘smileys’ or similar initiatives would need further investigation. **CELCAA** notes that such a system has little relevance for B2B communication. In addition caution and diligence should be used in developing such a performance rating and in defining the criteria to be used. **FEFAC** is not opposed in principle to a system of performance rating. As a matter of fact, they believe performance of individual companies is an element to be taken into account by control authorities when establishing their control plan. However, they are not in favour of a publication of this performance rating by individual companies. They suggest instead encouraging Member States to develop tools allowing to measure an overall performance level for the whole feed and food chain in order to provide a picture of the evolution of the overall safety status of feed and food over time.

2. Right of second opinion (extent of the right provided in Article 12)

The three stakeholders who expressed their views on this question claimed that the right to get a second opinion should be systematic.

It is considered by **CELCAA** as one of the FBOs' basic right. It would be useful to get a second opinion of a neutral arbitrator when tolerance levels approach the detection level.

FEFAC is of the opinion that the possibility for an operator to call for a second expert opinion should be systematic. However, they underline that the legislation should specify the conditions under which this second expert opinion may be requested and what should happen in case of contradictory opinions. They insist in particular, on the fact that the method of analysis to be used is an essential element to be clarified. Regulation (EC) No 882/2004 indeed favours official EU analytical methods over standardized (ISO/CEN) methods over in-house methods (cascade approach). However, official or CEN methods are tested and validated for certain matrixes or sample types. In case the composition of a sample to be tested deviates from these "standard samples", the official / standardised method may not be as accurate and should be in principle validated for each type of sample, which is never the case in practice. As a result, the analytical data obtained by a standard routine may not be more correct than results obtained by an in-house method which is well adapted to the

specific properties of a sample. We therefore hold the view that second expert opinion based on analytical results should allow using a second sample preparation / analytical method.

UECBV is strongly in favour of such a right as the urgent need for such a system has been emphasized in different food crises, including the latest incident regarding "ecoli in cucumbers". However, UECBV is not in favour of a system such as that in DK and in FR, where only one party is heard i.e. the Competent Authorities. On the contrary they are in favour of a referee system, consisting of members of different disciplines and composed of representatives both from FBOs and from CAs. It must be fair and balanced, involving independent experts.

The **European Snack Association** argues that the lack of a clear specified timeframe for the second opinion test (and reference test) can discourage food operators from exercising their rights if told it will take 30 days for a retest. They suggest establishing an obligation on inspection authority to adhere to timelines – either fees are not charged or, at least, goods undergoing retest should be allowed to be moved (under supervision) to avoid incurring further charges.

3. Import controls

3.1. Use of improved IT tools

CELCAA claims that TRACES should be expanded to products of non-animal origin, in order to provide reliable information on serious risks detected in relation to food and feed. They further suggest the Commission to look closely at the community customs code and the e-customs initiative.

3.2. Documentary checks v Analytical checks (Article 16)

FEFAC highlights that EU legislation gives priority to analytical controls, in particular for the control of the presence of contaminants or constituents. They underline that it may happen that even if a method of analysis exists, it may not always be relevant for control purposes. They give two examples to illustrate this:

- control of the added amount of copper as declared on the compound feed label: copper can be analysed by an analytical method but this method will not be able to differentiate between added and native copper; therefore, the result of the analysis is likely to exceed the amount of added copper declared under the feed additive heading on the compound feed label.

- control of added amounts of antioxidants: the level of antioxidants in compound feed is decreasing overtime as they are eliminated when performing their function; therefore, the amount of antioxidants to be determined by analytical means is likely to be below the declared amount on the label.

In both cases, they claim that the only adequate way to control that the declaration on the label of the added amount of copper or antioxidant is correct is documentary checks.

They therefore suggest to introducing a provision in the Regulation (EC) No 882/2004 whereby specific rules for the performance of official controls could be developed by comitology, in particular as regards the relevance of documentary vs. analytical checks.

3.3. Points of entry and prior notification (Article 17)

The **European Snack Association** stresses that not all points of entry have facility to inspect consignments – e.g. to unload containers, warehousing, etc…

3.4. Special treatment (Article 20)

The **European Snack Association** argues that in the absence of any effective recourse on damage resulting from delays the net result is that all these costs end up with the consumer and add to food inflation. Moreover they underline that the administration costs for this regulation are hidden but are huge in terms of communications, claims, etc. They also emphasise the absurd situation whereby small sample consignments, (e.g. 200g), which some DPE's insist are covered by the requirement for a CED (at a cost of £75).

3.5. Approval of pre-export checks by third countries (Article 23)

The **European Snack Association** claims that no real account appears to be taken of companies who have invested in GAP, GMP, certification and which undertake origin testing before shipment. They state that it is possible that investments towards safeguarding imports into the EU would be adversely affected if Article 23 was not changed, since implementing such costly pre-export controls does not provide any additional consideration or confidence among EU authorities. According to them it is crucial that the Commission specifies that controls should be <1%, otherwise it is left to Member States interpretation. It is also important to ensure that documentation is clearly different from commodities coming in under emergency measures – again, import authorities do not easily distinguish between the two schemes, since the documentation is very similar (basically the same CED).

3.6. Border Control Points

BREIZ highlights that the EU lacks a coherent policy concerning food imports controls and particularly the BIPs. They underline that they are more than 300 BIPs (with comparison to ten in the US for veterinary and phytosanitary controls). Consequently they argue that a reduction of the number of BIPs would enhance their administrative, financial and staff resources.

4. Administrative assistance and cooperation

4.1 Assistance in the event of non-compliance (Article 38)

The **European Seed Association** is in favour of the introduction of a harmonized approach to address non-compliance on the national as well as on EU level in respect of S&PM and PH legislation. **UGAL** welcomes the initiative to overhaul the provisions on administrative assistance so that competent authorities more systematically and effectively work together to enforce food law against the Union operators actually responsible for food risks and non-compliances.

4.2 Relations with third countries (Article 39)

The **European Snack Association** requests that where emergency measures are to be introduced, there should be more formal consultation with third country governments; otherwise it is unclear how they are to respond or work with their industries to improve a perceived deficiency in their production practices.

4.3. Coordinated assistance and follow-up by the Commission (Article 40)

The **European Snack Association**'s opinion is that where issues are raised to the Commission, there should be a transparent way of having these issues added to the agenda of a Working Group meeting.

II. Other issues

5. General comments

Fooddrink underlines the following shortcomings of the system: fees are not posted, it is unclear when reprocessing is/is not allowed, process for selecting consignments is not clear, FBOs do not receive any summary information regarding the number of consignments received, inspected, and percentage rejected.

6. Scope of the Regulation

While the three stakeholders who addressed this issue supported the extension of the scope of the regulation to include PH and S&PM, two of them underlined that the sectoral specificities should be carefully taken into account.

Eurogroup has welcomed the inclusion of animal welfare legislation in the scope of the official control regulation. They believe that guaranteeing the welfare of animals is essential to provide for a high degree of food safety.

FEFANA supports the idea of including the review of Regulation No 882/2004 within the context of an integrated package. Nevertheless they stress that sufficient attention has to be paid to the different provisions of the sectorial legislations and their combination.

The European Seed Association is, in general, in favor of harmonization and therefore supports the idea of making use of the already existing harmonized EU framework also in respect of controls for the purposes of S&PM and PH legislation as long as it is consistent with the specificities of these sectoral legislations. In particular they support the introduction of harmonized EU controls over the controls carried out on national level also in the field of S&PM and PH legislation. Nevertheless they underline that they are in favour of leaving the sector specific elements in place whenever it appears appropriate (e.g. seed certification and delegation of official tasks under official supervision to third parties, including private operators).

7. Risk-based controls (Article 3)

All three stakeholders who addressed this issue supported the risk-based approach.

According to **Fooddrink** it is essential that the future EU framework for a control system clearly defines that official controls should be carried out on a risk basis. **CELCAA** believes

official controls should be carried out based on the risk involved as well. They precise that the risk should be determined by clearly defined, objectively verifiable and harmonised criteria. The risk-based analysis should determine the nature and intensity of the controls to which the diverse agricultural commodities should undergo.

The English National Federation of Meat & Food Traders (member of **IBC**) believes that meat inspection should be greatly reduced in scale. Operator responsibility should be enhanced and legislation should be based on a risk based approach.

8. Competent authorities (Title II, Chapter 2)

Eurogroup has highlighted the following problems relating to the infrastructure of national authorities:

- Failure to carry out or include the necessary proportion of animal welfare checks in the annual inspection programmes

- Lack of staff or appropriately trained staff

- Failure to put in place effective and dissuasive sanction systems to react to infringements

They underline that standards are especially poorly enforced in the area of:

- the protection of live animals during transport: insufficient controls at the start of journeys including on journey plans;

- production systems for laying hens: lack of progress in the conversion of barren battery cages into enriched cages or alternative systems

- the protection of pigs: tail docking is performed routinely and no foraging material is generally provided.

CELCAA makes two observations:

- The quality and efficiency of controls has an impact on the costs

- Decisions taken by the competent authorities may have great consequences for the business operators.

They conclude that the time efficiency in performing official controls, in terms of staff, procedures and equipment as well as in delivering results by control authorities is essential. They stress that inefficiencies by control authorities should be avoided as far as possible as they create additional burden to FBOs in terms of costs and delays in discharging/delivering the goods.

8.1. Delegation of tasks (Article 5)

The **European Seed Association** is of the opinion that the specificities of the Seed sector are key to a flexible and well-functioning seed legislation and that there is a risk that these key elements may be harmed with a full integration of the S&PM and PH legislations into the scope of the Regulation (EC) No 882/2004. In particular, bringing the seed-related controls under this regulation should not have any consequences for existing and new possibilities for delegation of official tasks under official supervision to third parties, including private operators.

Bundesinnung der Fleischer (member of **IBC**) claims that meat inspections in slaughterhouses slaughtering 1,000 livestock units or less per year should be authorized to be carried out by an

official meat inspector instead of an official veterinarian (only in case of doubt an official veterinarian should have to be consulted). The English National Federation of Meat & Food Traders (member of IBC) also stresses that there is no need for extensive veterinary attendance in the case of meat inspection. They argue that meat inspectors (auxiliaries) can carry out post mortem inspections after slaughtering has finished if it can be proved that it is necessary and efficient.

8.2. Verification procedures (Article 8)

Eurogroup believes that the verification procedures are essential provisions and therefore guidelines should be established for their preparation. They suggest adding to Paragraph 4(d) a requirement for the documented procedures to be submitted to the European Commission for advice.

8.3. Reports (Article 9)

The **European Snack Association** and **Fooddrink** recommend that inspection reports should always be provided as one of the specific documentation accompanying a consignment the Authorities require. They stress that their members have reported situations where laboratory analyses were not provided, even when requested. In the light of two concrete examples they underline the need for maximum transparency and best practice shared between Member States and more commitment on the part of the authorities to avoid unnecessary recalls. They suggest that a basic level of information on reports (e.g. date codes etc.) should be harmonised across the EU to prevent uncertainty for FBO's who operate across different Member States.

Eurogroup states that reports should be made available to the public.

9. Methods of sampling and analysis (Article 11)

The **European Snack Association** stresses the importance of protecting both product quality and food safety during this part of the inspection procedure. They have been informed that some inspection points do not have the ability to move goods to a warehouse to unload the container before inspection or while awaiting testing results, leading to excessive costs/demurrage and exposure to weather. Furthermore where containers are unloaded, there is frequently a problem with re-loading the entire product back into the container, leaving individual pallet(s) with no where to go. Food operators have reported containers being unloaded, and authorities not properly reloading, resulting in losses/damage during onward transit. In the light of these information they claim that not having specific areas for unloading can also result in the product being exposed to cross contamination/microbial contamination from standing water, birds, etc. Moreover they underline that importers have no realistic recourse to the Port companies or PHA's for any damage caused and that labs are often not all located at the port, resulting in delays for analysis.

10. Official certification (Article 30)

Eurogroup states that the kind of certification covered and its purpose needs to be clarified in Article 30.

The **European Snack Association** emphasises the fact that lab reports/inspection reports should always be provided.

The **European Seed Association** believes it has to be noted that both the S&PM and the PH legislation contain some very specific provisions as regards controls that have to be carried out for the purposes of seed certification. Since decades seed certification under the EU S&PM legislation is carried out according to the rules as defined by ISTA, the International Seed Testing Agency. Similarly, seed certified in third countries in accordance with OECD seed schemes is eligible for equivalence recognition in the EU. As these international standards exist and have long been used by the seed industry the EU should continue to make use of them instead of creating new ones.

10.1 Veterinary certificate

BREIZ underlines that the veterinary certificate that FBOs receive in exchange of the fees they pay (which hinders their competitivity) is not recognize by administrations whose control tasks are relating to other legislations than those of sanitary rules. This is particularly problematic when the customs services do not recognize the certificate and refuse to allow a product to be exported to third countries. Breiz's opinion is that it discredits the entire OC system in the eyes of the European and international firms.

10.2 Third party certification

FEFANA They believe that the revision of this Regulation should be an excellent opportunity to explore with Member States and Commission the role of **third party certification** as a support to the official control and to bring the feed legislation closer to the Commission communication on third party certification.

11. Registration/approval of feed and food business establishments (Article 31)

The **European Seed Association** is in favour of the introduction of an obligation for S&PM suppliers of being registered at national and/or EU level. They are of the opinion that from the perspective of controls such a registration obligation could be very helpful in spotting or avoiding non-compliance with the legislation as well as other possible illegal activities.

12. National enforcement measures

12.1. Action in case of non-compliance (Article 54)

The **European Snack Association** notices that not all Member States allow the practices provided by technological improvement in terms of resorting, reprocessing, etc... It is important in their view to have a better understanding of individual Member State's interpretation of this Article.

12.2. Sanctions (Article 55)

Eurogroup argues that since sanctions play an important role in improving enforcement of EU rules, they should be harmonised. They underline that in the field of animal welfare sanctions are not always dissuasive and thus not effective. They would welcome guidelines from the European Commission on what they consider to be appropriate sanctions in specific infringement cases.

Annex X: FEES – Executive summary of the study on fees or charges collected by the MS to cover the costs occasioned by official controls prepared by food chain evaluation consortium (FCEC)

Regulation 882/2004[128] (hereafter referred to as 'The Regulation') sets out requirements for the authorities in EU Member States that have responsibility for monitoring and verifying compliance with, and enforcement of, feed and food law, animal health and animal welfare rules, i.e. the 'Competent Authorities' (CAs) responsible for organising and undertaking 'official controls' (OCs).

According to Article 65 of the Regulation, three years after its entry into force, the Commission should review the experience gained from its application, in particular in terms of scope and the fee-setting mechanism, and whether/how the current fees regime can be improved. The data collected and results of this study, which focused on the implementation of the financing provisions of the Regulation (Articles 26-29), will feed into a Commission Report to the European Parliament and Council for a possible modification of the current legislation.

The objectives of the study are two-fold:

a) to establish a detailed picture and evaluate the present situation as regards the application of the current fees regime, in particular the way in which the system operates in practice; and,

b) to assess the advantages and disadvantages of a range of policy options (regarding the scope of current rules and the fee-setting mechanism).

As such, the final aim is to provide input to the Commission's development of proposals to improve the fees system in future.

The assessment of the current system and future policy options take into account the wider objectives and principles of EU policy in this sector. As such, the study considers the overall objective of the Regulation to ensure a harmonised approach with regard to official controls, the objectives of EU food and feed law[129] to ensure a high level of protection of human life and health and achieve the free movement in the Community of compliant feed and food, and the objectives of the Lisbon Strategy to promote better regulation and support industry competitiveness. Furthermore, the principles of proportionality, subsidiarity (Article 5 of the Treaty) and FBO responsibility (in accordance with current food and feed law) frame the approach of this study.

The study was carried out in the period April-November 2008 through a survey of EU27 CAs, in depth analysis (case studies) in six MS representing a variety of fee regimes (Germany, the UK, Italy, Poland, France and Slovakia), interviews with key experts and stakeholders at EU

[128] 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 animal welfare rules.

[129] Regulation (EC) 178/2002 (General Food law) and the Hygiene Package (Regulations (EC) 852/2004, 853/2004 and 854/2004).

level[130], and extensive literature and data review (including relevant FVO reports and national legislation).

The study has found that significant progress has been made in the application of the Regulation by MS, and in particular the financing provisions of Articles 26-29, since their entry into force on 1 January 2007. However, the enforcement of these provisions has been slow and gradual, with significant delays in most MS. In some cases, full implementation is still pending subject to the approval of draft national legislation enacting Article 27, despite the fact that the deadline for its definitive entry into force was 1 January 2008. In these cases the fee system in place is largely based on that laid down in previous, repealed legislation (Directive 85/73).

Despite progress a number of important shortcomings have been identified in the current state of implementation of Articles 26-29, as follows:

Competent Authorities (CAs): There are significant differences in the organisation, structure and staffing (number and profiles of staff) between MS, which have financial implications for the cost of official controls (OCs). Contrary to the Commission's expectations, more than one CA is involved in most cases, which may create lack of transparency and of central/overall responsibility. In MS with decentralised management, the central CA is not always in control and efficient/effective coordination is not always ensured. The study findings confirm issues which are already highlighted in relevant FVO reports. In several MS initiatives are under way to rationalize veterinary services, such as the use of appropriately trained contractual staff for the OCs rather than civil servants.

Activities for which fees are collected: A distinction is made throughout the study between OC activities for which fee collection is 'compulsory' (Article 27.2, activities of Annexes IV and V), and those for which fee collection is optional or 'non-compulsory' (Article 27.1). The study has found that, in the case of **'compulsory**' fees: 9 MS collect such fees only partly; fees for milk production and for residue controls were found to be 'controversial' and often not collected at all; on the other hand, in some MS fees are collected for the same OCs more than once along the production chain (e.g. at slaughter and cutting plant even within the same establishment, contrary to Article 27.7). In the case of '**non-compulsory**' fees: 19 MS collect fees for activities beyond those of Article 27.2, while 6 do not collect any such fees; fees are collected in some MS for OCs on products of non-animal origin.

Fee rates used: Regulation 882/2004 leaves it up to MS to define fee system: either minimum fees as defined in Annex IV (domestic controls) and V (import controls) or fee rates calculated on the basis of the actual costs of OCs ('flat rates'). In practice, a multitude of fee rates apply for the various activities: 18 MS use a mix of the two systems (flat rates and minimum rates); the current situation is quite complex, not transparent and confusing for FBOs; the CAs appear to have interpreted relevant provisions of Article 27 rather 'openly'. Furthermore, 12 MS apply fees below minimum rates, however it is not clear or sufficiently justified whether the conditions of Article 27.6 (controls of reduced frequency and criteria of para 5) are respected in these cases.

Fee calculation: Article 27.4 stipulates that where flat rates are used, fee levels need to be set within the limits of the minimum fees set out in Annexes IV and V, and a maximum set by the actual controls costs; the fee calculation in this case must respect the criteria of Annex VI. In practice: the calculation method used is not always available, or has not always been communicated to the Commission (contrary to requirements of Article 27.12); even when the

[130] Including consultations with the following EU professional organisations: AVEC, CIBC/IMV/IBC, CLITRAVI, EDA, FEFAC, FVE, and the UECBV.

method is available, it is not always transparent what type of costs are included under the various cost categories and what reference time period is used; in most cases it is not clear whether the actual costs included in the calculation respect the criteria of Annex VI (staff salaries; staff costs including overheads; lab analysis and sampling).

Fee collection & use of revenue: The rationale of the system is to ensure adequate financial resources to provide the necessary staff and other resources (Article 26). In practice: in the majority of MS the collected revenue is incorporated into the General State Budget, either entirely (11 MS) on in part (7 MS); only 9 MS claim to be 'ring fencing' revenues specifically for the CAs performing the controls; 14 MS indicated they do not cover the OC costs through the fees, while a further 6 MS claim this is occurring in some cases (regions, activities). This partial cost coverage may be due to inappropriate fee setting (insufficient fee levels) as well as inappropriate fee collection / use of revenue. The position appears to be better in the case of imports controls, partly because Article 27.8 stipulates that such fees should be paid to the CA in charge.

Enforcement of Article 27: Although the Regulation should be directly enforceable, Article 27 allows some discretion to MS on the actual fee system to use and the activities for which OCs should be charged beyond those of Article 27.2. The study has found that, in practice, there is significant variation between MS in the enforcement of Articles 26-29. Underlying this, there is a strong perception - in some cases documented by FVO reports - of significant variation in the organisation and effectiveness of OCs, and that – as documented by the study findings - CAs have rather liberally interpreted provisions of Articles 26-29 (this is particularly a problem in some MS with decentralised management and lack of sufficient central control by the CCA).

The study has therefore concluded that, as it currently stands, the system of fees for OCs does not fully fulfil its key objective: to provide sufficient resources for the effective and efficient operation of the OCs. Furthermore, the actual implementation of the system raises issues with regard to its contribution to the functioning of the internal market and the cost-efficiency of the system of OCs.

Contribution to the functioning of the internal market: MS broadly agree with the rationale of Articles 26-29. However, could the heterogeneity in their application in practice cause distortions in competition? The study has investigated various potential distortions that may arise in this context. It has found that in practice:

- **Distortions at EU level**: There is a general concern amongst stakeholders in the various MS that implementation of rules by national authorities put them at disadvantage vis-a-vis other MS. However, it is difficult to substantiate these claims due to lack of clarity and uniformity in MS approaches which makes the comparison of actual fees difficult. Although evidence of unjustified variations in fee levels were found between MS, there is no evidence of significant distortion in competitiveness between MS caused by differing fee levels. Other key factors affecting competitiveness appear to be more significant.
- **Regional distortions** are a concern particularly in some MS with decentralised management e.g. amongst the case study countries (Germany, also Italy and Spain);
- Discrimination against the **meat sector**, which is seen as unfairly bearing the cost of the OCs, from which other sectors along the chain also benefit;
- Discrimination against **smaller or disadvantaged FBOs**, which compound the difficulties they face in the general economic climate; this is particularly evident for those MS that have not adopted special provisions for these businesses in line with Article 27.5.

Cost efficiency issues have been raised with regard to:

- **Staff costs**: Stakeholders argue that Regulation 882/2004 could go further than the general requirement to have "a sufficient number of suitably qualified and experienced staff". In practice, there are wide variations in the number and profile of staff involved in controls, and this has repercussions on salary costs;
- **Administrative costs**: There is lack of transparency on what type of costs are taken into account, the formulation of Annex VI is considered too broad (in particular criterion 2: 'associated costs'), resulting in wide variation between MS and unjustifiably high costs in some cases;
- **Proportionate and risk based controls:** important cost savings could be made in the costs of OCs if the guiding principles of OCs (risk basis, FBO responsibility and 'self-control' systems) were sufficiently taken into account by MS in implementing the provisions of Articles 26-29.

To address the various shortcomings in the current application of the Regulation[131], the study has examined the following key options: moving from the current system towards more harmonisation; moving towards more subsidiarity; and, the continuation of the *status quo*. A complementary option, which transcends the above three alternative options, is the extension of the financing obligation to sectors beyond those currently covered by the Regulation.

The key components of the financing system (basis of fee charging; level of fee rates; fee calculation method; fee reductions and penalties; and, list of activities covered by fees), as identified on the basis of the intervention logic of the current legislation (Articles 26-29), were combined to develop a range of scenarios within the above options (**Error! Reference source not found.**). The basis of fee charging is compulsory for all MS under the harmonisation option, optional under the subsidiarity option, and a mixed approach under the continuation of current rules.

The scenarios were assessed in terms of advantages and disadvantages, feasibility (whether and under which conditions they would work in practice), and the acceptance that they might have from the various groups of stakeholders. Key criteria for the assessment were the main goals and principles of the Regulation, as well as the wider objectives of Community food and feed law and the Lisbon strategy, in particular: improving the effectiveness and efficiency of the official controls; simplification of the current system; and providing the right incentives for FBOs to encourage compliance and discourage non-compliance. As these criteria may not necessarily point in the same direction, the initial assessment of the scenarios provided here aims to provide a balance between the various objectives and needs of stakeholders.

The assessment has shown that neither harmonisation nor subsidiarity would work in their most extreme expression. Although both scenarios would simplify the current system at the level of central management (particularly if full subsidiarity is pursued), they ultimately carry the risk that they may not lead to sufficient cost-recovery in some MS, and that the level of cost-recovery may vary significantly between MS. This could undermine the overall effectiveness of the official control system at EU level, and/or act as a disincentive to improving its efficiency.

[131] It is noted that addressing some of the current shortcomings identified by this study requires action that extends beyond the financing provisions of Regulation 882/2004, to the wider legislation in the area of food and feed safety. The discussion of solutions to such shortcomings was therefore limited to its relevance to the costs and the financing of the official controls.

An intermediate solution would clearly provide the most pragmatic way forward. Intermediate scenarios provide different degrees of balance between the flexibility that the majority of MS require, as an incentive *inter alia* to rationalise the system, with the simplification needed at the level of central management (Commission, MS CCAs). The study has found that the rationale for a flexible approach, which underlies the current Regulation, continues to apply today. The majority of MS CAs and stakeholders have indicated that a system that allows MS flexibility to set the fee rates, within a commonly agreed set of rules, continues to be the most favoured option. This approach is considered the most appropriate for the system to be able to adapt to national conditions.

On balance, amongst the various scenarios that can be envisaged at an intermediate level, those leading to more subsidiarity appear to be more attractive than those that lead to more harmonisation. This is because the degree of flexibility given to MS diminishes, while the degree of complexity of the legislation increases.

Moving towards more subsidiarity, if the primary aim of the legislation is to ensure that MS have the funds necessary to cover the costs of official controls whatever the means, scenario 4 (maintain only the general obligation for MS to provide adequate funding, in the line of a modified Article 26) could present an attractive alternative to pursue for the purposes of simplification.

The disadvantage of this scenario would be that it could result in wider variations between MS than those created by the current system. To reduce these variations, conditions could be attached in the form of common principles at EU level for a more harmonised calculation of the fees and/or fee reductions/penalties across the EU (scenario 3).

Although the continuation of the *status quo* would be an alternative intermediate solution, the analysis of current shortcomings under section **Error! Reference source not found.** has shown that to *do nothing* is clearly not an acceptable or a pragmatic option. However, if the current mixed approach of the Regulation (which represents the political reality of the evolution of the system since Directive 85/73) was to be maintained, certain improvements could be introduced as follows: at a general level improve the understanding of the Regulation; provide a rationale for setting minimum fee levels and review Annexes IV and V in the light of this rationale; reinforce transparency and accountability criteria; refine and define certain provisions more precisely at technical level; update Articles 26-29 with the progress made since the adoption of the General Food Law and the Hygiene Package.

Whatever the scenario to be pursued at an intermediate level, the study has identified the need for the definition of common principles that can apply for a more harmonised calculation of the fees and/or fee reductions/penalties across the EU. These could be general principles only or they could be more detailed criteria defined at a technical level. General principles would include: transparency in the calculation method of fee setting and for calculating fee reductions/penalties, on the basis of actual costs; and, the obligation for MS to communicate these to the Commission and the public. Detailed technical criteria would include for instance the calculation method to be followed for fee setting and for fee reductions/penalties, cost-recovery targets that should be sought, precise cost categories that should be taken into account, and even maxima/ceilings for each cost element.

The level at which common principles should be set needs to be further explored, as it is crucial in controlling MS flexibility and mitigating the potential disadvantages of subsidiarity. The greater the degree to which EU legislation moves from defining common principles and general guidelines (as is currently the case with Articles 27-29) to more technical criteria, the more difficult it will be for MS to deviate from a common denominator.

On the other hand, this increases the complexity of the provisions and the extent of follow up needed at central level (Commission, MS CCAs).

In terms of the calculation of fee reductions and penalties, in particular, the principles could build on the advantages and benefits of self-control systems, as introduced at EU level by the Hygiene Package. Both MS and stakeholders are in principle in favour of providing incentives to FBOs to assume greater responsibility. The study has examined the possibility to follow an integrated approach more consistently linking compliance and non-compliance, and therefore fee reductions and penalties, to the uptake of self-control systems by industry (through a *bonus-malus* system). Such systems have already been developed in few MS (e.g. Belgium), highlighting the advantages of an integrated approach. The study has concluded that, although the development of such systems needs to be encouraged at EU level, their actual design can at present only be pursued at MS level.

Furthermore, the cross-cutting theme of the extension in scope of the Regulation was favourably assessed, in relation in particular to the inclusion of all stages along the food chain. The case of the extension of the system to stages upstream and downstream of the slaughtering and meat cutting operations along the meat production chain was a case in point. The study has concluded that an extension in this form would spread the costs of controls currently pursued only at a particular point in the chain but for the benefit of stages upstream/downstream more equitably along the food chain. Again, this approach is currently being adopted/explored in several MS.

This forward looking element of the project aimed to provide an initial assessment of certain key scenarios. The purpose was not to provide a full feasibility analysis (whether at political or technical level). Nonetheless, specific recommendations were made to develop these scenarios, or indeed other potential combinations of their components, including through future impact assessments.

Annex XI: FEES – Executive summary of the study carried out by GHK to support the impact assessment as regards the financing of official controls

Preparatory work to support the impact assessment on reviewing the rules on the financing of official controls

A final report to DG SANCO

Date: 20 September 2011

Executive Summary

E.1 This report examines the impacts of proposed changes to Regulation (EC) 882/2004 regarding the rules on financing official controls

This is the final report of a study to assess the impacts of potential revisions to Regulation (EC) 882/2004 regarding the rules on financing official controls. The report presents results of the research conducted and impact analysis on options proposed by the Directorate-General for Health and Consumers (DG SANCO) to change the current system in order to improve shortcomings identified in an evaluation of the Regulation conducted in 2008. The study was led by GHK Consulting Ltd working with ADAS UK Ltd.

This study contributes to the preparation of an impact assessment of proposed revisions to Regulation 882/2004/EC regarding the rules on financing official controls. The objective of the study was to provide the Commission with:

- Data that substantiate the problems in the current operation of the legislation with respect to financing official controls; and
- An assessment of the impacts of policy options identified by the Commission to address these problems.

The analysis demonstrates that there are options available that, when suitably packaged and with careful implementation, could mobilise the resources needed to finance efficient controls at the same time as fostering the development of a system that is fairer, more transparent, and does more to encourage efficient management of risk by both food business operators and competent authorities.

E.2 The objectives of the existing legislation are not being met

The objective of Articles 26-29 of the Regulation is to ensure that the approach to financing official controls is consistent across Member States (MS). The Regulation describes the general approach that should be taken by MS, and the principles that should be adopted by the relevant authorities. Articles 26-29 of the Regulation outline the provisions related to the financing of official controls. They specify that:

- Member States must ensure that adequate financial resources are made available for official controls (Article 26);
- Where inspection fees are imposed on feed and food business operators, common principles must be observed for fee-setting and the methods and data used for calculating the fees must be published or otherwise made available to the public (Article 27); and
- When official controls reveal non-compliance with feed and food law, the extra costs that result from more intensive controls must be borne by the feed and food business operator concerned (Article 28).

Previous analysis of the implementation of Articles 26-29 has identified four main problems with the legislation and its implementation: a lack of clarity and uniformity, a lack of transparency in the calculation of costs by competent authorities, the fact that in most instances fees do not cover inspection costs, and a lack of flexibility in the current legal framework. The reforms are intended to address those issues.

E.2.1 There is a lack of clarity and uniformity in the Regulation, which results in diverging interpretations in EU Member States

Text of the Regulation is imprecise in places. This has resulted in differences of interpretation by Member States and led, in turn, to significantly different fee charging systems in which Member States calculate fees on different bases. Fees that, according to EU law, are compulsory are not always collected. The level of cost recovery achieved varies widely. Article 3 specifies criteria that Member States should follow in the design of their official control fees systems. These are particularly relevant where Member States adapt their controls systems in light of risk factors, the degree of businesses' past compliance and own checks, the presence of small businesses and issues related to the location of remote businesses. The way in which these criteria are described in the legislation makes them difficult to implement.

E.2.2 There is a lack of transparency in the calculation of costs at Member State level

Many Member States calculate fees in breach of the terms set out in Article 27 of the Regulation. Many also fail to provide the Commission with the calculation method they use as required by Article 27.12. Where the calculation method has been made available it has often not been transparent: the cost categories included and the Competent Authority that has incurred them are unclear, as are the time periods to which the costs relate. Furthermore, under Annex VI of the Regulation fees can be used to recover 'staff salaries', 'staff costs' and 'laboratory analysis and sampling'. But the wording of the Annex is insufficiently precise and has proven to be open to various interpretations – resulting in a lack of consistency of approach across and even within Member States.

E.2.3 Fees do not cover inspection costs

The general principle of financing official controls is that funding should be made available to Competent Authorities for control activities and that for some controls a fee must be levied. Where fees must be levied, these should cover the costs of carrying out the specified control activities. In the majority of Member States, however, the fees collected do not cover the inspection costs. Fees collected are often incorporated into a Member State's general revenues (either in entirety or in part), with no restrictions or conditions regarding how they should be used subsequently.

E.3 The Commission has developed proposals for revision of the legislation that are intended to address these problems

The legislative revision is intended to develop a clearer, simpler and more transparent system, while taking into account the principles of proportionality and subsidiarity and the need to avoid disturbing the internal market. Embedded in the general objectives are principles of proportionality, subsidiarity and food business operator responsibility that to be taken into account by Member States when considering the scope and specification of fees. The specific objectives for the reforms are to ensure:

- *Mobilisation of resources for efficiently delivered controls*: ensuring that Member State official bodies have adequate financial means to efficiently perform official controls to ensure food safety;
- *Simplification*: providing a clearer and simpler legal framework;
- *Comparability*: avoiding disturbance of the internal market while accounting for different cost structures across Member States;
- *Streamlining*: reducing the administrative burden on Member States and stakeholders as far as possible; and

- *Accountability*: ensuring that stakeholders have access to information on how resources are collected and used.

DG SANCO has identified three policy options, drawing on an conducted in evaluation in 2008 and further evidence collected from stakeholders and the Food and Veterinary Office. These options are:

- *Option A*: Improve the current system;
- *Option B*: Harmonise inspection fees; and
- *Option C*: Implement full subsidiarity of inspection fees.

Option A includes a number of distinct sub-options. In this analysis interactions between sub-options have been considered with a view to the development of a coherent 'package' of complementary and mutually reinforcing measures. Options have been assessed against a reference 'do nothing' scenario represented by the Member States' current arrangements for financing official controls.

E.4 The analysis suggests that the problems with the Regulation would best be remedied by improving the current system, rather than moving to a model based on full harmonisation or on full subsidiarity

Option A – improvement of the current system – is the most promising reform option. The various potential components of the option have each been assessed on their own merits, and the way in which they might best be 'packaged' also considered. The paragraphs below summarise that analysis.

E.4.1 Extend the scope of mandatory fees

This sub-option specifies an extension in the scope of the mandatory fees (i.e. increasing the number of official controls for which Member States are obliged to collect fees). In simple terms, it shifts the financing of controls from tax revenue to the businesses that are subject to controls but do not currently pay fees. Managed appropriately and in combination with other sub-options, this sub-option could encourage processes that improve Competent Authority efficiency and improve comparability, creating a level playing field across the EU and the food chain. The measure would result in new costs for those sectors that are not currently charged. It could also increase administrative costs to Competent Authorities in the additional assessment and collection of fees (though such costs could themselves be covered by fees if the legislation was appropriately worded). The controls for which fees are mandatory should be clearly stated. Clearer definitions of cost should be considered in conjunction with potentially extending the scope of fees. Some of the industry which pays fees today believes that extension of mandatory fees across the food chain would reduce the cost of controls to those businesses.

E.4.2 Require full cost recovery

This sub-option would impose a legal requirement on Member States to achieve full cost recovery of the (eligible) costs of official controls where mandatory fees apply. This is likely to have a positive impact on mobilisation of resources to finance controls, and therefore meets the primary objective that this sub-option is designed to achieve. Most Member States do not achieve full cost recovery at present, and a requirement would enable Member States to put systems in place to do so. It would shift the financing burden from general taxation to the food chain, increasing costs to FBOs. A year-by-year staged increase in cost recovery rates (where these are currently less than 100%) would provide time for adjustment both by FBOs and by Competent Authorities. If businesses are being asked to pay more it is important that the system is seen to be fair, transparent and efficient therefore this option would best be

combined with complementary measures on transparency, governance and clear definition of eligible costs. The sub-option that gives Member States the option to provide fee exemptions to micro-enterprises would also enable Member States to mitigate impacts of full cost recovery on very small businesses where necessary.

E.4.3 Clearly define eligible costs

This sub-option would change Annex VI of the Regulation in order to define more clearly the costs that can be recovered via fees linked to performing official controls. A precise definition of eligible costs is required. Definitions that leave scope for differences of interpretation (e.g. on the recovery of overheads and administrative costs) are unlikely to solve the present problems. An alternative list of eligible costs proposed by the Commission provides a solid basis for discussion. It would be helpful to have clear rules on recovery of competent authorities' overheads and administrative costs, such as by setting a ceiling on such recovery that is set at a given percentage of eligible staff costs.

E.4.4 Introduce time-based fees

This sub-option would require that time-based fees (rather than flat fees) are used for official controls that require continuous or systematic presence of officials, and potentially for other controls too. Time-based fees can be aligned to efficient, risk-based inspection strategies. A shift from flat fees to time-based fees where continuous/systematic presence of officials is needed can affect the distribution of payments within a sector. Larger operations with high throughput may pay less under a time-based fee regime while small operations with low throughputs may find that charges increase. The potential risks to FBOs of time-based fees – that is, of excess payments for inefficiently delivered inspections – can be mitigated by other sub-options on governance, transparency, clear definition of eligible costs and the option for micro-enterprise exemptions. The extension of time-based fees to controls where continuous presence is not required warrants careful consideration on a case-by-case basis.

E.4.5 Require ring-fencing of resources

Under this sub-option the Regulation would introduce a requirement that fee revenue be used exclusively to cover the costs of the official controls for which they are being charged. This sub-option could have significant positive impacts on mobilisation of resources for official controls and result in improved accountability and comparability of official controls systems.

E.4.6 Incorporate bonus-malus principles

This sub-option would introduce new wording into the Regulation that supports the incorporation of bonus-malus principles in the fee system for official controls such that best performers are rewarded while the worst performers are penalised. Bonus-malus principles are likely to have a positive impact on the efficiency of official controls systems by encouraging risk-minimising behaviour. They can reinforce risk-based controls strategies in which resources are used to target establishments that pose greater risks to the food chain. It may be difficult to provide specific measures within the Regulation's text on the financing of official controls but Articles 26-29 should be screened to ensure that they do not inadvertently inhibit use of such strategies and application of bonus-malus principles. The specification of minimum fees in EU legislation, for instance, can inhibit the application of fee schedules that reward good performance with lower fees.

E.4.7 Introduce transparency and reporting requirements

In this sub-option the Regulation would require Member States to provide information to the Commission regarding the financial resources devoted to official controls each year, and to the public regarding fees, modes of payment and other administrative procedures. Providing

information to the public regarding fees for official controls will have positive impacts on accountability and the additional administrative costs are expected to be modest. A requirement to report to the Commission on resources devoted to official controls will have similarly positive impacts on accountability, but comes with greater administrative cost burdens to Competent Authorities, particularly in Member States with decentralised systems. The scale of that burden will vary depending on exactly what data or indicators are required and on whether existing reporting requirements are rationalised and clarified. Increased transparency will contribute to the creation of a fairer, more efficient system and thus has significant indirect positive impacts for FBOs.

E.4.8 Provide for industry participation

In this sub-option the Regulation would provide FBOs with the right to participate in the *process* of setting the structure of fee rates (though not in determining the fee levels). More participatory governance arrangements should have positive impacts on accountability, giving industry a voice in the fee setting process. Industry participation could provide opportunities for FBOs and Competent Authorities to work together to pursue common objectives. Fee acceptance is also likely to be higher where industry can participate in the process. Enhancing provisions for consultation, together with improved transparency, ought to promote efficiency in the application of official controls and the emergence of a fairer system.

E.4.9 Introduce exemptions and reductions for micro-enterprises

Under this sub-option the Regulation would provide reduced fees or fee exemptions for micro-enterprises (or provide an option for Member States to apply such exemptions). Where this sub-option is made a requirement, it may reduce cost recovery in Member States, particularly for those with a large number of such businesses. Respondents indicated a clear preference for having an option to provide such an exemption or no provision of such an exemption, rather than a requirement to provide universal exemptions or reductions. Providing Member States with the option to determine whether or not to provide an exemption or reduction would allow this decision to be made on a case-by-case basis in each Member State. This would also enable Member States to make judgements about how to mitigate impacts of other sub-options (e.g. full cost recovery) on their smallest food businesses.

E.5 A policy 'package' built from the proposed sub- options under Option A has the potential to significantly reduce administrative burdens, improve cost recovery and create greater efficiencies in the system, if the potential for positive interactions between the sub-options is exploited

It is clear from the consultations and analysis that the sub-components of Option A need to be considered as a 'package'. The individual components deal with different elements of the 'system' and have a cumulative and collective impact on the problems that the reforms are intended to address. The interactions between sub-options are mostly positive but sometimes negative.

The core purpose of the reforms is to ensure that the official controls are properly resourced but also efficiently delivered and that charges that are fair, transparent and based on principles common to all within the EU. Several of the core sub-options would increase payments made by food business operators for the financing of official controls, shifting the financial burden from pressurised public finances to the food chain. In some cases this represents a shift in approach, moving away from controls being a free public service. If the scope and level of fees for business is to increase then there needs to be counter-veiling pressures on competent authorities to discharge their responsibilities efficiently, not least to reduce the financial

impact to FBOs. This can be done through, for instance, enhanced transparency, industry participation, a clearer definition of what costs can be included. Risk-based control strategies that result in efficient use of authorities' resources and focus effort on FBOs which pose greater risk will also help relieve burdens on well-run businesses. A coherent reform package can thus encourage a restructuring of the cost base (where needed) at the same time as addressing fees and revenues.

E.6 Full harmonisation of inspection fees for official controls is unlikely to be feasible

There are valid questions about the feasibility of full harmonisation of inspection fees for official controls throughout the EU, as proposed in Option B. Developing a cost model or set of pricing principles for each official control that was seen by stakeholders to be fair and appropriate (given control costs) would be an extremely challenging exercise. Due to the significant differences in the organisation of official controls systems, variation in cost factors, etc. amongst Member States it would be impossible to identify a fee level that would be appropriate for every country. Harmonised fees would also be politically difficult to implement in Member States with highly decentralised decision making and governance structures. In Member States with decentralised control systems, it may not be possible to specify the fee rates under existing national legislative arrangements. There are cases where new national legislation would be needed.

E6.1 Introduce unified fees for the EU-27

In this sub-option fees for the provision of controls are determined on a unified basis for the EU as a whole (i.e. the same fee rates apply in each Member State). This is likely to have a negative impact on official controls systems across the EU-27. Full harmonisation, applying a unified rate across the EU-27, is likely to reduce the efficiency of the official control system. The distribution of impacts is affected by the level at which harmonised fees are set. If fees were harmonised at the level of the highest prevailing fee in Europe then aggregate payment by industry would rise substantially. If the fees were harmonised at the level of the lowest prevailing fee then industry would, on balance, gain but there would be a corresponding deficit in government income and in the overall cost-recovery rate. If fees were set in the middle of the current range then there would be 'winners' and 'losers' on a state-by-state basis.

E.6.2 Adjust unified fees using a cost of living index

This sub-option is a modified version of the above, in which harmonised fees are adjusted for each Member State using a cost of living index. Indexation of rates according to the cost of living would mitigate some of the impacts of harmonisation on a unified basis but the process of setting an appropriate harmonised fee would remain burdensome and is very unlikely to result in a schedule of fees that reflects the actual costs of inspecting individual FBOs or even whole sectors at a Member State level. Although the sub-option could result in positive impacts on comparability and streamlining, these are likely to be outweighed by the significant negative impacts on efficiency and also of fairness and adherence to principles of cost recovery.

E.6.3 Introduce EU harmonised fees only for certain import controls

Under this sub-option the Regulation would require that certain import controls are subject to harmonised fees, particularly those controls where there is a higher degree of harmonisation (e.g. BIPS and DPEs). A single, uniform price would apply to any EU border point. As with the other sub-options for harmonised fees, harmonisation of fees for import controls is likely to have a negative impact on the official controls systems across the EU-27. Development of a cost model or set of pricing principles for import controls would be an extremely challenging

exercise, and due to variance in the current controls systems it would be impossible to identify a fee level that would be appropriate for every country.

E.7 Repealing Articles 26-29 of the Regulation and moving to full subsidiarity is expected to increase problems associated with lack of coherence and consistency in the application of fees for official controls

Option C considers the possibility that Member States are obliged to allocate 'sufficient resources' to official controls but that each Member State will be free to determine the approach they follow. Option C requires repeal of Articles 26-29 in Regulation 882/2004/EC. This option is likely to have a negative impact on the coherence and consistency of the financing of official controls system in the EU. It is likely to widen disparities between Member States. Some Competent Authorities may be pressured to lower fees in order to maintain industry's competitive advantage which would constrain the resources available for proper delivery of official controls. Other CAs may increase fees and/or expand fee collection for control activities in order to achieve full cost recovery.

E.8 Monitoring indicators should be collected in order to assess the effectiveness and impact of the legislative revision

In order to assess whether the legislative revision is achieving its objectives, and whether there are any unexpected impacts, the European Commission will need to collect, review and publish monitoring indicators. It will also be necessary to undertake a more detailed evaluation exercise once sufficient time has elapsed, in order to thoroughly review the performance of the revised legislation.

Two sets of indicators can be considered. Macro indicators linked to strategic objectives can be used to track progress of the system as a whole, using aggregate data reported by Member States. Alongside that a set of micro indicators can be used to identify impacts on specific groups of actors within the system, particularly food business operators and competent authorities. These impacts could be identified and tracked through following a cohort over time and/or through periodic sampling of the population of FBOs and authorities.

Work by the Commission, previous evaluations, and this study have all demonstrated the challenges of mapping the situation in Member States in a context where arrangements for the financing of controls vary widely, interpretation of the legislation varies and there has not always been timely compliance with European legislation. In Member States, the central Competent Authorities themselves often have limited visibility of the situation in different parts of their own countries due to the devolution of powers of control to local and regional authorities and limited pass-through of information back up to the centre.

Changes in the financing of official controls could be tracked more easily if two changes are made. First, the annual reports produced by Member States under Regulation 882/2004/EC need to be improved in terms of their consistency, coverage and clarity. There is a case for reviewing the existing system of reporting under the Regulation so that the performance of the overall system can be monitored more effectively and efficiently against a set of key indicators without imposing undue burden on Member States. Second, adoption of sub-option A7 on publication of cost data (and/or the second component of sub-option A7 on reporting to the Commission) would ensure that information is made available to track changes over time.

Annex XII: FEES - Summary of the opinions of stakeholders

This Annex presents an overview of the positions taken by the stakeholders in reply to the consultations, either at conferences and consultation meetings or in writing about specific issues relation to the financing of official controls. Positions were summarised and compiled for the purposes of this Annex[132].

1. Cost recovery principle

Stakeholders are in general (predictably) opposed to charges being collected for official controls, and thus to the cost recovery principle. Many would claim that official controls are a public service, whose costs should be borne by society at large.

Positions become more nuanced when questions refer to what changes to the current system would be needed in order to ensure the sustainability of the system and its increased efficiency. The answers suggest that the position of full cost recovery is dependent of the range of costs which are being considered. Opposition to full cost recovery is linked particularly to certain costs (e.g. transport) and on costs which would impact disproportionately on mall scale or remote businesses.

CLITRAVI, CELCAA, UEAPME Food Forum and the **National Federation of Meat and Food Traders (member of the IBC)** claim that here should be no charges at all of official controls. **FEFAC** believes that the principle of fees is an obstacle to improve control cost efficiency. An incentive to control authorities to reduce costs can only be achieved if the costs are born by authorities. Fees also raise issues of independency of control bodies. **HOTREC** considers that, as far as food hygiene inspections in restaurants are concerned, the possibility for national authorities to charge fees for inspections should remain optional.

UEAPME also argues that any full cost recovery would prejudice small remote food businesses (because of transport costs), thus full costs recovery is not acceptable for SME. **Bundesinnung der Fleischer** (member of **IBC**) states that the cost recovery principle always leads to higher fees, as there is no link between the work involved and the result. **The English National Federation of Meat & Food Traders** argues that full cost recovery should be abandoned as it is unfair for operators to pay travel costs and overtime etc. (which impact most on smaller operators). **UECBV** is not in favour of including transport costs in the fees as the geographical location and travelling distances of officials are decided by the Competent Authorities. If the principle of full cost recovery is retained, UECBV can accept this only in respect of direct costs. All indirect costs, including transport, must be borne by the CA.

<u>In favour of a system of shared costs</u>

Danish Agriculture Food Council argues there is a strong need for official control to be fully or partly publicly financed by the EU and MS. **EDA** also claims that part of the costs of inspections should be publicly funded (with **FRUCOM** and **UGAL)**. **AVEC** claims that cost sharing will be an incentive for both sides to do the job as efficiently and effectively as possible. **CIAA** claims that each Member State should prove that it is charging the entire food chain for at least 50% of the total cost of controls (the remaining 50% can be paid by the MS).

[132] This Annex only refers to the inspection fees collected for the purpose of control activities currently covered by Regulation 882/2004 (feed and food law, animal health and animal welfare rules).

AVEC claims that up to 75% of the official inspection costs should be funded through taxation in case of well performing operators.

2. Extension of the scope of mandatory fees

As to the question of whether the list of mandatory fees should be extended to cover sectors currently not charged for controls, answers depend largely on whether the respondents are currently charges a mandatory fee (meat, milk, imports) or not (other animal origin products, non-animal origin products).

In favour

Some stakeholders would welcome an extension of the scope of mandatory fees. In particular, according to **AVEC** mandatory fees are essential. **CLITRAVI** would like to see the principle of mandatory fees extended to food sectors other than the one of fresh meat. The **Danish Agriculture Food Council** argues that a fees system covering the whole food chain (where e.g. retailers would also contribute to the general principle of ensuring the adequate financial resources for official control is needed.

Against

UGAL claims that the extension of mandatory fees along feed/food chain is not justified and would result in illegitimate costs and burdens for operators. According to them it is repugnant to the principle of primary responsibility of food business operators to charge producers whose operations do not involve major veterinary risks. Moreover, there is a risk that by extending mandatory fees to other operators in the supply chain, competent authorities will increase inspections of large low risk operators as a way to generate revenue. Outside the veterinary area, it is the responsibility of MS to ensure that adequate resources are provided via national budgetary allocations.

3. Harmonised/Non-harmonised fee rates

While no one argues in favour of fully harmonised fee rates, opinions are divided on what criteria should be used to limit variances of fee rates (minimum levels, maximum levels, indexation).

Against harmonised fee rates

AVEC argues that a system of harmonized fees would be too rigid and suggests that fees should reflect the different cost structures between MS, with a maximum fee payable by any individual slaughterhouse. Verband Schweizer Metzgermeister (member of **ICB**) remarks that a harmonized fee rates system will probably lead to an increase of the fees and therefore oppose this proposition.

In favour of harmonised fees

Koninklijke Nederlandse Slagersorganisatie (member of **IBC**) claims that it would be a good idea to harmonized fee rates if this leads to a reduction of the costs for small slaughterhouses. Another member of IBC (and **FEFANA**) state that harmonized fee rates would put an end to competitive distortion and ensure a level-playing-field. According to them harmonisation does not necessarily mean that a single identical fee is applied in all MS, but rather that the system is consistent and does not create unfair competition.

In favour of minimum/maximum fees

UECBV argues that to avoid the disregard of the veterinary fees system by any MS, it is necessary to fix a minimum amount for the fees. They are also in favour of a maximum fee. **AVEC** warns that although a minimum fee per animal might be considered it should not discourage an efficient and effective inspection.

Verband Schweizer Metzgermeister (member of **IBC**) suggest to introduce an explicit rule stating that the authorities can go below the minimum fees (eg. by one third), 'to counterbalance unfair competition for decentralized small businesses'.

4. Harmonised/Non-harmonised fee calculation

Most stakeholders would agree that harmonised common criteria for the calculation of fees are necessary.

In favour of a harmonized framework for fee calculation

Most respondents are in favour of harmonised calculation criteria. **CIAA** would favour further harmonisation regarding the calculation of fees since it believes that the current rules cause distortion in competition between Member States and sometimes even between companies in different regions of a Member State. **ESA** believes that the inspection costs charged to importers should be calculated following a harmonized method and list of criteria, which should be fully transparent and available for consideration by industry prior to shipment. **AVEC** argues that the actual costs components to be included in the calculation of the fee should be harmonised and that the calculation should be kept simple and be based upon the time spent by the inspector and using the average salary per hour of all inspectors involved. **CLITRAVI** supports the harmonization since in their view it would ensure the right mix of flexibility and fair competition. **FRUCOM** suggests that inspection costs charged to importers should be calculated following a harmonised method and list of criteria, based only on the direct costs. **UGAL** is also in favour of a harmonized framework.

In the opinion of **CELCAA** criteria for calculating the fees have to be transparent and should be harmonized. **FEFAC** understands that, for sectors already subject to fees, further harmonization in the method for the calculation of fees might be needed. **Breiz Europe** supports the idea of a harmonized framework for fee rates. They argue that the current situation is extremely complicated and constraining for the FBOs. Furthermore they claim that the national difference concerning the fee rates impedes the smooth functioning of the single market.

Criticisms of existent system / suggestions for improvements

Others expressed criticism with regard to the current system. **CLITRAVI**'s opinion is that fixing the fee per head of animal slaughtered is not the right approach when considering that the real cost comes from the staff inspectors in slaughterhouses. According to them, this method of calculation is seriously penalizing the largest and more efficient slaughterhouses which are bearing exorbitant costs. **UECBV** remarks that the existing payment per tonnage (in slaughterhouses and cutting plants) is not related to the actual costs incurred by CAs.

VION suggests to clarify in Art. 27(4) that the costs borne encompass the actual costs but not the theoretical costs. The term "single fee" in Art. 27 (7) should be clarified as well. Finally in Annex IV the definition of the costs for staff involved in the official controls has to be

clarified, in particular that only the direct costs should be calculated. For example it should be clearer that the costs of the training of assistants should not be included.

AVEC believes that an average of full EU rate should be calculated and that only 50% of this rate will be the reference for charging the inspections fees. They suggest that this 50% rate may be adjusted per MS by an index which is based on the difference between the costs of living or average salary per hour in that MSs compared to the same indicators in the EU. They stress that in this fee no differentiation should be made between the time spent by a veterinarian or an auxiliary.

5. Bonus-malus system

Stakeholders generally support the introduction of bonus-malus mechanisms.

In favour of an integrated bonus-malus system

CIAA argues that fee reductions/ penalties should be linked to the uptake of self-control systems by industry through an integrated bonus-malus system. **CLITRAVI** underlines that a bonus-malus system should be risk-based and foresee clear implementing measures in order to guarantee that establishments with reliable and strong self-controls and precautionary systems would have their premises visited by a gradually reduced number of inspectors and thus paying a low inspection cost. **UECBV** thinks that the basic principle of a future veterinary fee system should be a bonus-malus system open to all operators i.e. each plant has to be regarded individually and has to be charged with fees proportionally to its individual cost. **UGAL** is also in favour of this measure.

FEFANA suggests increasing the scope of the bonus-malus system, already present in the current regulation, particularly taking into account the use of certification bodies and Code of Good Practice established by a number of regulations affecting the products. **CELCAA** supports the idea of criteria of a bonus-malus system. However they underline that the criteria for the establishment of such a system have to be well reflected and clearly defined in the Regulation. **FEFAC** emphasizes that bonus-malus systems should be established at national level in order to encourage companies in further investing in effective certified feed safety systems.

Against a harmonised bonus-malus system

Two stakeholders do not hold this measure for necessary. **Danish Agriculture & Food Council**'s view is that it should not be a matter for the EU to set up a penalty system towards individual citizens in MS. It may nevertheless be considered to launch community guidelines supporting a common approach. **AVEC** claims that if fees are directly related to the time spent on inspections (as they suggest) the reward or penalty is already incorporated for operators who contribute to a higher efficiency of the inspection services, will be charged less. A bonus-malus system is therefore not needed.

FEFANA claims that the costs of controls should be based on a specific control strategy and plan, and thus on a risk assessment (example of increased control at the border for certain products). Furthermore they emphasize that there should be a strong connection between the established control plans and the determination of the fee. This would be a good incentive for operators to source from safer manufacturing site and processes, in order to avoid that their products are subject to increased control.

6. Costs to be covered by the fees

Stakeholders criticise the wording of the list of cost elements in Annex VI, as it allows CA to "overprice" controls. Some stakeholders have views on which costs should be covered by the MS and which ones by FBOs, most take issue with administrative/overhead costs.

Critics of the current system / suggestions to improve

UEAPME stresses that there is under the current system no common interpretation of what might be considered as the costs of inspections and what might be seen as extras. **FRUCOM** underlines the fact that the lack of infrastructure should not create extra-costs for importers as it is currently done. For example in ports where there is a shortage of space to store containers, the related costs are charged to importers as part of the inspection fees although it is not in line with Art. 16(3) of Regulation 882/2004. **UGAL** argues that a list of the activities to be covered by fess should be established in order to create a harmonized framework.

Costs to be covered by the MSs

FRUCOM claims that the extra costs as well as the random/routine controls have to be covered by the budget of the MS. They assert as well that indirect costs should be bornby CAs. **UEAPME** argues that visits to enforce general food hygiene regulations, to approve premises to be used for the processing of products of animal origin should not carry any charge on the FBOs. **UECBV** states that overhead costs (indirect costs) have to be borne by CAs. **VION** specifies with regards to Annex VI that the salaries of the staff involved should not include the working breaks and the times for changing clothes.

Costs to be covered by the FBOs

FRUCOM suggests that the costs of reinforced controls at the specific levels set in the EU legislation be covered by importers. **Danish Agriculture & Food Council** stresses that a fees system must cover the actual costs but not the additional ones. It is important to them that fees collected for the purpose of official controls shall not be higher than the costs born by the responsible competent authorities. **EDA** claims that the fees that FBOs pay should cover the real costs only, as it would consequently encourage CAs to operate in an efficient manner and to demonstrate that their overheads are reasonable.

7. Transparency to the Commission and the FBOs

Stakeholders are largely in favour of increased transparency of the methods and assumptions used by CA when costing the controls and establishing fees.

Criticisms of the current system

Danish Agriculture & Food Council complains about the fact that although according to Regulation 882/2004 MSs must provide information to the Commission on the application of the Regulation, e.g. the method of calculation of fees, this is not done.

In favour of a more transparent system

Some stakeholders made suggestions on how to improve the transparency. **FRUCOM** argues that MSs should be required to report to the Commission and explain in detail the method applied for calculating and charging inspection fees on operators. **UEBCV** claims that the detailed calculation of the fees, showing how each parameter is taken into account for the calculation of the fee of each FBO, must be available for the FBO concerned. **VION** shares the view that MSs shall make the detailed method of calculation regularly public to the FBOs.

They specify that the report shall include the actual times worked by the veterinarians and the assistants, a description of the kind of work, and the details of the additional costs. ESA claims that Member States should be required to post the costs they charge.

8. The Principle of Thriftiness

Many stakeholders worry that revenues collected through fees would not be used efficiently by CAs.

Suggestion of new dispositions to be introduced in Regulation 882/2204

Two stakeholders underlined the importance of the principle of thriftiness and suggested referring to it in the new Regulation. **UEBV** underlined that a clear stipulation should be established in Regulation 882/2004 which specifies that the administration must strictly follow the economic principles of thriftiness while fulfilling inspection tasks pursuant to Regulation 854/2004. **VION** suggests that a new paragraph should be added to Art. 27(13) in order to oblige the authorities to follow the principle of thriftiness, especially concerning the costs of the staff involved to employ not more persons than needed and not more expensive staff than needed as defined in the regulation 854/2004.

UECBV underlines that since the main cost of the ante and post mortem inspection consists of salaries it has to be ruled how many persons-hours are needed for the corresponding tasks. They add that the approach must be risk-based proportionately to the individual plant-risk for food safety.

9. Ringfencing

FRUCOM states that inspection fees collected by the Competent Authorities from operators should be allocated to a specific budget and not to the general budget.

10. Time-based calculation of fees

Views are divided and vary depending on the area considered. Consequences of time based fees are difficult to anticipate.

Views on the merits and consequences of time-based fees

AVEC argues that the fees should be calculated on a time basis to encourage and reward the establishments that adopt best practice and reduce the hygiene risks and therefore the official time that needs to be spent in the establishment. **UECBV** remarks that combined with minimum inspection times and maximum inspection figures it leads to disproportionate incomes of the veterinarian personal to the prejudice of the industry. They believe the risk of such a system, is that more time is spent in the establishments than needed.

In favour of time-based calculation of fees

AVEC thinks the EU should establish a rate per hour that might be charged and in this way harmonize the system. **UECBV** is in favour of a time-based fee in cutting plants, where the presence of CA officials is not permanent and a fee of 2€ per tonne is most commonly applied amongst the Member States, independently of the presence of the official authorities. It is important to link the fee with the effective work of the official authorities.

Other position

CELCAA underlines that time based fee may be difficult to apply for certain kinds of businesses. They believe that their feasibility and impact on businesses has to be carefully evaluated sector-by-sector. They clarify that if this becomes the favored approach it would be essential to ensure that in the counterpart competent authorities commit to perform as efficient and timely controls as possible.

11. Small establishments

Views are divided. No respondents supports the automatic exemption of small businesses from the payment of fees. Larger scale operators are of the view that smaller ones already benefit from the current system, by paying less than actual costs would require, at the expenses of larger competitors.

In favour of a system that favours small establishments

Two stakeholders argued that the new Regulation should include a system protecting small establishments from paying to high fees. **AVEC** claims that there is a need for having at least a maximum fee per animal or tonnage to avoid small establishments will have no chance at all to survive due to disproportionate share of inspections fees in the total costs. **CLITRAVI** states that as a consequence of the different fees according to the size of slaughterhouses, big establishments usually pay lower fees per animal. If an equal amount were to be imposed regardless of the throughput, this would imply that big slaughterhouses would subsidize the official controls for small establishments.

Koninklijke Nederlandse Slagersorganisatie (member of the **IBC**) argues that special rules regarding fees should apply to small slaughterhouses.

In favour of a system that does not taken into account the size of the establishment

Two stakeholders underlined that the current system already favoured small establishments. **FRUCOM** suggested that large importers should be controlled in the same proportion as smaller companies so as to better spread the potentiality of finding a problem and to better share the total costs of inspection fees. **VION** argued that MS tend to calculate fees on the total costs of the authorities and not with the total costs at the individual plant. As a result, while small FBOs do not have to pay for all the costs they caused, bigger FBOs have to. In addition they claim that Art. 27 (5) (b) might be confusing and should be clarified.

VION suggested clarifying Art 27 (5) (b), in particular, that the subsidizing of businesses with a low throughput has to be done by the national authorities and not with the fees of the businesses with a high throughput.

Annex XIII: FEES – Summary of MS' opinions

Introduction

MS were consulted in the context of a first study contracted out by the Commission to an external contractor[133] on the state of the application of the rules of Regulation 882/2004 governing the financing of official controls (2009)[134]; and during a second study carried out in the same field by another external contractor[135] to support the assessment of the options identified (2011)[136][137].

In addition to the two contractor studies referred to above, however, the key issues were discussed within the Working Group on the general application of Regulation 882/2004[138] set up within the Standing Committee on the Food Chain and Animal Health (SCFCAH)[139]. These discussions are summarised below (Sections 1 and 2). Moreover the main problems identified and provisional options were also presented and discussed at meetings of the Heads of Food Safety Agencies on 29 June-1 July 2011 and on 8 December 2011. Discussions are summarised here at Sections 3 and 4.

It should be stressed that views expressed at these *fora* do not necessarily represent the agreed positions of the MSs but are in fact an opportunity to discuss the issues at hand with national experts from the different MS.

Nonetheless, the points raised in discussion at these meetings were given careful consideration when developing the Impact Assessment.

NB: The numbering of options which the MS were consulted on does not correspond to the ones used in this Impact Assessment. Option 1 (Full subsidiarity) is in Option 1 of the IA; Option 2 (Improvement of the financing of official controls through fees) is in Options 2 and 3. Option 3 (Extend the scope of mandatory fees) is in Option 4 of the IA; Option 4 (Fully harmonise inspection fees for official controls) was discarded and is not included in the analysis carried out in the IA.

[133] Food Chain Evaluation Consortium (FCEC), consisting of Civic Consulting, Agra CEAS Consulting (project leader), Van Dijk Management Consultants and Arcadia International.
[134] http://ec.europa.eu/food/food/controls/inspection_fees/docs/external_study_en.pdf; Annex II provides for the executive summary of this study.
[135] GHK
[136] Annex III provides for the study carried out by GHK to support the impact assessment on reviewing the rules on the financing of official controls.
[137] This Annex only refers to the inspection fees collected for the purpose of control activities currently covered by Regulation 882/2004 (feed and food law, animal health and animal welfare rules).
[138] At it's meetings of 10 November and 5 December 2011.
[139] http://ec.europa.eu/food/committees/regulatory/index_en.htm

1. SUMMARY OF THE COMMENTS MADE ON INSPECTION FEES DURING THE MS WORKING GROUP MEETING, BRUSSELS, 10 NOVEMBER 2011.

The Commission presented the Contractor Study (Annex XI of this Impact Assessment).

Option 1 - Full subsidiarity (deregulation)

DE, IE, FR, LV against full subsidiarity but all stressed the need for room for MS flexibility.

Option 2 – Improvement of the financing of official controls through fees

2. i) - Eliminate minimum / standard fees

UK, FI supported option noting the minimum fees hinder recovery of actual costs if lower than min. fee.

SE, NL, IE, DE, LV, against this option. Preferred maintaining minimum fees whilst making it more effective. For example:

- indexing the minimum fees to the costs of living

- calculating on a time-basis

- calculating them as a percentage of the costs charged for carrying out official controls,

2. ii) - clarify the list of activities for which fees are mandatory

SE and **FI** supported. **FI** suggested that two approaches. (i) fees charged "product by product", (ii) horizontal (activity-based) approach (e.g. residues control for all sectors except the meat sector). In this case, the amount of fees should be defined according to the kind of control activity.

2.iii) - Clarify list of eligible costs

- **NL, FR, PT**, supported but wished for broad interpretation.,

2. (iv) - Ring fence fees revenue

No comments in support of or against this issue.

2. (v) - Micro-enterprises

NL, CY, PT, LXsupported. However, they pointed out the necessity to agree on a definition of micro-enterprises in order to avoid distortions of competition within the single market.

FI argued that this measure could lead to enterprises splitting their activities into micro enterprises in order to benefit from the exemption. As a consequence they preferred a risk-based approach to a size-based one.

2. (vi) - Introduce transparency and reporting requirements

SE, LT, FR, DE against this option, (supported transparency *per se*, but believed it would increase the administrative burden.

2.(vii) – Incorporate bonus-malus principles

NL, BE, UK, FI, SE supported in principle and **NL** referred back to discussions on standard fees, agreeing that they hindered bonus malus. MS also noted that in most cases it would be

sufficient to apply a risk-based system, taking into account the past record of compliance (or non-compliance) of the operator.

FR cautioned against increased administrative burdens.

NL noted that this system was used by there CAs and expanded further, saying that fees were calculated not company by company bur rather by sector. If the sector performed well, fees went down, whereas if the sector performed badly, fees went up. In this way, "good" operators from the sector would automatically pressure "bad" ones. They felt, therefore, that in this way bonus-malus principles were used. They noted too that Article 28 still applied to individual underperforming operators.

Option 3 – Extend the scope of mandatory fees

Those against (**SE, IE, DK**), argued that:

- it is too extreme an option, since it would include the primary producers and the retail area (risk of distortion of competition in these sectors is the main concern of the stakeholders),

- based on previous experience, one **DK** noted that it would create administrative problems and high administrative costs,

- will make food more expensive for the consumers (to be avoided in the context of the financial crisis)

Those in favour (**FI, FR, LV**) pointed out that:

- in some cases they already collected fees across the whole food production chain,

- supermarkets and canteens, with high food safety risks, they should also be subject to mandatory fees,

- one **FR** proposed expanding mandatory fees further than the proposed option, to finance control activities on the primary producers in the animal health sector.

Option 4 – Fully harmonise inspection fees for official controls

NL against any extreme option (1 or 4). Favour intermediate solution (option 2 or 3).

LV supported harmonised fees for border controls.

2. SUMMARY OF THE COMMENTS MADE ON INSPECTION FEES DURING THE MS WORKING GROUP MEETING, BRUSSELS, 5 DECEMBER 2011.

Option	Supported by:	Opposed by:
1	LV, but with harmonisation in the areas of • A defined maximum fee • Clarification of eligible costs • Expenses arising from additional official controls • Recognition of operator own-checks with regard to bonus malus	IT
2	DE, FR, SE, IE	
3	UK, NL, IT, PT, DK	LV, FR, IE
4A		
4B	DE, LV	

Additional Comments

Expanding scope

Direct **support** from IT, UK, NL. **Opposition** from **FR**.

Concerns regarding high **admin burden** from **FR, DK, IE**. However, **UK** suggested that it can be **cost effective.**

Eligible Costs

NL, FI, DK, UK, FR, SE wish for **wide** interpretation.

NL prefers **subsidiarity** with regard to **indirect** costs.

Ring Fencing

No direct support.

IE, DE, FI and **SE opposed**, but

IT, DE, NL, FR, UK in support of '**ring fencing principles**'.

Bonus Malus

Supported by **UK, IT, FR, SE, NL, LV, IE, DK**.

LV, FR - strong role for 3rd party accreditation.

SE - should apply at the **company** level on a case by case basis.

Concern regarding wider review

LV – PH / AH needs to be addressed specifically.

PL – Bringing in 12 pieces of legislation will cause problems.

Harmonisation of Import Fees

NL - current **minimum fees** sufficient.

Minimum Fees

No support for **EU-wide** minimum fees, but **flexible mechanisms** suggested by **NL** (all direct costs to be collected) and **IE** (a minimum % of total cost).

3. SUMMARY OF THE COMMENTS MADE ON INSPECTION FEES DURING THE HEADS OF AGENCIES MEETING (ROTTERDAM, JUNE 30TH – JULY 1ST 2011)

The Heads of Agencies considered it necessary to have a flexible framework in the 882 to enable the introduction of fees in the entire food supply chain. Flexibility is needed because of the differences in traditions regarding fees in the different member states.

The HoA suggested to explicitly mention the option of bonus malus in the 882. Experience in member states which have such a system shows that it contributes to a safer food chain. A clarification in the 882 would enable the introduction of this in the member states.

When considering the introduction of bonus malus systems it is advised to have a good discussion with the sectors involved, beforehand. The objective has to be to make the food chain safer and to stimulate the FBO's to act in conformity with the law. In this respect is it of importance that the system is transparent in terms of the fee calculation and the way the system is applied. The agencies should be able to report to the sector that it contributes to a safer food system with less costs for the "good" FBO's and higher costs for the "bad" operators.

It helps also when the fees collected are used for improving food safety, not just as a contribution (tax) to the state budget or a municipality budget.

The HoA suggested the bonus part could be a reduced frequency of inspections or a lower fee. The malus part could be just to let them pay for the additional and a full fee until there is compliance. At a certain stage other instruments as penalties and other enforcement measures are necessary.

4. SUMMARY OF THE COMMENTS MADE DURING THE HEADS OF AGENCIES MEETING (LODTZ, 8 DECEMBER 2011)

COM gave a presentation of the state of play of the Review of Regulation (EC) No 882/2004, in particular as regards the fees chapter. Tour de table:

HoA	Comment	Preferred option
CZ	Asked how standard fees would be replaced under the new system	Option 2
HU	Support for extending scope of mandatory fees -FBO should share costs, risk map has changed, resources for contingencies / emergency should be made available	Option 3
IE	Fees = taxes, FBO look at overall cost (including fees/taxes) and see no difference	Option 1(?)
UK	OK to expanding the scope of mandatory fees, insist on bonus malus, on flexibility and subsidiarity in implementation, no to exemption for small businesses, ok to deletion of minimum fees, support for cost recovery principles but MS should be free to determine how to recover money.	Option 3
FI	Asks whether there is a clear link between suggested changes and food safety	
PL	Apart from border checks, other fees should not be harmonised; yes to reduced fees for microbusiness, yes to bonus malus, doubts that any option will reach consensus	(?) + Option 4 B
NL	Fees review should consider that FBO are responsible for safety and therefore pay for checks – suggestion: link fees with custom duties?	Option 3
IT	Agrees with L. Miko (fees necessary to maintain food safety) Important to ring fence resources	Option 3 + Cost of living (?)
DK	Agrees with NL and UK	Option 3
BE	Minimum levels of controls should not be dependent on fees, ok to transparency	Option 2 or 3
SW	Ok to bonus malus	Option 2 or 3

Annex XIV - Evidence concerning problems of interpretation/implementation of the rules governing the financing of official controls[140]

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Regulation (EC) No 882/2204			
Annex VI (list of eligible costs)	**1) Author**: International Butchers' Confederation **Question**: Are the UK's competent authorities allowed to include a pension deficit in their calculation of inspection fees? **2) Author**: Farmers' Union of Wales **Question**: Is the UK's Food Standard Agency's inclusion of their pension deficit in the calculation of transferable costs legal under EC 882/2004?		

[140] This Annex only refers to the inspection fees collected for the purpose of control activities currently covered by Regulation 882/2004 (feed and food law, animal health and animal welfare rules).

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Article 27			**2008/4966, 4967, 4968 and 4969** **Complainant**: law firm Keul & Farber **Complaint**: The Länder Northrhine-Westphalia (Case 2008/4966), Schleswig-Holstein – Kreis Steinfurt (Case 2008/4967) and Baden-Württemberg – Landratsamt Waldshut-Tiengen(2008/4968) are said to have violated Article 27 (2) to Regulation (EC) No 882/2004, by not having charged some of the fees for activities covered by Article 27 (2) in conjunction with Annex IV Part A and Annex V Part A , e.g. milk, imported fishery products, poultry, rabbit meat, import and transit of live animals. In Case 2008/4967, Article 27 (10) is said to be violated because separate control fees are charged for the meat-cutting division of the complainant. In Case 2008/4968, Article 27 (12) is said to be violated because the authorities claim that they were under no obligation to make a detailed calculation method available to the complainant. In Case 2008/4969 (Rhineland-Palatinate – Eifelkreis Bitburg-Prüm) there are travel supplements and percentage-wise increases of the basic rate, which are particularly disadvantageous for small establishments.

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Annex IV, Section A (list of activities for which a fee shall be collected)	**Author**: French Ministry of Agriculture and Fisheries **Question**: Are pet food establishments included among feed establishments for which point 2, Section A, Annex IV of Regulation (EC) No 882/2004 requires the collection of a fee for their approval?		
Article 27(3) in relation with 27(4)	**Author:** UK, Imports Border Controls **Question**: Could the Commission exlpain the apparent contradiction between Article 27.3 of Regulation (EC) No 882/2004 (where it is stated that inspection fees shall not be lower than the minimum set out in the Regulation) and Article 27.4 of the same Regulation (where it is stated that inspection fees should not be higher than the costs borne by the Competent Authorities)?		

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Article 27 (4)	**Author**: RA'e Dr Fuchs und Renger **Questions**: **a)** According to the legal interpretation by Germany's highest administrative court (the Federal Administrative Court), under the previous Directive 85/73/EEC as amended by Directive 96/43/EC, collection of fees other than the flat-rate fees fixed in Annex A, Chapter I, Nos 1 and 2a was possible, according to either No 4a or No 4b. However, the competent authority had to opt for one of the two alternatives. Can this interpretation also be applied to the wording of Article 27.4.b? If so, is a combination of both alternatives within an authority's area of competence possible? **b)** If the Competent Authority opts to collect a flat-rate fee, can it then calculate fees on the basis of the costs borne over a given period of time as a result of all the controls carried out pursuant to paragraphs 1or 2, taking into account only the types of costs referred to in Annex VI?		
	c) If the Competent Authority opts for minimum fees in accordance with Annexes IV and V of Regulation (EC) No 882/2004, is the fixing of fees by the Competent Authority in compliance with the provisions of Article 27 of Regulation (EC) No 882/2004? **d)** Is the Competent Authority obliged to fix at least the minimum fees referred to there for all the activities listed in Annexes IV and V (official		

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Article 27(4)(a)		**C-523/09** 7 July 2011 Maag Piimattööstus AS v Veterinaar- ja Toiduamet (reference for preliminary ruling) **Question**: Must Article 27(4)(a) of Regulation [No 882/2004] be interpreted as not prohibiting the demanding of a fee from an operator at the minimum rate laid down in Part B of Annex IV to that regulation for the activities listed in Part A of Annex IV to the regulation, even if the costs borne by the responsible competent authorities in connection with the items listed in Annex VI to that regulation are lower than the abovementioned minimum rates?	
Article 27(4)(b)	**Author**: Counsellor for Agricultural Affairs, Permanent Representation of Estonia to the EU **Question**: When a Member State implements Regulation (EC) No 882/2004 in such a way that the fees collected for the official controls are fixed at the minimum rates provided in Annex IV Section B [Article 27 part 4(b)], is that Member State required to take into consideration the actual costs borne by the competent authorities in order to make sure that the fees are not higher than the costs?"	-	

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Article 27(7)	**Author**: Association of Independant Meat Suppliers **Question**: What is your view on the way Article 27.7 of Regulation (EC) No 882/2004 has been implemented in the UK (who charges two fees for establishments carrying out both slaughter and cutting)?	-	
Article 27(12)	**1) Author**: Studio Giffoni sprl/bvba Customs Consultancy **Question**: Article 27 paragraph 12) says that "Member States shall make public the method of calculation of fees and communicate it to the Commission".Is it possible to receive the complete list of fees or charges related to official controls in the Communityapplied by each Member States? **2) Author**: International Butchers' Confederation **Question**: What charges are levied in the different	-	
	3) Author: Belgian federal Agency for the Safety of the Food Chain **Question:** How is the method of calculation of fees to be made public? is it sufficient for the person in question to be informed in a meeting, and for the information to be set out in the minutes?	-	

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Annex IV , Section A		**C-523/09** 7 July 2011 Maag Piimattööstus AS v Veterinaar- ja Toiduamet (reference for preliminary ruling) **Question**: Is a Member State entitled, on the conditions mentioned in the previous question [*see Article 27(4)(a)*], to establish fees for the activities listed in Part A of Annex IV to [Regulation No 882/2004] that are lower than the minimum amounts laid down in Part B of Annex IV to that regulation, if the costs borne by the responsible competent authorities in connection with the items listed in Annex VI to that regulation are lower than the above mentioned minimum rates, without the conditions laid down in Article 27(6) of that regulation being satisfied?'	

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Annex IV, Section B	**Author**: Belgian Federal Agency for the Safety of the Food Chain **Question**: Why are no minimum tariffs laid down for all official controls, e.g.: controls on imported feed and food of non-animal origin; registration/recognition of feed and food companies, export of feed and food?	-	**2007/4703** **Complainant**: Keul & Farber **Complaint**: The veterinary fees charged by the District of Bergstraße, Hessen are higher than the minimum fees set out in Annex IV, Part B, to Regulation (EC) No 882/2004 on official controls. **2007/4755** **Complainant**: Keul & Farber **Complain**: The veterinary fees charged by the District of Steinburg, Schleswig-Holstein, are higher than the minimum fees set out in Annex IV, Part B, to Regulation (EC) No 882/2004 without there being a proper implementing act.
Annex IV, Section B, Chapter I	**Author**: Belgian Federal Agency for the Safety of the Food Chain **Question**: Do the fees for inspections during slaughter include the fees for sampling, residue analysis and BSE analysis (in cattle)?	-	
Annex IV, Section B, Chapter II	**Author**: Law firm Tuengerthal & Liebenau **Question**: What is the opinion of the Commission on their own interpretation of the legislation: the collection of fees for controls in cutting plants pursuant to Annex IV, Chapter II leads to fees that are not reflecting the actual costs that the authority has to bear?	-	

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Annex IV , Section B, Chapter IV	**Author**: Ministry of Foreign Affairs of Latvia **Question**: Regulation 882, Annex IV, Section B, Chapter IV milk production – what exactly is meant – raw milk production in the holdings or milk processing in dairies?	-	
Annex IV, Section B, Chapter V	**1) Author**: Belgian Federal Agency for Safety of the Food Chain **Question**: What is the difference between 'first placing on the market of fishery and aquaculture products' and 'first sale in fish market' ? **2) Author**: Veterinary Directorate General **Questions**: **a)** What is the difference between "first placing on the market of fishery" and "first sale in fish market"? **b)** The correct implementation of Regulation 882/2204 implies the rupture with the repealed Directive procedures and determines the charge of first placing on the market to the primary producer? **c)** If so to whom should be charged the first sale in fish market: to the auction all operator or to the first purchaser?	-	
Annex VI, point 2	**Author:** Belgian Federal Agency for Safety of the Food Chain **Questions**: **a)** What exactly does "associated costs" mean? **b)** To what extend can overheads be charged? For example can electricity and heating costs be partly through-charged by the Personnel Department?	-	

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Directive 85/73/CEE as amended by Directive 96/43/CEE		-	**C-270/07** 19 March 2009 Commission of the European Communities v Federal Republic of Germany (failure to fulfil obligation) **Request**: The applicant requested the Court to declare that, by failing to adapt to the Community provisions Paragraph 4 of the law implementing the legislation on the health inspection of meat and poultrymeat in the Land Schleswig-Holstein, the Federal Republic of Germany has failed or continues to fail to fulfil its obligations under Articles 1 and 5(3) and (4) of Council Directive 85/73/EEC and under Article 27(2), (4) and (10) of Regulation (EC) No 882/2004

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
		C284/00 and C-288/00 30 May 2002 C-284/00 Stratmann GmbH und CO.KG and Landrätin des Kreises Wesel C-288/00 Fleischversorgung Neuss GmbH und Co. KG and Landrat des Kreioses Neuss (references for a preliminary ruling) **Questions**: **a)** Does the standard fee applicable under Council Directive 85/73/EEC for the inspection of fresh meat intended for the domestic market, in accordance with Council Directive 64/433/EEC, also cover the costs of carrying out examinations of fresh pigmeat for trichinae? **b)** Does the standard fee applicable under Council Directive 85/73/EEC, in conjunction with Council Decision 88/408/EEC, for the inspection of fresh meat intended for the domestic market, also cover the costs of carrying out a bacteriological examination required in an individual case?	**2006/4749** **Complainant**: Keul & Farber **Complaint**: The Land Schleswig-Holstein did not transpose Directive 85/73, Decision 88/408 and Directive 93/118. The relevant law of 12.1.1998, which provides for veterinary fees which cover the costs, including for bacteriological and trichinae examinations had retroactive effect. **2006/4750 and 4773** **Complainant**: Keul & Farber **Complaint**: The Land Niedersachsen did not transpose Decision 88/408 and Directive 93/118. Directive 85/73 as amended by Directive 96/43 has not been transposed completely and accurately. An amendment of 23.01.2003 still maintains specific fees for bacteriological and trichinae examinations by way of an increase of the general examination fee.

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
			2006/4751 **Complainant**: Keul & Farber **Complaint**:The Land Brandenburg did not transpose Directive 85/73 as amended by Directive 93/118 and transposed Directive 85/73 as amended by Directive 96/43 incompletely and incorrectly. It charges fees in excess of the Community flat rate and adds specific fees for bacteriological and trichinae examinations, which is in contradiction with the Directive as interpreted by the Court in Cases C-284/00 and C-288/00 - Stratmann. **2006/4761** **Complainant**: Keul & Farber **Complaint**: The Land Nordrhein-Westfalen transposed Directive 85/73 as amended by Directive 96/43 belatedly, incompletely and with retroactive effect and increased the Community flat rate. In a regulation of 18.9.2000 it provides for specific fees in addition to the general examination fee in contradiction with the Directive as interpreted by the Court in Cases C-284/00 and C-288/00.

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
			2006/4762 **Complainant**: Keul & Farber **Complaint**: A local authority in Sachsen-Anhalt has requested fees which the complainant considers to be in contradiction with the ECJ judgements in C-284/00 and C-288/00 - Stratmann since the inclusion of specific fees is considered to be contrary to the principles of a uniform fee and transparency. **2006/4763** **Complainant**: Keul & Farber **Complaint**: The Land Niedersachsen did not transpose Decision 88/408 and Directive 93/118. Directive 85/73 as amended by Directive 96/43 has not been transposed completely and acurately. An amendment of 23.01.2003 still maintains specific fees for bacteriological and trichinae examinations by way of an increase of the general examination fee. **2006/4764 and 4766** **Complainant**: Keul & Farber **Complaint**: In Hessen a regulation adds fees for trichinae examinations to the general veterinary examination fee, which is said to be incompatible with Directive 85/73 and the Stratmann case law (Cases C-284/00 and C-288/00).

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
			2006/4767 **Complainant**: Keul & farber **Complain**: A local authority in Sachsen-Anhalt has requested fees which the complainant considers to be in contradiction with the ECJ judgements in C-284/00 and C-288/00 - Stratmann since the inclusion of specific fees is considered to be contrary to the principles of a uniform fee and transparency. In addition the complainant criticises the retroactive application of derogations in Directive 85/73/EEC in Sachsen-Anhalt. **2006/4778** **Complainant**: Keul & Farber **Complaint**: The competent local authority in Rheinland-Pfalz charges veterinary fees which include fees for bacteriological and trichinae examinations. These fees are higher than the flat rate provided for in Directive 85/73 and the complainant considers them to be incompatible the Directive as interpreted by the Court in Cases C-284/00 and C-288/00 - Stratmann. **2006/4843 and 4915** **Complainant**: Keul & Farber **Complaint**: In Bavaria the Directive was transposed and applied at local level (Landkreise). Additional fees were charged, e.g. for examinations for trichinae.

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Article 2(3)		**C-374/97** 9 September 1999 Anton Feyer and Landkreis Rottal-Inn, Intervener: Landesanwaltschaft Bayern (reference for prelimanry ruling) **Question**: Is the authorisation given to Member States under Article 2(3) of Council Directive 85/73/EEC as amended by Directive 93/118/EC to collect an amount exceeding the Community fees dependent on the total fee collected in the Member State as a whole and the actual figure for inspection costs incurred in the Member State as a whole or is it sufficient, when the Member State has delegated authorisation to collect the fees to the local authorities, that the total fee collected by the local authority is not greater than the actual figure for inspection costs incurred by that authority?	

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Annex relating to Article 2(1)		**C-374/97** 9 September 1999 Anton Feyer and Landkreis Rottal-Inn, Intervener: Landesanwaltschaft Bayern (reference for prelimanry ruling) **Questions:** **a)** Can an individual oppose the collection of fees higher than the standard amounts listed in point 1 of the annex relating to Article 2(1) of Council Directive 85/73/EEC as amended by Council Directive 93/118/EC where the Member State has not transposed Directive 93/118/EC into national law within the prescribed period? **b)** Can a Member State collect fees higher than the standard amounts in reliance on point 4(b) of the annex relating to Article 2(1) of Council Directive 85/73/EEC as amended by Directive 93/118/EC provided that the fees levied do not exceed the actual costs, no further conditions being imposed?	

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Article 5(3) and Chapter I of Annex A		**C-309/07** 19 March 2009 Baumann GmbH v Land Hessen (reference for a preliminary ruling) **Questions**: **a)** Is a national legislature, when availing itself of the power laid down in Article 5(3) of [Directive 85/73] and in point 4(a) of Chapter I of Annex A thereto to increase the standard amounts of fees for individual establishment and in point 4(b) to collect a fee which covers actual costs, strictly bound by the fee structure laid down in points 1 and 2(a) of Chapter I of Annex A or may it make a distinction, when setting the amounts of scales of fees, between inspections of slaughtering units in large establishments and other inspections and, in addition, also within those two groups adjust the rate of fees on a diminishing scale according to the number of animals slaughtered within the animal types, provided only that that reflects the actual costs?	
		b) On the basis of the abovementioned provisions, may a national legislature collect, in respect of slaughtering carried out outside normal slaughtering hours at the request of the owner, an additional fee on a percentage basis on top of the fee collected for slaughtering inspections in	

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
		normal slaughtering hours when that increase reflects the additional actual costs, or must those costs be contained in the standard (increased) fee for all persons subject to a fee?	
Article 5(4), second subparagraph		**C-430/07** 25 June 2009 Exportslachterij J. Gosschlak & Zoon B v Minister van Landbouw, Natuur en Voedselkwaliteit (reference for a preliminary ruling) **Question**: Must the second subparagraph of Article 5(4) of Directive 85/73/EEC be interpreted as meaning that this Directive does not preclude the Member State from charging a fee on account of the costs of the BSE tests which were carried out? If so, what requirements must be met by a fee for the BSE tests which were carried out?'	
Annex A, Chaper 1,No 4(b)			**2006/4747 and 4830** **Complainant**: Keul & Farber **Complaint**: Incorrect transposition/application in Baden-Württemberg of Directive 85/73 as amended by Directive 93/118 and 96/43. Although the relevant provision provided for an increase of the EC flat rate based on the particularities of the establishment, additional fees for bacteriological and trichinae examination were charged. The Directive was re-transposed retroactively.

Provision concerned/ Sources	Requests for interpretation addressed to the COM by MS	ECJ Judgements	Infringement cases
Directive 96/23/EC	**Author**: Fuchs und Renger **Question**: According to which criteria must the competent authority take account of the costs of testing for residues (Directive 96/23/EC): - when fixing flat-rate fees? - when fixing minimum fees?	-	**2006/4746, 4774, 4781, 4809, 4963 and 5034** **Complainant:** Keul & Farber **Complaint:** The Land Nordrhein-Westfalen transposed Directive 85/73 as amended by Directive 96/43 belatedly, incompletely and with retroactive effect and increased the Community flat rate. In a regulation of 18.9.2000 it provides for specific fees in addition to the general examination fee in contradiction with the Directive as interpreted by the Court in Cases C-284/00 and C-288/00 - Stratmann.
Annex A, Chaper 1,No 2(a)			**2006/4703** **Complainant**: law firm Keul & Farber **Complaint**: Germany (and in particular the city of Koblenz) is violating Directive 85/73/EEC, as amended by Directive 96/43/EC, which provides, in Annex A Chapter 1 No 2(a), that the hygiene controls and inspections connected with meat cutting establishments must be covered a standard fee of € 3/tonne of meat. Derogation from the standard fee is only allowed under certain conditions. The City of Koblenz (Rhineland-Palatinate) has disregarded these conditions by adopting a blanket scale of fees on the basis of which an increased flat-rate fee of € 30.91 is being charged.

Annex XV: FEES - Examples of stated limited availability of resources as reported in FVO reports

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
ES	2008-7781 SA (residues and contaminants in live animals and animal products, including veterinary medicinal products)	"In the autonomous community visited there had been no controls on private veterinary practitioners. The competent authority explained that this was due to the **need to prioritise resources.** Controls on retailers were deemed to be of greater importance."	Lack of financial resources
HU	2008-7774 SA (residues and contaminants in live animals and animal products, including veterinary medicinal products)	"The discrepancy between planned arrangements and the factual number of controls is due to **budgetary reductions"**	Lack of financial resources
DK	2010-8440 SA (residues and contaminants and the use of veterinary medicinal products in food producing animals)	"At one of the RVFA offices delays in follow-up investigations were ascribed to a **lack of staff**, particularly during holiday periods, and due to subsequent priority setting."	Lack of staff
SE	2010-8438 SA (residues and contaminants and the use of veterinary medicinal products in food producing animals)	"According to the two County Administrative Boards visited, **limited staff resources** had led to strict prioritisation of official controls. [...] A lack of staff and a re-organisation of the District Veterinary Organisation by the Board of Agriculture had led to under-sampling for the NRCP (on-farm samples) in 2009. [...] **Participation in training** was sometimes **restricted due to lack of staff and resources**."	Lack of financial resources, staff and training

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
BU	2010-8436 SA (residues and contaminants and the use of veterinary medicinal products in food producing animals)	"At regional level, appropriate and properly maintained facilities and equipment were available to staff in charge of controls. However, this was not the case in the laboratory where (laboratory management) claims of **inadequate funding** have resulted in a situation whereby the competent authority is not complying with Articles 4 (2) c of Regulation (EC) No 882/2004 and can not meet its obligations under Article 15 of Council Directive 96/23/EC."	Lack of resources results in lack of appropriate facilities and equipment
RO	2010-8441 SA (residues and contaminants and the use of veterinary medicinal products in food producing animals)	"As a result of **substantial budgetary constraints**, there is currently **insufficient laboratory capacity** or capability to enable the analyses of the number of samples and substances included in the NRCP"; "So far in 2010, the IHVPH has received 15% of its annual budget and has announced that as a result, analyses of a range of substances can no longer be performed";"although the laboratories visited had sufficient analytical equipment, the Director of one laboratory stated that **substantial refurbishment was necessary** [...]"; "Officials met in the counties visited had been provided with relevant training during 2008 but little or none in 2009 owing to budgetary issues". "**Little relevant training has been provided** and the resulting lack of awareness of certain requirements, combined with the effects of on-going budgetary problems and limited ability to oblige farmers and FBOs to undergo sampling, prevents the effective implementation of the official control system for residues and the NRCP in particular."	Lack of financial resources resulting in insufficient laboratory capability; inappropriate equipment, no/little training.

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
RO	2010-8479 SA (controls on feed legislation)	"**Training** concerning feedingstuffs for 2009 and 2010 has been **cancelled due to financial reasons**"	Lack of financial resources resulting in a lack of training
BU	2010-8478 SA (controls on feed legislation)	"In the regions visited, the audit team noted that **neither NVS feed inspectors nor municipality inspectors met were supplied with the equipment necessary** to take samples of feed"; "Representatives of NVS at central and regional level acknowledged that **NVS feed inspectors** in the 28 regions and municipality veterinarians **had not received training** prior to their appointment [...] NVS representatives met informed the audit that, **at present, there is no training programme** related to feed issues neither for regional NVS inspectors nor for municipality veterinarians".	Lack of equipment and training
SK	2010-8807 SA (health rules on animal by-products (ABP))	"the officials from the RVFAs and the DVFAs visited as well as the inspectors responsible for official controls met in the processing plants visited, stated that **they had not received training** on HACCP based procedures nor on their assessment. According to the SVFASR representatives met, **training in this respect was planned for end of 2010 but due to financial limitations has been postponed to 2011.**"	Lack of financial resources results in a lack of training.
SK	2008-7776 SA (residues and contaminants in live animals and animal products, veterinary medicinal products)	"The SVFA stated that due to **budgetary limitations**, 'suspect' samples are taken and submitted to the laboratory as ordinary 'targeted' NRCP samples which means that the carcasses are not detained in the slaughterhouse as required by Article 24 of Council Directive 96/23/EC."	Lack of financial resources

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
GR	2008-7793 MR (animal health - bovine brucellosis and tuberculosis, ovine & caprine brucellosis)	"In the Prefectures visited the number of veterinarians employed was very low compared with the posts in the organisation chart (e.g. in one Prefecture 21 out of 76, in another one 3 out of 11). Due to the **lack of veterinary staff**, in one Prefecture visited one LVS (Local veterinary station) was not in operation and in another one, only 6 LVSs out of 9 were actually in operation. In another Prefecture visited, the activities of the local level were performed by the official of the Prefectural level. [...] No specific technical training has been organized at Central level for new or existing staff since 2003 and **no training has been planned** at central or Prefectural level for 2008 on issues related to the programmes."	Lack of staff and training
LT	2009-8131 SA (residues and contaminants and the use of veterinary medicinal products in food producing animals)	"In 2008, the ratio between samples taken for Group A analyses in bovines on farms and in the slaughterhouses was 40:60 and not 50:50 as planned and required under Council Directive 96/23/EC. The NRCP coordinator explained that this discrepancy was spotted after the second quarter of the sampling year. However, due to the number of samples already taken, it was impossible to rectify the situation without additional **financial resources** - which **were not available.**"	Lack of financial resources
MT	2009-8278 MR (Public Health - Food Hygiene)	"The CA stated that certain laboratory analyses were not carried out due to a **shortage of staff** in the laboratory."	Lack of staff
MT	2010-8590 SA (Food hygiene, food contact materials and food additives)	"**Staffing levels** in the PHL **are insufficient** [...]. **Inspectors have not been adequately trained** in FCM and FA [...]."	Lack of staff and appropriate training

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
MT	2010-8558 SA (import/transit control system and border inspection posts)	"BIP infrastructure is generally in accordance with requirements except in Luqa airport BIP where significant **shortcomings in maintenance and operational hygiene** were noted[...]. The attribution of **staff resources** especially official veterinarians for BIPs is **not satisfactory**. This leads to certain veterinary controls being carried out by improperly qualified staff, as a result veterinary checks are not carried out appropriately. [...] Training is provided for BIP matters, and a plan is in place for 2010. However, some of the shortcomings noted regarding veterinary checks and veterinary decision indicate that **the training provided is not satisfactory**."	No properly mantained facilities and equipment; lack of staff and appropriate training
NL	2009-8095 MR (controls on feed legislation)	"Training arrangements were mainly satisfactory except in the areas of import controls and inspections at primary production of feed, for which the **official met had not received the appropriate training** required by Art. 6 of Regulation (EC) No 882/2004. The resources dedicated by AID and VWA to the implementation of official controls on feed were insufficient to meet the objectives of their respective control programmes. **Resources were** also **inadequate** in order to provide a timely follow-up on corrective actions imposed and to undertake all necessary legal proceedings."	Lack of human and financial resources; lack of appropriate training

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
GR	2009-8077 SA (import/transit control system and border inspection posts)	"The CA indicated that due to a **long-term staff shortage** at the Animal Health Directorate (AHD) it has not been possible to set up a centrally approved sampling programme for BIPs. [...] The lack of staff at central level is central to problems in the provision of training, updating and development of necessary manuals and the implementation of a verification system. This has also contributed to the lack of a system to ensure ongoing training needs are identified and met.[...] For Customs **training is insufficient**, in those entry points where they are responsible for checks on accompanied pet animals, to ensure correct execution of controls. (as evidenced by a lack ofawareness of the requirements by officials encountered)."	Lack of staff and training
FI	2009-8316 GA	"Various **competent authorities stated that they had not access to a sufficient number of suitably qualified and experienced staff** as required by Article 4 of Regulation (EC) No 882/2004. Subsequently auditing and control tasks were not consistently completed [..] **No specific training on FA was provided** to the official inspectors in the last two years at any level.[..] Some theoretical training related to post mortem inspection has been provided to slaughterhouse staff also by official veterinarian in charge of slaughterhouse. However overall **training duration was less than 30 hours** for the course led by the official veterinarian. There was **no evidence of training provided to the newcomers**."	Lack of staff and training

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
MT	2010-8458 SA (poultry meat and the systems in place to control the Salmonella risk in poultry)	"There is **insufficient number of staff** to complete the assigned tasks in poultry meat producing establishments.[...] Scheduled frequency of inspections in poultry establishments is based on risk assessment however due to the lack of human resources the planned schedule set in 2009 is currently not being met."	Lack of staff
GR	2009-8333 MR (health rules on animal by-products (ABP))	"**Significant staff shortages** remain in the CA with responsibilities for the ABP chain which might affect the implementation of the official controls required by Art. 26 of Regulation (EC) No 1774/2002. As such, the relevant recommendation made following report 2007-7611 has not been addressed and the requirements of Art. 4(2) of Regulation (EC) No 882/2004 ave not been fulfilled."	Lack of staff and training
FR	2007-7185 MR (import controls - food of non-animal origin)	"In the DDCCRF of Marseille, the **human resources** available for the control of imported foodstuffs **were not sufficient**, which could compromise the frequency of sampling established in Commission Decision 2006/504/EC."	Lack of staff
IT	2009-8233 MR (public health - baby food)	"The LSV and the SIAN are using the same risk classification but the frequency of the visits is not the same. In one establishment visited (under the joint supervision of the LVS and the SIAN) which was classified as high risk, the LVS carry out monthly inspections whereas the SIAN officers visit once a year. In one other establishment visited, also classified as high risk, the LVS performs 8 inspections per year and the SIAN only 3. The CA stated that this is because of **limited human resources** in the SIAN."	Lack of staff

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
UK	2009-8299 SA (Plant Health - import controls; Bursaphelenchus xylophilus; and Anoplophora chinensis)	"Mainly because of **lack of human resources**, the frequency of documentary checks, physical identity checks and plant health checks falls far short of meeting EU requirements for import controls, and the mission team considers that these shortcomings result in a significant risk of introduction and spread of harmful organisms into the Community. Furthermore having no or reduced frequency checks outside the framework of the EC legislation could result in redirection of trade in favour of UK points of entry."	Lack of staff
DE	2010-8567 MR (import/transit control system applied in the border inspection post of Bremerhaven)	"According to the head of BIP the failure to enter all relevant data in TRACES was due to **lack of staff**"	Lack of staff

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
RO	2010-8528 SA (Fishery products)	"According to the information provided to the AT during the mission 910 jobs were lost this year for budgetary reasons. [...] At central level, it appeared during the mission that due the numerous responsibilities applied to a limited number of staff, some planned activities cannot be always ensured. [...] at central level where staff is accommodated in premises with limited working area per person and where many people have to share the same room. In another county once the official samples are taken and sealed by the OVs, it is the responsibility of the FBOs to deliver them to the laboratory due to limited availability of means of transport for the official sampletaker.[...] Since 2009, the training frequency has decreased (one training session every two months took place in 2008 while in 2009 only one training session took place). [...] **The efficiency of the implementation of the official control system is diminished by insufficient staffing at central level, insufficient training of inspecting staff at county level and insufficient availability of means of transport** identified in some counties.	Lack of financial resources resulting in staff shortages, lack of appropriate training and equipment
RO	2010-8512 SA (public health - food hygiene)	"The CCA stated that there has not been considerable progress in the re-evaluation of approved establishments due to a **limited number of staff available** for this task and due to financial problems concerning travel expenses. In addition the CCA informed the FVO team that they had a salary cut of 25% in 2010. [...] According to the CCA a **shortage of financial resources has had an impact on training** organised in 2010. Recommendation 2 has not been satisfactorily addressed and inadequate training for OVs in certain areas was noted by the FVO team."	Lack of financial resources resulting in lack of staff and training

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
BU	2010-8513 SA (public health - food hygiene)	"The NVS informed the FVO team that the GDCVA prepare an audit plan each year. In 2010 ten audits were planned to ten different RVS, however the CA stated that **only six of these audits had been carried out due to budgetary constraints**."	Lack of financial resources
RO	2008-8003 MR (Control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products)	"Significant delays in allocation of the budget allied with the fact that the national residue control plan is not yet financed by fees pursuant to Article 27 and Annex IV Section B to Regulation (EC) No 882/2004, have contributed to the marked delay in the implementation of the 2008 plan which is not in line with point 2.1. of Annex to 16 Commission Decision 98/179/EC. **Budgetary constraints and late implementation of the plan collectively undermine the effectiveness of the residues control system**."	Lack of financial resources
GR	2011-8840 MR (Poultry meat and poultry meat products)	"The number of controls performed varied between regions. In one region visited the set target was achieved. In a second region, **due to budgetary constraints, only approximately 20% of foreseen checks were performed**. As a result some establishments were never controlled in 2010. The audit team was informed that for 2011 this specific region will be in the same situation."	Lack of financial resources
GR	2011-8810 MR (Health rules on animal by-products (ABP))	"At two prefectures out of the 11 visited by the audit team, evidence was shown that a risk based plan was set up, however; the inspectors met by the audit team declared that they were not able to execute this plan due to **lack of resources**."	Lack of financial resources

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
GR	2010-8609 MR (Protected zones, harmful organisms and controls for Rhynchophorus ferrugineus)	"Greece has organised an official action programme aiming to seek confirmation that the relevant harmful organisms are not endemic or established in the protected zones in 2009. The action programme is generally based on appropriate planning and methodology. However, **a number of Prefectures were omitted from the survey plan because of a lack of resources**."	Lack of financial resources
RO	2010-8560 SA (Import/transit control system and border inspection posts)	"All BIPs in Romania are approved for HC and NHC and they are also listed as Designated Points of Entry under Regulation (EC) No. 669/2009. The BIP facilities are shared for controls of POAO and products of non-animal origin. At the BIPs visited no formal system for minimising the risk of cross-contamination was in place. The effectiveness of the existing measures,however, cannot be ensured due to the **lack of resources** for cleaning and disinfection of the shared facilities."	Lack of financial resources
UK	2009-8092 SA (Official controls on feed legislation)	One of the LAs responsible for official controls on imported feed at one seaport visited (England) had no documented procedure in place for the implementation of such controls. According to a representative from this LA, **documentary checks were not performed and physical checks (sampling) were very limited due to a lack of resources** [..]. As a result, few samples were taken and they were tested for melamine and genetically modified organisms only."	Lack of resources

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
RO	2010-8460 SA (Salmonella National Control Programme in particular poultry populations)	"A shortage of financial resources has had an impact on sampling levels in 2009 and training organised in 2009/2010. As of today, the CA has the necessary legal powers needed for the SNCP implementation. While some training has been organised relevant to SNCP, in some cases this has been insufficient/ineffective."	Lack of financial resources affecting controls and training
FI	2009-8065 SA (poultry meat and poultry meat products)	"Sampling plans were not always fully mplemented; in one MFCA visited the plan for first half of 2008 was not implemented at all and no official samples were taken.As a reason the MFCA indicated lack of financial resources."	lack of financial resources
PL	2010-8602 SA (Plant Health - potatos and the general system of surveillance for harmful organisms)	"The mission team noted that in one of the local offices visited, the chief inspector reported that there was too few staff to carry out the minimum level of planned checks, in particular, that in 2009, it had not been possible to carry out the mandatory annual documentary check at premises registered in accordance with Directive 92/90/EC."	Lack of staff
PT	2010-8611 MR (Pinewood Nematode)	Trucks sealed with private seals are not controlled and due to a **lack of resources** there is no system in place to control that trucks intercepted with non-compliant material follow the instructions of GNR.	Lack of financial resources
BU	2010-8552 SA (Import/transit control system and border inspection posts)	"**No internal or external audits** subject to independent scrutiny and transparency have been done in the framework of Regulation (EC) No 882/2004. According to the CA this was **due to lack of resources**. No concrete plans were in place for implementation of such audits for BIPs. [...] The lack of supervision for the biggest BIP in Bulgaria cannot ensure that official controls are carried out correctly."	Lack of financial resources

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
SE	2010-8501 SA (Public Health - Food Hygiene)	"The NFA stated that **there is not yet a uniform training system in place** across the different CAs in Sweden to ensure the competence of officials carrying out official controls. […] the basis for future training has been established through the completion of the "skills in food control" project but so far **no funding** for the implementation of the project has been secured."	Lack of financial resources resulting in lack of training
SE	2007-7433 MR (Import controls for plant health)	"Most of the shortcomings are related to **limited human resources**. Not all regulated articles are checked, and some checks are carried out after customs clearance.[...] The competent authorities in Sweden are recommended to ensure that: (1) There are adequate staff available to enable plant health checks to be carried out [..]"	Lack of staff
SE	2010-8606 SA (plant health import controls)	"**Understaffing** is the major limiting factor for carrying out plant health controls. This affects for example import controls, where not all checks are carried out, where it is required by EU legislation. […] despite the increase in the number of ID inspectors, there still appears to be a shortage of staff and inspectors are charged with a wide range of tasks in other food and feed safety areas. Thus, recommendation 1 of the 2007 mission report has not been fully addressed."	Lack of staff

MS	FVO Audit Reference	Instances where MS have stated that they could not carry out controls because of a lack of resources	Problem raised by the MS
IE	2010-8408 MR (Animal health - bovine tuberculosis)	"The CCA indicated that the reduction in staff did not significantly affect the performance in the field. However:◦ One DVO visited lacked supervisory staff: it had no district superintending veterinary officer (SVI) (not replaced), and had been for the last two years without Higher Executive Officer (HEO, in charge of administrative and staff matters). Poor supervision and enforcement was observed in this DVO.◦ Significant delays in notifying IUT movements were explained by the staff in charge (at the DVO level) as due to the **limitation of human resources**.[...] Impact of the reduction of staff, and consequently the field presence of the CA in charge of the TB eradication programme, is mitigated by the automation of tasks and the reorganisation of official controls on a risk basis. However, the level of implementation of official controls is insufficiently verified to ensure their effectiveness throughout the country. This verification is all the more necessary in the execution of the TB eradication plan [...]."	Lack of staff
GR	2011-8901 MR (Monitoring of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products)	"[...] the insufficient provision of staff, equipment and reagents commensurate with designated tasks remains a significant obstacle to the proper functioning of the laboratory network and the Greek competent authorities have therefore not met their obligations under Article 4(2)(a), 4(2)(c) and 4(4) of Regulation (EC) No 882/2004."	Lack of staff and equipment

Annex XVI FEES - Validated baseline scenario[141]

Issue to be considered	Belgium	Italy	UK
Fees as a tool of financing official controls	Belgium's system is based on the the idea that costs for official controls need to be shared between FBOs and MS. So FBOs only contribute to part of the costs and the rest is financed with the general budget (at the moment around 40%FBOs-60%MS). There are 2 types of fees: - retributions: these are the areas covered by mandatory fees and an hourly rate between 40 and 60 eur is applicable (depending on the qualifications of the inspectors) unless the application of throughput charges is higher than that (these charges are similar to the mandatory fees in 882/2004). - contributions: paid by all FBOs at the beginning of the year depending on size and sectors. They cover routine inspections throughout the year regardless if inspections take place for a specific FBO. Out of office hours activities have, in certain cases, a surcharge.	With the new legislation of 2008 (Legislative Decree 194/2008) Italy intends to use the fees to cover 100% of the costs related to official controls along the food chain but with the exclusion of retail, ABP, primary production, feed. There are 2 types of fees: - mandatory fees under Reg. 882/2004 are calculated on a throughput/quantity basis (similar to Annex IV and V) - fees are provided also for import of food of non-animal origin - fees for all the other FBOs are calculated as a flat rate contribution paid at the beginning of the year depending on size/category (from 400 to 1500 eur /year)	UK mainly collect the mandatory fees. From 9/2009 a time-based fee has been introduced in the meat slaughterhouses and cutting plants The fee to the establishments varies depending on their size, as the percentage of cost recovery was originally based on previous charges that hinged on livestock and throughput units. The aim is to reach 100% coverage of costs in a few years. Fees are not applied in the dairy sector. According to UK the fact that they did not apply those fees prior to Reg. 882/2004 exempts them from this obligation. There are differing levels of fees being applied on the fish sector as it is acknowledged that the actual administrative burden of running the fee system in some establishments is greater than the fees collected An exercise to improve efficiency of the inspection services in the meat sector is on going and has led to a decrease of costs. However fees are growing at the moment because: - UK aim at increasing cost coverage towards

[141] This Annex only refers to the inspection fees collected for the purpose of control activities currently covered by Regulation 882/2004 (feed and food law, animal health and animal welfare rules).

Issue to be considered	Belgium	Italy	UK
			100% - the weak pound.
Costs covered with fees	2005: 42% of total costs 2006: 46% of total costs 2007: 39% of total costs 2008: 38% of total costs 2009: 37% of total costs	2005: 50% estimate 2006: 50% estimate 2007: 50% estimate From 2009 fees are to be applied with an automatic 20% increase, then after the end of the year the actual cost is calculated and the automatic increase/decrease is re-calculated to reach 100% cost coverage. A 0.5% increase is meant to cover costs related to the implementation of MANCP and ring fenced for this purpose to the Ministry of Health.	Annex VI is the reference including social security costs and overheads. In the slaughterhouse and cutting plant sector the following level of cost recovery was achieved 2007:41% 2008:43% 2009:44%
Non-mandatory fees	Covered by the contributions paid by all participants to the food chain at the beginning of the year.	Covered by the flat rates contributions paid by FBOs at the beginning of the year + fees on import of food of non animal origin.	Only specific areas: approval of irradiation facilities, pesticide residues programme (fee on chemical industry), sampling and testing of raw cow milk in England and Wales
Activities covered	The whole food chain (also primary production). Also activities carried out on FBOs request are subject to fees (e.g. export certificates) - a combination of cost per certificate and hourly rates. In general authorisation/registration requests are not covered by fees even if they require an inspection on the spot. However the authorisation of some establishments (agrement) is subject to a fee.	The food chain with exclusion of retail, ABP, feed and primary production. Authorisation of establishments (also feed) is subject to a flat rate fee. Export certification is subject to hourly rate of 50 eur. Out of office hours activities have a surcharge (30%). Italy is considering the possibility to extend fees also to the transhipment part of import.	Only mandatory areas under Reg. 882/2004 (with the exclusion of dairy sector and the few exceptions mentioned above)

Issue to be considered	Belgium	Italy	UK
Calculation method	For retributions, the hourly rates/throughput fees are determined by legislation. For contributions a declaration is made every year (also electronically) and yearly fees depend on size and sector (from 50eur up to 11,000).	All fees are calculated on the basis of Annex VI of Reg. 882/2004 (including social contributions) and reviewed at least every 2 years to ensure coverage of 100% of costs. For administrative costs a reference is made to them being "linked to the controls carried out".	Fees are calculated on the basis of annex VI of Reg. 882/2004 including social contributions and overheads. In the meat slaughterhouses and cutting plant establishments fees are calculated as a percentage of actual costs, the percentage being paid will differ depending on the size of the business, therefore it takes into account livestock and throughput units. In the case of the percentage that is being charged being lower than the EU minima, charges will then be increased to meet EU minima. In the fish sector guidance provided to Local Authorities explains a calculation method that is based on relevant 882/2004 annex.
Small/disadvantaged FBOs	Some small establishments and businesses are exempted from payment or payment reduced.	Some flexibility is mentioned in the basic law with a reference to paragraphs 5 and 6 of Art. 27 Reg. 882/2004 but that cannot derogate 100% cost recovery. Unclear if specific rules are needed.	A discount is calculated on the time-based fee as the percentage to be paid decreases as throughtput and livestock units decrease. Guidance on "Cold inspection" have been developed to maximize CA efficiency
Transparency	All information is available on line and regularly updated. www.afsca.be	Basic law is published on the official journal. Then information are prepared and published by local competent authorities. No centralized information. The basic law prescribe regular information to the Commission on: - calculation method - figures on use of income from fees.	All information is available on line and regularly updated. www.food.gov.uk

Issue to be considered	Belgium	Italy	UK
Mechanisms to increase efficiency	A bonus-malus system is in place. If haccp system of the FBO is certified by accredited bodies recognized by AFSCA, then the yearly contributions is reduced by 50%. If not, a malus of 20%(2009), 60% (2010) and 100% (from 2011) is applied. For poultry slaughterhouses where FBOs are involved in controls the fees are reduced.	Application of mandatory fees can take into consideration previous record of conformity, risk category and efficient own checks but cannot derogate to 100% cost recovery. With an agreement State/Regions it is possible to detemine time-based fees for slaughterhouses on the basis of minimum inspection times to be respected by the CA (e.g. 4 minutes per cattle).	CA and FBOs sign Business Agreements where the presence of the CA is agreed. In case of disagreements a mechanism is in place to solve them. If the CA loses the case and they believe an increased presence of the CA is all the same needed, they pay for it. FBOs can propose changes to the way of production in order to decrease the need for CA presence. This system has ensured that the pressure to ensure efficient and effective delivery of OCs has been shared with FBOs.
Reward/penalize systems	See above. For the mandatory fees a specific system is not in place apart from an increase in the fees in case animals with unclear identification (slaughterhouse)	See above	The UK was to further develop a fee system that clearly takes into account FBO compliance levels when setting the fee system. Unclearness within the UK as to the legal meaning and scope of articles 27 and 28 has previously hampered developments on that front.
Fees for several controls at the same place	/	The principle included in Art. 27.7 of Reg. 882/2004 is repeated in the basic legislation clarifying that the single fee to be applied is based on the recovery of actual costs.	No specific rules. In general fees take into consideration the proximity of slaughterhouses and cutting plants which is to be considered in line with Art. 27.7 of Reg. 882/2004.
Operators charged	The FBOs	The FBOs	the FBOs
Ring-fence	Ring-fenced for AFSCA activities	95% of the income from fees on domestic activities is ring fenced for the local CA and laboratories. 5% is for regional and central authorities to cover costs related to implementation of MANCP. 20% of the income from fees on imported products is ring fenced for the CA. 80% goes to the general budget.	In part. Controls carried out by Food standards agency operations in slaughterhouses and meat cutting plants are ring fenced (collected and used within the agency). The rest of the sectors when monies are collected this is done through Local Authorities and kept within the authority.

Issue to be considered	Belgium	Italy	UK
Art. 28 - non-routine checks	Inspections which reveal non-compliances are not charged per se. However the costs related to sampling and analysis and further enforcement actions (destruction, treatment, etc.) are paid by the FBOs.	Controls under Article 28 (and on the basis of EU emergency measures) are charged to the operators with an hourly rate of 50eur + costs of analysis (rate calculated on the basis of Annex VI Reg. 882/2004).	UK has a very restrictive understanding of Art. 28 which leads to its application only in extreme cases of non compliances which lead to a risk for consumers. So, in general, additional controls are not charged to FBOs even if they reveal non-compliances as it was felt at a UK level that art. 28 was not drafted to that effect, and that it was unclear whether art. 27 applied instead.
Information sources	AFSCA website Questionnaire submitted in 2008 (fees study)	Legislative Decree 194/2008 Case study in the 2008 fees study Web sites of a few local authorities	FSA web site Case study in 2008 fees study Questionnaire submitted in 2008 (fees study) Information received from UK CA after working group with MSs

Issue to be considered	France	Poland	Germany
Fees as a tool of financing official controls	France only collect mandatory fees. Fees are based on cost recovery. For import on the basis of the costs calculated the year before (BIP by BIP) and then adjusted for the next year to cover 100% costs. For domestic production following rules similar to the national rules on VAT. Rates are slightly below minimum fees in Reg. 882/2004. From June 2010 a fee has been introduced for the authorisation of animal feed producers. From 1 January 2010, fees for controls on slaughtering and aquaculture production now include also costs related to the control of residues of veterinary medicines (before they were separately charged). In the fish and aquaculture sectors a process of alligning the mandatory fees to the requirements of Regulation 882/2004 is on-going.	Poland collects all the mandatory fees under Reg. 882/2004 at the minimum levels indicated (some differences are due to the exchange rate). In the veterinary area some non-mandatory fees are set (feed, certification, ABP, etc.). In 2009 Regulation of the Minister of Health 656/2009 introduced fees for all official controls performed on FBOs dealing with food (and not included in the veterinary sector). In this way fees cover the whole food chain (apart from primary production)	Fees are under the responsibility of each Lander and therefore systems vary greatly. In general they only cover mandatory fees but a significant number of Landers cover also non mandatory fees in the areas of food safety and animal health. Also approval of plants is mentioned among non mandatory fees.
Costs covered with fees	2005: For import: 3.8 million costs - 3.7 million recovered 2006: For import: 4.1 million costs - 4.4 million recovered 2008: For import : 4,16 million costs - 4,21 million recovered For domestic production: 70% estimate (80 million euro costs, 56 million recovered) => 45 % estimate (125 million euro costs, 55 millions recovered) For import: around 100% (but in general rental costs are not included here and paid by operators directly. This accounts for about 20% of total costs)	2008: CA claims 100% cost coverage (no data)	No data

Issue to be considered	France	Poland	Germany
Non-mandatory fees	No. Fees for export certification and authorisation of plants are being considered inside and outside of the EU A fee for animal by-products during slaughter is collected on national basis (part fee part subsidy).	In the veterinary area. They refer mainly to certification (export, health), feed (domestic), ABP, emergency slaughter outside plant, genetic materials, markets, animal quarantine. Outside the veterinary area, Regulation 656/2009 introduces a fee for official controls on food other than veterinary area.	Charged in some Landers.
Activities covered	Only mandatory areas under Reg. 882/2004 (with some exceptions)	The whole food chain (apart from primary production) but with specific systems for veterinary and non veterinary areas.	Mainly veterinary area but in some Landers also food safety in general (whole food chain).
Calculation method	For import the following elements are considered:rental costs for BIPs if not already paid by operators, equipment, training, cleaning, travelling expenses, salaries of staff directly involved in controls, sampling. For domestic production salaries of staff directly involved, training, property charges, operational costs including sampling.	In the veterinary area: fees include the costs for salaries of personnel involved in controls, administrative costs related to controls, training of inspectors, sampling and testing. Minimum fees are used for areas covered as mandatory by Reg. 882/2004. Specific fees for veterinary non mandatory fees Outside the veterinary area: fees include transport costs, document control, sampling and testing, verification procedures. Flat rate of 45 PLN (13 EUR) is charged per control + 15 PLN (4 EUR) per hour + sampling + testing (specific rates). Specific rates are also set for import.	In general a mix between minimum fees and cost based fees is used. Costs are calculated but then the minimum fee acts as a lower limit (apart from Bavaria). In some Landers fees are calculated for each establishment. In some Landers also maximum ceilings are included. The costs recorded the previous year are the basis for the fees in the following one. For some fees (e.g. authorisation of plants) a hourly fee is set (with min and max) at 44 eur/hour + travel
Small/disadvantaged FBOs	No specific rules but the way fees are applied seems not to create particular problems to them.	No specific rules.	No specific rules
Transparency	Legislation is published in the OJ. Notes de service are sent to the CA. Relevant ministries publish information	Legislation is published in the OJ.	Legislation published in the OJ

Issue to be considered	France	Poland	Germany
	(Agriculture, Customs)		
Mechanisms to increase efficiency	No specific rules.	No specific rules.	No specific system in place. A system of categorization of meat establishments according to risk is being tried in some Landers in order to modulate frequency of inspections to the related risk category. Industry is asking for consultation on the setting of fees in order to increase efficiency and risk based approach. Salaries are one of the biggest cost but industry is not involved in their setting (only CA and trade unions)
Reward/penalize systems	A bonus malus system is being considered. Slaughterhouses are classified in 4 categories depending on level of compliance. The first 2 categories would have a bonus, the others a malus.	No specific rules.	No specific rules
Fees for several controls at the same place	No specific rules	No specific rules.	No specific rules
Operators charged	The FBOs	The FBOs	The FBOs
Ring-fence	Fees for import are ring fenced but not for domestic production. All fees are reversed to the general budget. A direct budget line is against national tax legislation.	Fees go to the general budget. Fees for veterinary controls are ring-fenced for the CA when contractors are used.	In general fees are collected to be directly used to finance the official controls (they are in fact mainly based on full cost recovery). In those Landers where fees go to the general budget in any case they are earmarked for the CA.
Art. 28 - non-routine checks	No specific rules	No specific rules.	No specific rules

Issue to be considered	France	Poland	Germany
Information sources	Case study in 2008 fees study Questionnaire submitted in 2008 (fees study) Information received from France after an FVO inspection Notification from France under Art. 27.12	Case study in 2008 fees study Questionnaire submitted in 2008 (fees study) Notification from Poland under Art. 27.12	Case study in 2008 fees study Questionnaire submitted in 2008 (fees study) Notification from Germany under Art. 27.12

Issue to be considered	Slovakia	Estonia	Latvia
Fees as a tool of financing official controls	Fees included in Annexes IV and V are collected at the minimum rates. Non mandatory fees are also collected for import of food of non-animal origin, veterinary controls of animals, hatching eggs, germinal products and animal by products (also with reference to export). These fees are collected as time-based fees.	Fees included in Annexes IV and V are collected at the minimum rates. Outside these sectors: - food sector: FBOs are charged using a time based fee - feed sector: rates are calculated quarterly on the basis of quantities produced/exported - veterinary sector other than Annexes IV and V: a time based fee is used.	Fees cover all mandatory fees (but not milk) and some minor activities outside these sectors. Specific rules and calculation method apply fo fees in the residues area (Dir. 96/23). The other sectors are either covered with the minimum fee or a flat rate based on actual costs (depending on the activity)
Costs covered with fees	2005: 52% 2006: 55% 2007: 51%	2005: 31% 2006: 28% 2007: 20%	100% (according to the CA)
Non-mandatory fees	Non mandatory fees are also collected for import of food of non-animal origin, veterinary controls of animals, hatching eggs, germinal products and animal by products (also with reference to export). These fees are collected as time-based fees.	The whole food and feed chain is covered but fees are calculated in different ways according to sector.	Fees cover issuing of health certificates and permits. Fees cover also import of food contact materials and feed of non-animal origin
Activities covered	mandatory fees, import of food of non-animal origin, veterinary controls of animals, hatching eggs, germinal products and animal by products (also with reference to export).	The whole food and feed chain.	Only mandatory fees and minor activities outside them.

Issue to be considered	Slovakia	Estonia	Latvia
Calculation method	Minimum fees for the mandatory ones. For import controls on food of non animal origin, veterinary controls of animals, hatching eggs, germinal products and animal by products (also with reference to export) a time based fee (hourly) is calculated on the basis of the items included in Annex VI of the Regulation.	Fees under Annex IV and V are collected at the minimum rates. Feed sector: fees depend on quantity and quality of feed. Other veterinary fees and food sector: hourly fee calculated on the basis of average remuneration of a supervisory official + average administrative and economic costs relating to carrying out the inspection. The remuneration refers to an official working for the local CA or at BIPs - the average refers to remuneration in the previous year. The administrative and economic costs are the average cost per official with reference to the items listed in point 2 of Annex VI to the Regulation and related to the inspection activities. Every year the hourly fee is updated taking into consideration the costs of the year before.	Covering the costs mentioned in Annex VI (administrative costs are included adding 10% to the direct costs)
Small/disadvantaged FBOs	No specific rules (CA feel that different rules would put some business categories at disadvantage compared to others - there is also the need to maintain a minimum level of income for official controls).	Fully considered in the food sector and partly considered in the veterinary area with the use of a time based fee outside Annexes IV and V.	No information
Transparency	Relevant legislation is published in the official journal.	Legislation published in the OJ.	No information
Mechanisms to increase efficiency	No specific rules.	No specific rules.	No information
Reward/penalize systems	No specific rules.	No specific rules.	No information

Issue to be considered	Slovakia	Estonia	Latvia
Fees for several controls at the same place	CA apply only one fee in slaughterhouses with annexed cutting plants.	No specific rules.	No information
Operators charged	FBOs In the milk sector only dairy farms (not processors) are charged.	FBOs	FBOs
Ring-fence	Fees go to the general budget and only in part it goes back to the competent authorities	Fees (except for feed control) are used directly to finance official controls. Fees for feed control go to the general budget.	Yes, fully.
Art. 28 - non-routine checks	Specific legislation for additional official controls needed after detection of non compliance. FBOs are charged using a time based fee (hourly) identical to the one foreseen for import of food of non-animal origin and veterinary controls of animals, hatching eggs, germinal products and animal by products (also with reference to export). Costs related to sampling needed in relation to the detected non compliance are also included.	FBOs are charged using a time based fee, in case of laboratory investigations the costs of these are added.	In the residues area, if non compliance is detected the costs of the controls carried out are charged to the operators.
Information sources	Case study in 2008 fees study Questionnaire submitted in 2008 (fees study) Notification from Slovakia under Art. 27.12	Estonia notification under Art. 27.12	Questionnaire submitted in 2008 (fees study)

Issue to be considered	Lithuania	Bulgaria	Cyprus
Fees as a tool of financing official controls	Fees cover all mandatory fees and some minor activities outside these sectors. Flat rate fees are calculated on the basis of actual costs.	Fees cover all mandatory fees and some minor activities outside these sectors. Flat rate fees are calculated on the basis of actual costs.	Fees cover all mandatory fees and some minor activities outside these sectors. Minimum fees are followed apart from cutting plants where an hourly rate is used.
Costs covered with fees	100% (according to the CA)	2005: no data 2006: 25% 2007: 29%	No data (CA state that fees do not cover costs but no data are available)
Non-mandatory fees	Fees cover issuing of specific certificates	Fees cover animal welfare controls and import of feed of non animal origin,	Fees cover export certificates and import of products of animal origin outside Regulation 882/2004.
Activities covered	Only mandatory fees and minor activities outside them.	Only mandatory fees and minor activities outside them.	Only mandatory fees and minor activities outside them.
Calculation method	Covering the costs included in Annex VI (including social security of inspectors). Fees are calculated on the basis of actual costs and can go below minimum fees if costs are lower.	Covering the costs included in Annex VI (including social security of inspectors). Fees are calculated on the basis of actual costs using average costs and a specific hourly fee per inspector (10 BGN)	Minimum fees for all mandatory sectors apart from cutting plants where an hourly fee is used (calculated on the basis of the salaries of inspectors)
Small/disadvantaged FBOs	No information	No information.	No information
Transparency	Basic law (Resolution) and annual updates are published in the official journal	No information.	No information
Mechanisms to increase efficiency	No information	No information.	No information
Reward/penalize systems	No information	No information.	No information
Fees for several controls at the same place	No information	No information.	No information
Operators charged	FBOs	FBOs	FBOs
Ring-fence	Fees go to the general budget and only in part it goes back to the competent	Fees go to the general budget and only in part it goes back to the competent authorities	Fees go to the general budget and only in part it goes back to the competent authorities

Issue to be considered	Lithuania	Bulgaria	Cyprus
	authorities		
Art. 28 - non-routine checks	No information	No information.	No information
Information sources	Questionnaire submitted in 2008 (fees study)	Questionnaire submitted in 2008 (fees study)	Questionnaire submitted in 2008 (fees study)

Issue to be considered	Czech Republic	Denmark	Finland
Fees as a tool of financing official controls	Fees cover all mandatory fees and some minor activities outside these sectors. Minimum fees are followed for activities within the EU and flat rates, on the basis of actual costs, for import.	Fees cover all mandatory fees and some other activities outside these sectors. Flat rates are used and calculated on the basis of actual costs. Minimum fees are used for small abattoirs	Fees cover all mandatory fees and some other activities outside these sectors. Flat rates are used and calculated on the basis of actual costs. Minimum fees can be used for smaller establishments under the responsibility of municipalities.
Costs covered with fees	2005: 36% 2006: 33% 2007: 28%	CA state full cost coverage with the exception of small abattoirs where only 35% of costs is recovered (this subsidy is calculated in around 10 million DKK a year)	2005: around 100% (20% for small plants) 2006: around 100% (20% for small plants) 2007: around 100% (20% for small plants)
Non-mandatory fees	Fees cover issuing certificates and approval and registration of establishments and laboratories	Fees cover food and feed of non animal origin, food additives, ABP, food contact materials, animal welfare during transport, approval and registration of establishments	Fees cover all feed controls and approval of establishments
Activities covered	Only mandatory fees and minor activities outside them.	Mandatory fees and some activities outside them.	Mandatory fees and some activities outside them.
Calculation method	Minimum fees for domestic activities. For import, flat rates are calculated on the basis of actual costs according to the items of Annex VI	Flat rates are calculated on the basis of actual costs. Small abattoirs are charged minimum fees. A time based fee is calculated plus a starting fee for each control which covers associated costs). Feed establishments pay also an annual fee. Analysis are charged at cost. For residues a quantity based fee is calculated.	Flat rates are calculated with a time based fee. Smaller establishments are under the responsibility of municipalities and they can be charged on the basis of costs or at minimum fees depending on the municipality.
Small/disadvantaged FBOs	No information	Small abattoirs are charged only minimum fees and the extra costs are paid with the state budget.	Smaller establishments in municipalities can be charged minimum fees instead of at cost.
Transparency	No information	No information	Relevant legislation is published in the official journal and on the EVIRA wesite
Mechanisms to	No information	No information	No information

Issue to be considered	Czech Republic	Denmark	Finland
increase efficiency			
Reward/penalize systems	No information	No information	No information
Fees for several controls at the same place	No information	No information	No information
Operators charged	FBOs	FBOs	FBOs
Ring-fence	Fees go to the general budget and only in part it goes back to the competent authorities	Fees are used direclty to finance official controls.	Fees are used directly to finance official controls in case of controls under the responsibility of municipalities. Otherwise it goes to the general budget and only in part it goes back to the competent authorities.
Art. 28 - non-routine checks	Outside the veterinary sector, when inspections detect a non compliance, the cost of the analysis that detected the non compliance is charged to the FBOs	No information	No information
Information sources	Questionnaire submitted in 2008 (fees study)	Questionnaire submitted in 2008 (fees study)	Questionnaire submitted in 2008 (fees study)

Issue to be considered	Ireland	Greece	Spain
Fees as a tool of financing official controls	Ireland collect mandatory and some non-mandatory fees. Minimum fees are followed for imports of animal origin. For meat, a system of standard unit charges (which may or may not recover the full cost of the service). In the dairy sector a flat-rate system applies, based on the quantity of milk purchased on a monthly basis. The level of Inspection fee currently applying for imports of products of animal origin exceeds the minimum level requirements under Regulation (EC) No. 882/2004. The National Standards Authority of Ireland (NSAI) provide official food control services in premises requiring recognition for the extraction of natural mineral water. A fees is charged by the NSAI to cover the costs of audit and on site activites.	Fees cover all mandatory fees and some minor activities outside these sectors, with the exception of the costs for the approval of feedingstuffs' establishments that is covered by annual fees. Flat rates are used and calculated on the basis of actual costs.	Fees are under the responsibility of each Autonomous Community, not all control activities are covered by rules or specific provisions on fees collection under Reg. 882/2004. For imports of differents products the fees are under responsability of the Central Competente Authority and they are different of the indicated in the Reg.882/2004.In this moment,it is preparing a new rule on reinforced controls in the products of non animal origin (Reg 669/2009) and a new fee should be created.
Costs covered with fees	2005: Meat: 48% Milk: 90% Animal Feed: 82% 2006: Meat: 38% Milk: 90% Animal Feed: 80% 2007: Meat: 42% Milk: 90% Animal Feed: 76% Imports of animal origin: 27% 2009 Meat: 40% Milk: 90% (approx) Imports of animal origin no change, Mineral Water Establishments 50-70%	Fees do not cover costs. No data available (for the years before 2008 fees were not collected).	In general the fees do not cover the costs.
Non-mandatory fees	Yes for meat cold stores supervised by DAFF. The NSAI fees for premises requiring recognition for the extraction of natural mineral water.	Fees cover all type of inspections in feedingstuffs.	Charged in some Autonomous Communities.Also la Agencia Española de Seguridad Alimentaria y Nutrición (AESAN) has some fees on several dietetic foods in relation with the evaluation and registration.

Issue to be considered	Ireland	Greece	Spain
Activities covered	Mandatory areas under Reg. 882/2004 and non mandatory fees charged for official controls in coldstores (See Appendix from Ireland for further information on rates)	Mandatory fees and other minor activities outside them.	Not all control activities are covered by rules or specific provisions on fees collection under Reg. 882/2004.In imports they cover the imports of food of animal origin.
Calculation method	On what concerns meat these fees are either a fee per animal slaughtered, a fee per tonne of product going through cutting plants and independent cold stores or an hourly charge for time spent supervising product in processing plants, integrated cold stores and for overtime on meat inspection work. In the dairy sector a flat rate system is followed, fees are collected according to quantity of milk produced and cost of services on a monthly basis.	Flat rates are calculated on the basis of actual costs, according to the criteria of Annex VI of Regulation 882/2004.	In principle, minimum fees are applied. In the dairy sector, flat-rates and minimum rates are both used.In imports the calculation of fees is based on the type of product and the weight and it is calculateted by telematique way.
Small/disadvantaged FBOs	Some small establishments are exempted from payment or payment reduced	The budget for the cost of controls has been planned and it was allocated according to the amounts that each establishment produced and disposed.	There are no exemptions for the small establisments.
Transparency	Relevant legislation is accessible on the website www.fsai.ie and www.irishstatutebook.ie	No information	Basic laws and annual updates are published on the official journals of the State (imports and fees of AESAN) and the Autonomous Communities.For the imports is also in the web page of Ministerio de Sanidad y Politica Social.Also some Autonomous Communities and AESAN have developped informatic applications in their web pages.
Mechanisms to increase efficiency	A working group has been established to review and evaluate the fees charged by the Department of Agriculture, Fisheries and Food for the provision of official controls	No information	Industry is asking for consultation on the setting of fees when a basic law or an update is preparing.

Issue to be considered	Ireland	Greece	Spain
	and inspection services in the meat and dairy hygiene sector as required under EU legislation		
Reward/penalize systems	Not applied	No information	Application of mandatory fees can take into consideration previous record of conformity, risk category , efficient own checks and other items (not working at night ,administrative support) but cannot derogate to 100% cost recovery.
Fees for several controls at the same place	Not applied	No information	There is not a general rule.In some case is charged a single fee (the highest).In other cases there is an acumulation of the fees.
Operators charged	FBOs of approved meat and milk etsbalishments and importers of food of animal origin (for imports of non animal origin see details in Annex)	FBOs	FBOs included importers or responsibles for the consignements.
Ring-fence	Fees go to the general budget and only a percentage is used to cover the costs of the controls carried out.	Fees go to the general budget of the Ministry of Rural Develpoment and Food and only a percentage is used to cover the costs of the contros carried out.	Fees go to the general budget and only in part it goes back to the competent authorities.
Art. 28 - non-routine checks	Not applied	No information	In the most part of the cases when there are detections of non compliance the additional official controls are charged FBOs (operators responsible for the non compliance or importers or FBO responsible for the consignements).
Information sources	Questionnaire submitted in 2008 (fees study); notification from Ireland under art. 27.12.	Questionnaire submitted in 2008 (fees study)	Questionnaire submitted in 2008 (fees study).Consult to competent authorities(june 2010).

Issue to be considered	Luxembourg	Hungary	Malta
Fees as a tool of financing official controls		Fees cover all mandatory activites and some other activites outside them. Flat rates are used and calculated on the basis of actual costs, in the case of import control a fee below the minimum rate is applied.	Fees are collected according to the Fees for Abattoir and Veterinary Service Regulations (LN 68/1986) (SL 35.10). Implementing legislation covers only red meat inspection fees. However, fees charged by Border Inspection Posts are collected according to Annex V of Regulation 882/2004, under a minimum rate system. SL 35.10 is currently under review to render collection of fees for red meat inspection in line with minimum rates of Annex IV of Council Regulation (EC) 882/2004 and introduce new fees for other areas that are not covered by Council Regulation (EC) 882/2004 or SL 35.10
Costs covered with fees		2005: around 60% 2006: around 60% 2007: around 60%	2005: 36.5 % 2006: 36.9 % 2007: 39.4 %
Non-mandatory fees		Fees cover inspection of herds; certification and control of animals and animal products transport; control of animal exhibition, competition; tuberculine testing and sampling.	No, implementing legislation is required.
Activities covered		Mandatory fees and some activities outside them.	The present implementing legislation directly covers only red meat inspection fees. However, fees charged by Border Inspection Posts are in line with Annex V since July 2007.
Calculation method		Flat rates are calculated on the basis of the actual costs. In the case of import control, a fee below the minimum rate is being applied.	Fees under Annex V of Regulation 882/2004 are collected at minimum rates. Cost of salaries of staff involved in official controls are included.

Issue to be considered	Luxembourg	Hungary	Malta
Small/disadvantaged FBOs		No information	Malta's largest FBOs are to be considerd small enterprises as per definition of SMEs. The greater majority of Maltese FBOs are microenterprises with highly reduced activity and personnel.
Transparency		No information	Collection of funds by the Agriculture and Fisheries Regulation Department for official controls and meat inspection are all recorded in a general direct accounting system (DAS) under the revenue vote. An electronic receipt is issued for each payment. The system falls under the Public Service Auditing system and is audited as part of the normal audits that take place from time to time.
Mechanisms to increase efficiency		No information	We have combined various controls to be carried out during inspections. This saves sending numerous teams of veterinarians and officers to the same establishments or farms to carry out inspections for different issues/purposes.
Reward/penalize systems		No information	No mechanism exists for reward systems but an administrative fine procedure exists in the parent Act (CAP 437) for breaches of regulations falling under this Act.
Fees for several controls at the same place		No information	The system of compunding fees is not adopted at present.
Operators charged		FBOs	FBOs are charged. Red meat slaughtering establishments are run by the state and therefore only internal paper transactions are considered.
Ring-fence		Fees are used directly to finance official	Fees go to the general budget and only in part

Issue to be considered	Luxembourg	Hungary	Malta
		controls.	return back to the competent authorities
Art. 28 - non-routine checks		No information	At present there is no extra collection of fees for enforcement work arising out of additional official controls for non-compliance.
Information sources		Questionnaire submitted in 2008 (fees study)	Questionnaire submitted in 2008 (fees study) (Updated 30.06.10)

Issue to be considered	Netherlands	Austria	Portugal
Fees as a tool of financing official controls	Fees cover mandatory areas and some activites outside them. For imports minimum fees are followed, for other activites under Annex IV of Reg.882/2004, meat and official controls on residues a flat-rate system is used. In fee calculation the principles of direct benefit and cost/effectiveness are considered. For milk the fee is below the minimum rate because the actual costs of these official controls are below the minimum fee.	Fees cover all mandatory fees and some minor activites outside them. Flat rates are used and calculated on the basis of actual costs. The fees for border checks are calculated on a minimum rate basis. For small establishments, fee setting is under responsibility of the different Landers.	Fees cover all mandatory fees and some other activities. Minimum fees are applied, with the exception of plant approval and inspection on HACCP, where a flat-rate is adopted. The plant health fees, are the minimal fees according the EU regulation.
Costs covered with fees	2005: 75 % 2006: 86 % 2007: 81 % 2008/2009: 90% (est.)	CA state that fees entirely cover costs, with the exception of border checks (no data available). At the Swiss border, lower fees are charged in accordance with an agreement between the Ec and Switzerland.	No data (CA state that fees do not cover costs but no data are available)
Non-mandatory fees	Fees cover all official controls and analyses in FBO's (meat and feed). There are also fees for registration of other foodoperators, approval an maintenance of approvals for dairy and milk products and eggs and egg products.	Fees cover hygiene checks in establishments that are subject to approval in accordance with Regulation (EC) No 853/2004 (processing; milk; eggs; fish).	Fees cover certification, slaughter, rabies vaccination, medicines and veterinary products approval and licensing. other fees cover oficial checks in establishments that are subject to approval in accordance with Regulation (EC) No 853/2004 (processing; milk; eggs; fish), and subject to control under Regulation (EC) no 1774/2002 and import from third countries (BIP, minimum annex V).; considering vaccines it is in place a fee, due to lab control, before release to market/users. On the import control of foodstuffs of non-animal origin and within the scope of audits to verify the traceability and HACCP requirements, operators support the cost of the analysis.

Issue to be considered	Netherlands	Austria	Portugal
Activities covered	Mandatory fees and some activities outside them. In general fees are applied for all all official veterinary controls and analyses in approved FBO's and border inspection posts.	Mandatory fees and some minor activities outside them.	Mandatory fees and some activities outside them.
Calculation method	Minimum fees apply for import activities. In the areas under Annex IV of Reg.882/2004, for meat products and official controls on residues a flat-rate system is followed. In fee calculation the following principles are taken into consideration: direct benefit, a direct link is needed between the benefit of the control activites for the FBOs and the fee to be paid for such activity; the cost/effectiveness, fees have to cover integral costs, but never being higher than the costs to be covered in a (group of) sector(s) or activities. Most fees have an hourly rate.	Fees are charged on a flat rate basis taking into account the duration, the position of the person performing the activity, the type of activity and resources used, and the type of establishment, distinctions being made on the basis of throughput. The fees for border checks are calculated, under a minimum rate system, on the basis of Annex V to Regulation (EC) 882/2004.	Minimum fees are applied as defined in Regulation 882/2004. Minimum fees apply even if they can clash with other criteria set by the Regulation (e.g. fees cannot be higher than costs). For plant approval, plant inspection and HACCP (under the Regulation (EC) No 853/2004) a flat-rate system on the basis of the actual costs is adopted. On the import control of foodstuffs of non-animal origin a standard value for issuing certificates are applied to all operators. In addition, if the commodity is randomly selected for analytical control the full costs of laboratory analyses are billed directly to the operator Within the scope of audits to verify the traceability and HACCP requirements, operators support only the cost of the analysis if sampling is done.
Small/disadvantaged FBOs	There are reduced fees for AM and PM inspections in very small slaughteries taking into consideration their low throughput.	In the case small establishments, Landers are responsible for fee seeting.	Some small establishments (local micro-economies) outside from Annex IV of Reg (CE) n.º 882/2004 have reduced fees.
Transparency	Legislation and fees are published in OJ. This information an further information on calculation method is available on line (www.vwa.nl)	No information	No information

Issue to be considered	Netherlands	Austria	Portugal
Mechanisms to increase efficiency	> call fee and time based fee (fee by quarter of an hour): the better the FBO functions, shorter and fewer official controls are needed which reduce the costs for FBO's. > set of rules for requests for official controls by FBO's > surcharges for i) requests for controls outside regular working hours i) overtime (on top of original requested time)	No information	No information
Reward/penalize systems	If possible official controls are risk-based which in combination to the time based fees leads to less or more charges to FBOs	No information	No information
Fees for several controls at the same place	Just one call fee for the same official; the total time for each offical is charged according to the applicable fee for the specific control	No information	No information
Operators charged	FBOs, BIPs, cattle dealers, citizens who need a veterinary certificate	FBOs	FBOs
Ring-fence	Fees are directly and only used to finance control activities.	Fees are used directly to finance official controls. In the case of Border Checks they are incorporated into the State's General Budget.	Fees are used directly to finance official controls.
Art. 28 - non-routine checks	All FBOs, BIPs and cattle traders - including retail - are charged for additional official controls according to art. 28 of Reg. 882/2004.	No information	No information
Information sources	Questionnaire submitted in 2008 (fees study); questionnaire submitted in 2010	Questionnaire submitted in 2008 (fees study)	Questionnaire submitted in 2008 (fees study) Decreto-Lei nº 154/2005 (plant health inspection);Decreto-Lei n.º 178/2008 e Portaria n.º 1450/2009 (controls according Reg.(CE) n.º 853/2004; n.º 183/2005 e n.º1774/2002)

Issue to be considered	Romania	Slovenia	Sweden
Fees as a tool of financing official controls	Fees cover all mandatory fees and some other activites outside them. Minimum fees are used on a time-basis that takes into account the salaries and the training cvosts for the personnel. For official controls on residues, FBOs dealing with products of non animal origin and some general activites a flat-rate is applied.	Fees cover all mandatory fees and some control activites outside them. Minimum fees are followed, except for official controls on residues and all non-mandatory activities, where a flat-rate system based on the actual costs is used.	Food: Full cost recovery (Meat in 2010 approx 95% cost recovery). General national system where FBO's pay an annual fee for official controls. Annual fees are based on annual control time, which in its turn is calculated by using av model for risk classification of FBO's, taking into account type and size of the FBO's activities, the risks involved and the FBO's past record. For slaughterhouses and GHE (and, to a certain extent, cutting plants) a different system applies, with annual fees calculated by estimating control hours per year multiplied by hourly rates based on actual costs for control performed by official veterinarians and official auxiliaries.
Costs covered with fees	Fees entirely cover costs for FBOs processing products of animal origin, but not for FBOs that process, stores and trades products of non animal orgin. 2006: 60% 2007: 50%	100% (According to the CA)	Food: Generally speaking, the aim of the fees system is full cost recovery for all official controls. The fees charged must be sufficient to finance the official control deemed necessary, and fees may not be used to finance other activities. Administrative costs, training, overheads, development of OC are included in the hourly rate. Slaughter upp to 200 tonnes per year is partly subsidised (approx. total of 9 million SEK in subsidies 2010).
Non-mandatory fees	Fees cover businnesses of products of non animal origin	Fees cover animal feed (control of approved establishments) and official control not covered by Annex IV of Regulation 882/2004	Fees cover all official controls on food (including imports), pesticides and residues, and the import of feed of non animal origin and animal by-products.Animal welfare in slaughterhouses is included.

Issue to be considered	Romania	Slovenia	Sweden
Activities covered	Mandatory fees and some other activities outside them.	Mandatory areas and some activities outside them (animal feed for control of approved establishments, official controls not covered by Annex IV of Regulation 882/2004 - to be further described).	Food: The whole food chain, except primary producers.
Calculation method	Minimum fees are applied on a time-basis system that considers the total cost/hour for the control activites making the sum between the salaries of the involved personnel/hour and the costs for personnel training/hour. For what concerns official controls on residues, processing, storage and trading businesses of products of non animal origin and some other general activites (cold stores, repackaging units, en-gross market) flat-rates are applied.	Minimum fees for the mandatory sectors, including total costs under Annex VI to regulation 882/2004 and, in case of live animals in I/C trade, also the costs covered by Regulation 1857/2006. For what concerns official controls on residues (Directive 96/23) and all activites covered by non-mandatory fees a flat-rate system is adopted.	Food: Fees are calculated on the basis of Annex VI of Reg. 882/2004. Flat rates are used, they are based on an hourly rate including travel costs and out-of-office hours costs. Overheads, training, administrative costs are included. Minimum levels in EU-legislation are obeyed.
Small/disadvantaged FBOs	In the amount of time calculation, the production volume and the sector of activity are also taken into account.	No information	Food: Annual fees for control take into account the size of the FBO's activities. Reduced fees apply for small slaughterhouses, based on applicable minimum fees according to Regulation 882/2004
Transparency	No information	No information	Laws and regulations on fees are published officially. Guidelines on risk classification have been published by the NFA. Detailed information on the calculating of fees is published on the NFA's homepage. Detailed info on calculation of control hours regarding slaughter houses and GHE is published on the NFA´s homepage.FBO's and other organisations receive proposals for new fee rules or fee levels and are given opportunity to

Issue to be considered	Romania	Slovenia	Sweden
			comment the proposals.
Mechanisms to increase efficiency	No information	No information	Food: Risk-based approach to fees means that the risks in the FBO's activities are reflected in annual control time. System also takes into account the FBO's past record, where compliance or non-compliance can lead to a reduction or an increase in the annual control time and annual fees.
Reward/penalize systems	No information	No information	See above. FBO's past record affects the annual fee paid.
Fees for several controls at the same place	No information	No information	Food: Separate fees may apply for export authorisation, control of imported foodstuffs and of residues. Authorization covering several activities, i.e. Slaughterhouse with annexed cutting plant and/or production plant, will be charged one fee calculated on volumes placed on market from each separate activity, provided each activity can be considered separate from the other activities.
Operators charged	FBOs	FBOs	Food: FBOs
Ring-fence	Fees are used directly to finance official controls.	Fees go to the general budget and only in part it goes back to the competent authorities.	Local and central authorities use fees directly to finance their official controls. Fees may not be used to finance other activities.
Art. 28 - non-routine checks	No information	No information	Food: Article 28 is applied in all cases where non-compliance leads to extra control. An hourly rate applies. Costs for all types of control are covered.
Information sources	Questionnaire submitted in 2008 (fees study)	Questionnaire submitted in 2008 (fees study)	Questionnaire submitted in 2008 (fees study)

Annex XVII: FEES – Supporting data

(*)This Annex only refers to the inspection fees collected for the purpose of control activities currently covered by Regulation 882/2004 (feed and food law, animal health and animal welfare rules).

Table 1 Full cost recovery across EU Member States

Member state	Percentage of costs recovered	Percentage of costs not recovered	Impact of reaching 100% recovery
AT	100%	0%	No impact
BE	37% (2009)	63%	Medium
BG	27% (2007)	73%	High
CY	No information	Unknown	Unknown impact
CZ	28% (2007)	72%	High
DE	No information	Unknown	Unknown impact
DK	35% (small abattoirs)	65%	Medium
EE	20% (2007)	80%	High
ES	Costs not covered	Unknown	High
FI	20% (small FBOs)	80%	High
FR	45% - 70% (domestic)	30% - 55%	Medium
GR	Costs not covered	Unknown	High
HU	60% (2007)	40%	Medium
IE	40% meat 90% milk 76% imports (2009)	67% (average)	High
IT	100% (2009)	0%	No impact
LT	100%	0%	No impact
LU	No information	Unknown	Unknown impact
LV	100%	0%	No impact
MT	39% (2007)	61%	Medium
NL	81% (2007)	19%	Low
PT	100%	0%	No impact
PL[142]	100%	100%	No impact
RO	50% non-animal origin (2007)	50%	Medium
SE	Costs not covered	Unknown	High

[142] The baseline data provided by DG SANCO indicate that Poland achieves full cost recovery; interviews with the Polish CA for this study, however, suggest that there is little data on cost recovery and that cost recovery is thought to be insufficient.

Member state	Percentage of costs recovered	Percentage of costs not recovered	Impact of reaching 100% recovery
SI	100%	0%	No impact
SK	51% (2007)	49%	Medium
UK	43% (2008)	57%	Medium

DG SANCO baseline

Notes on the baseline data presented in Table 1

United Kingdom:

- Annex VI is the reference including social security costs and overheads. In the slaughterhouse and cutting plant sector the following level of cost recovery was achieved

Poland:

- The baseline data provided by DG SANCO indicate that Poland achieves full cost recovery; interviews with the Polish CA for this study, however, suggest that there is little data on cost recovery and that the available data indicate that cost recovery is insufficient.

Portugal:

- CA claims 100% but has no data to support claim

Lithuania

- CA claims 100%

Greece

- Fees do not cover costs. No data available (for the years before 2008 fees were not collected).

Austria

- At the Swiss border, lower fees are charged in accordance with an agreement between the EU and Switzerland.

Sweden

- Generally speaking, the aim of the fees system is full cost recovery for all official controls. The fees charged must be sufficient to finance the official control deemed necessary, and fees may not be used to finance other activities. Administrative costs, training, overheads, development of OC are included in the hourly rate. Slaughter upp to 200 tonnes per year is partly subsidised (approx. total of 9 million SEK in subsidies 2010).

Table 2 Ring-fencing of resources for official control activity in EU Member States

MS	All resources ring-fenced	Percentage 0f resources ring-fenced (if less than 100%)	Resources ring-fenced, with some exceptions	Resources to general budget	No information
AT			□	Border inspection fees	
BE		95% local CA and laboratories 5% regional and central CAs 20% import fees	For AFSCA activities		
BG				□	
CY				□	
CZ				□	
DE	□				
DK	□				
EE			□	Feed control	
ES				□	
FI			Controls by municipal authorities	Other controls	
FR			Imports	Domestic production	
GR				□	
HU	□				
IE				□	
IT		95% domestic fee income for local CA and laboratories 5% regional and central CAs 20% import fees			
LT				□	
LU					□
LV	□				
MT				□	
NL	□				
PT	□				
PL			Veterinary controls when contractors used	□	

MS	All resources ring-fenced	Percentage 0f resources ring-fenced (if less than 100%)	Resources ring-fenced, with some exceptions	Resources to general budget	No information
RO	□				
SE	□				
SI				□	
SK				□	
UK		100% FSA controls for slaughterhouses and cutting plant controls. Other controls are performed by local authorities and revenue remains at this level.			

DG SANCO baseline

Notes on baseline data for ring-fencing in EU MS:
United Kingom:

- Controls carried out by Food standards agency operations in slaughterhouses and meat cutting plants are ring fenced (collected and used within the agency).
- The rest of the sectors when monies are collected this is done through Local Authorities and kept within the authority.

Germany:

- In general fees are collected to be directly used to finance the official controls (they are in fact mainly based on full cost recovery). In those Landers where fees go to the general budget in any case they are earmarked for the CA.

Sweden:

- Local and central authorities use fees directly to finance their official controls. Fees may not be used to finance other activities.

Table 3 Member State bonus-malus arrangements for official controls fees

Member State	Description
BE	Annual contributions are reduced by 50% if the Hazard Analysis Critical Control Point system of the FBO is certified by accredited bodies (recognised by AFSCA). If such an accredited system is not in place then FBOs must pay an additional 20% (2009), 60% (2010) and 100% (2011). Poultry slaughterhouses where FBOs are involved in controls have reduced fees. Animals in slaughterhouses that are not clearly identified are subject to a higher fee.
FR	Slaughterhouses are classified in 4 categories depending on their level of compliance. FBOs in the two categories with good compliance receive a reward, while FBOs in the two categories with poor compliance receive a punishment. The reward / punishment system is specified in the case study analysis **Error! Reference source not found.**.
DE	Some Landers have trialled a system of categorising meat establishments according to risk. The frequency of inspections is changed to reflect the risk posed by the FBO.
IT	The application of mandatory fees may take into consideration the FBO's previous record of conformity, risk category and the efficiency of their own checks.
MT	No mechanism exists to reward FBOs. However there is a procedure to levy fines for breaches of some elements of the Regulation.
NL	There is a fee per inspection visit and a time-based fee charged per quarter of an hour. FBOs that have better organised operations and require less CA time have lower cost. Where possible official controls are risk-based. There are surcharges for requests for controls outside regular working hours, and CA overtime that is incurred over the time originally requested by the FBO.
SP	The application of mandatory fees may take account of an FBO's previous record of conformity, its risk category, the efficiency of its own checks, and other items such as the level of administrative support required, or if inspections occur at unsocial hours.
SE	FBO's deemed to have a higher risk incur longer and / or more frequent inspections, and thus have higher inspection costs. The level of risk posed by an FBO is determined by the FBO's past record; compliance or non-compliance can lead to a reduction or an increase in the annual control time and annual fees.
UK	FBOs and CAs agree to the amount of time a CA will spend during inspections. FBOs can propose changes to the production process to decrease the need for CA presence.

Source: DG SANCO baseline

Table 4 Transparency and reporting to the public on fees for official controls by EU Member State

	BE	IE	UK	ES	FL	NL	SE	DE	EE	FR	IT	LT	PL	SK	MT	AT	BG	CY	CZ	DK	GR	HU	LU	LV	PT	RO	SI
All information available online	□	□	□	□	□	□	□																				
Legislation published in the official journal				□	□	□	□	□	□	□	□	□	□	□													
Information recorded but not available / published															□												
No information available / identified																□	□	□	□	□	□	□	□	□	□	□	□
			High transparency					Medium transparency							Low transparency				No information available / identified								

DG SANCO baseline

Table 5 Fee rates used for official controls across the EU-27

Member State	Flat rates only	Minimum rates only	Flat + min rates	Reduction below minimum rates	Flat rates on throughput or time basis
AT			✓		
BE					✓
BG	✓				✓
CY			✓		✓
CZ			✓		
DE			✓	✓	✓
DK			✓		✓
EE			✓		✓
ES			✓		✓
FI			✓		✓
FR	✓			✓	
GR	✓				
HU			✓	✓	✓
IE			✓		✓
IT	✓				✓
LT	✓			✓	✓
LU*					
LV			✓		
MT		✓			
NL			✓	✓	✓
PT			✓		
PL			✓		
RO			✓		✓
SE	✓				✓
SI			✓		
SK			✓		✓
UK	✓				✓
TOTAL	7	1	17	5	17

Source: DG SANCO Baseline data (2010)

**Luxembourg – no data available*

Table 6 Data for the Standard Cost Model obtained through the survey indicate high variation in FTE rates across MS (between €3.31/hour and €64.74/hour)

MS	CA	Response		
		Q1	Q2	Q3
BE	Federal Agency for the Safety of the Food Chain (FASFC)	€64.74 / hr	Staff time: 836 hours External costs: 0	Staff time: 836 hours External costs: 0
BG	Bulgarian Food Safety Agency	€1.86 / employee / hr	n/a	n/a
ES	SG Sanidad Exterior (MSPSI); SG Acuerdos Sanitarios y Control en Frontera (MARM)	€20.42 / hr	n/a	n/a
FI	Finnish Food Safety Authority (Evira)	€42 / hr	Staff time: 4 FTE External costs: €500,000	n/a
FR	Direction générale de l'alimentation (DGAI) – Ministère chargé de l'agriculture	€29.50 / hr	n/a	n/a
LT	State Food and Veterinary Service of Republic of Lithuania	€3.31 / hr	n/a	n/a
UK	Food Standards Agency (FSA)	Grade 7: €55.44 / hr Senior Executive Officer: €42.07 / hr	Staff time: 5-6 FTE	n/a

Source: Survey of CAs conducted as part of GHK Impact Assessment study.

Table 7 Potential impact of extending the scope of mandatory fees to include enterprises related to Regulations 852 /2004 and 183/2005, excluding primary holdings*

	UK	ES	CY	SE	PT	BE	AT	IE	BG	LU	IT	De	NL	DK	HU	SL	RO	PL	FI	LV	SK	EE	LT	CZ	FR	GR	MT
High impact	✓	✓																									
Medium impact			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓												
Low impact																✓	✓	✓	✓	✓	✓	✓	✓				
No data available																								✓	✓	✓	✓
					High impact (>20% enterprises)								Medium impact (10% - 19% enterprises)						Low impact (0% - 9% enterprises)								

Eurostat 2008

**Total number of enterprises in the following sectors: Processing and preserving of fruit and vegetables; Manufacture of vegetable and animal oils and fats; Manufacture of grain mill products, starches and starch products; Manufacture of prepared animal feeds; Manufacture of beverages; Wholesale of agricultural raw materials and live animals; Wholesale of food, beverages and tobacco; Retail sale of food, beverages and tobacco in specialised stores; Restaurants and mobile food service activities; Event catering and other food service activities; and, Beverage serving activities.*

Table 8 Potential impact of extending the scope of mandatory fees to include primary holdings (excluding other potentially relevant enterprises) related to Regulations 852 /2004 and 183/2005*

	RO	LT	BG	LV	PL	SK	SL	HU	CY	IE	PT	AT	EE	IT	ES	SE	SE	UK	FI	FR	DK	NL	BE	LU	CZ	GR	MT
High impact	✓	✓	✓	✓	✓	✓																					
Medium impact							✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓								
Low impact																				✓	✓	✓	✓	✓	✓		
No data available																										✓	✓
					High impact (>67% enterprises)								Medium impact (33% - 66% enterprises)						Low impact (0% - 33% enterprises)								

Eurostat 2008

**Primary holdings include: All holdings with arable land; All holdings growing permanent crops; All holdings rearing livestock; and, All holdings rearing other livestock.*

Table 9 Potential impact of extending the scope of mandatory fees to include enterprises and primary holdings related to Regulations 852/2004 and 183/2005*

	RO	LT	BG	PL	LV	SK	SL	HU	CY	IE	UK	PT	AT	ES	SE	IT	EE	FI	DK	DE	BE	FR	NL	LU	CZ	GR	MT
High impact	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓																	
Medium impact											✓	✓	✓	✓	✓	✓	✓	✓	✓	✓							
Low impact																					✓	✓	✓	✓	✓		
No data available																										✓	✓

	High impact (>67% enterprises)
	Medium impact (33% - 66% enterprises)
	Low impact (0% - 33% enterprises)

Eurostat 2008

**Total number of enterprises in the following sectors: Processing and preserving of fruit and vegetables; Manufacture of vegetable and animal oils and fats; Manufacture of grain mill products, starches and starch products; Manufacture of prepared animal feeds; Manufacture of beverages; Wholesale of agricultural raw materials and live animals; Wholesale of food, beverages and tobacco; Retail sale of food, beverages and tobacco in specialised stores; Restaurants and mobile food service activities; Event catering and other food service activities; and, Beverage serving activities. Primary holdings include: All holdings with arable land; All holdings growing permanent crops; All holdings rearing livestock; and, All holdings rearing other livestock.*

Annex XVIII: LABORATORIES – Consultations on current issues related to the accreditation of official laboratories and possible options for improvement – Discussion paper and results of the consultations

A. Discussion paper sent to the Chief Veterinary Officers (CVOs) and to the Regulation (EC) No 882/2004 competent authorities on current issues related to the accreditation of official laboratories and possible options for improvement

Background

Article 12 of Regulation (EC) No 882/2004 establishes that competent authorities may only designate laboratories that are accredited in accordance with certain European standards listed in the Regulation (EN ISO/IEC 17025 applicable to laboratories and EN ISO/IEC 17011 applicable to Accreditation Bodies).

The transitional period (Commission Regulation (EC) No 2076/2005) is over (1 January 2010) and no derogation is applicable with the only exception of Trichinella laboratories attached to slaughterhouses or game handling establishments (transitional period extended until end of 2013, Article 6 of Commission Regulation (EC) No 1162/2009).

Results of laboratory analysis are a key element in the framework of official controls carried out in order to verify compliance with EU legislation and to ensure that food is safe. Many decisions are based on the results of those analyses, including remedial action in case of non compliance. The results of laboratory tests must therefore be as sound and as reliable as possible. It is thus necessary that the analyses are carried out according to agreed validated methods and standards which can be endorsed by all stakeholders across the food chain within the EU and by our trade partners.

The lack of accreditation of some laboratories is a recurrent finding of the Food and Veterinary Office (FVO) missions, in particular for certain sectors and with differences between MS (some being more advanced than others).

Accreditation was discussed at the first working group on Regulation 882/2004 in May 2010, where DG ENTR presented the EU common framework for accreditation[143], in particular the role of national accreditation bodies and the co-ordinating role of the European co-operation for Accreditation (EA). A representative from EA was invited at the 2nd meeting of the working group on 27th September 2010, and her presentation was followed by discussions with the Member States (MS).

The purpose of this paper is to summarise the main points identified during the discussions and the suggestions from the MS with the aim to reflect on available options to improve/facilitate the enforcement of this important requirement.

[143] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30–47)

1. Existing legislation

Accreditation Bodies (ABs) use legislation, reference methods laid down in legislation and official documents as benchmark for the accreditation.

1.1. Introduction of new legal requirements including new analytical techniques
Accreditation standard EN ISO/IEC 17025 requires the laboratory to use validated methods: the laboratory "shall validate non-standardised methods, laboratory designed/developed methods, standardised methods used outside their intended range and amplifications of standardised methods to confirm that the methods are fit for the intended use" (cf. requirement 5.4.5.2). Validation is the confirmation that the particular requirements for a specific intended use of the method are fulfilled (cf. EN ISO/IEC 17025 requirement 5.4.5.1).In fact, without proper validation, it cannot be proved that the method is fit for the intended use, produces comparable results and can be used when making decisions. This accreditation requirement is not always easy in particular with new analytical techniques.

⇒ *Are general rules on how to legislate about the introduction of new analytical methods necessary? Should it be considered when drafting new legislation or when introducing new methodological requirements that the laboratories might need some time for the validation of the methods?*

1.2. Not "up-to-date" legislation.

Reference methods laid down in the legislation might be out of date or no standards are available but nevertheless they are still in the legislation.

⇒ *This point was raised at the meeting. Any concrete example(s)?*

2. Flexible scope/fixed scope

Historically, accreditation has generally been based on so called fixed scopes of accreditation. The fixed scope provides for a certain degree of flexibility as limited extensions to the scope can be done at any time throughout the assessment cycle.

In 2008 EA has also published its requirements for the accreditation of flexible scopes. They allow not only to carry out the methods in use, but also to add methods within the defined limits to the scope of accreditation on the basis that the competence of the laboratory to develop and validate methods has been positively evaluated.

EA has carried out some surveys and has confirmed that most ABs offer accreditation on flexible scopes. Those ABs who don't yet are in the process of developing the service.

However, the choice of a flexible scope would not necessarily result in a reduced cost. In fact, this accreditation is more demanding both initially and on-going. The flexible scope should be considered depending on the case. It is in general more suitable for activities where changes are frequent.

⇒ *Could guidance from EA on differences, pros and cons, etc. of flexible scope accreditation and fixed scope accreditation help each laboratory in order for it to take the best decision as regards to its specific situation?*

3. Emergency situations

Under emergency situations, for example during a food crisis (melamine, Sudan red, etc.), there is a need for having reliable results under time pressure by an accredited laboratory using a validated method because results given by:

- a non validated method cannot be used when making decisions,
- a non-accredited laboratory can be legally challenged.

⇒ *Does the flexible scope offer a solution? Should this be mentioned in the EA guidance mentioned in 2.?*

⇒ *If not, what other options are available?*

4. **Scope of the accreditation**
ABs have diverging interpretations of Article 12.3 of Regulation (EC) No 882/2004 according to which "the accreditation and assessment of testing laboratories (in accordance with EN ISO/IEC 17025) may relate to individual tests or groups of tests".

⇒ *Should a clearer definition of what is covered by accreditations related to "groups of tests" be discussed in the framework of EA on the basis of examples of differences provided to better understand the issue? (e.g. HPLC analysis of aflatoxins in pistachios: in some MS the scope of accreditation covers "foodstuffs" and in other MS laboratories need to be accredited for every different matrix). Should this be mentioned in the EA guidance mentioned in 2.?*

5. New laboratories or new staff

For new official laboratories, accreditation is as well a requirement to start operating. However they might not have proven the necessary experience to the AB. This problem can also be applicable to new staff who need proper training and time to be considered sufficiently competent.

⇒ *Concerning new personnel, EN ISO/IEC 17025 allows new personnel under condition of their appropriate supervision and training (5.2.1 "The laboratory management shall ensure the competency of all who operate specific equipment, who perform tests and/or calibrations, evaluate results and sign test reports and calibration certificates. When using staff which is undergoing training, appropriate supervision shall be provided").*

⇒ *Concerning new laboratories, is there a need to regulate the pre-accreditation phase so as to allow new laboratories to operate (as official laboratories) prior to their formal accreditation? Which legal consequences would a pre-accreditation phase have?*

6. Proficiency tests

Participation at proficiency tests (PTs) is used as external quality control to prove that the laboratory is indeed capable of producing valid results. ISO 17025 recommends the participation at PTs ("5.9 The laboratory shall ensure the quality of results by monitoring test and/or calibration results. This monitoring shall be planned and reviewed and may include, but not limited to the … participation in inter-laboratory comparison or proficiency testing

programmes") and the results of the participation are considered by the ABs as an important source of information.

However, in some areas, like residues of veterinary medicines[144] and pesticides[145], legislation provides compulsory participation at PTs for official control laboratories. This apparently results in a heavier burden for laboratories with a large scope of accreditation.

Also, there can be areas for which there are no PTs schemes yet.

⇒ *Are there divergent interpretations of EN ISO/IEC 17025 requirement 5.9 made by ABs ?*

The problems raised seem more to be linked with the legal requirement of mandatory participation at PTs than with the EN ISO/IEC 17025 accreditation.

⇒ *Concerning residues of pesticides, could a common (e.g. together with EU Reference Laboratories) and precise understanding of the implementation of Article 28.3 of Regulation (CE) No 396/2008 ("All laboratories analysing samples for the official controls on pesticides residues shall participate in the Community proficiency tests for pesticides residues organised by the Commission") be of any help?*

⇒ *Concerning residues of veterinary medicines:*

1. *Should any legal modification be envisaged during the review of Directive 96/23/EC and its implementing Decision (EC) No 396/2008 (Annex : "laboratories must prove their competence by regularly and successfully participating in adequate proficiency testing schemes recognised or organised by the national or community reference laboratories");*
2. *Could a common (e.g. together with EU Reference Laboratories) and precise understanding of the implementation of this requirement of the Annex be of any help?*

7. Rapid tests

Rapid tests are by definition easy to use and don't require high expertise or sophisticated equipment. They provide results within a very short time, allowing testing of a high number of samples in a speedy manner; therefore they are very useful for controls purposes. Rapid tests aim at having low percentage of false negatives. However, these interesting characteristics make their performance difficult to accredit as they are not as accurate as other more sophisticated methods.

In some cases if the result obtained after a rapid test is positive, it needs confirmation by confirmatory methods and usually the scope of the accreditation covers the performance of both tests. If they are not used as screening i.e. if they have a meaning by themselves (e.g. microbiological tests for E. coli in water or Salmonella in meat), their performance can also be accredited independently.

⇒ *A discussion within EA on what are the difficulties for the ABs to accredit the performance of rapid tests could be organised. Are these difficulties linked to a lack of clear validation requirements for rapid tests? Would therefore guidance on the validation of rapid tests by the EURLs help?*

[144] Commission Decision 98/179/EC.
[145] Regulation (EC) No 396/2008

B. Results of the consultations carried out

Following input from the Member States and discussions have been taken into account in this part:

- meetings of the Working Group on the general application of Regulation (EC) No 882/2004 held in May and September 2010,
- answers from Regulation (EC) No 882/2004 competent authorities to the discussion paper presented in part A of this annex,
- meeting of the Working Group on the general application of Regulation (EC) No 882/2004 held in May 2011,
- answers from the Chief Veterinary Officers (CVOs) to the discussion paper presented in part A of this annex,
- meetings in 2011 of the Working Group of Chief Officers for Plant Health (COPHs) and of its Task Force on the inclusion of plant health in Regulation (EC) No 882/2004,
- meetings in 2011 of the Task Force on " Plant reproductive material" under Regulation (EC) No 882/2004.

Twelve issues have been identified during these consultations and discussions. Each issue as well as the main comments from the Member States on it and the corresponding favourite option(s) are described hereafter.

1. Article 12.3 of Regulation (EC) No 882/2004

Issue 1:

Article 12.3 of Regulation (EC) No 882/2004 according to which the accreditation of laboratories in accordance with ISO 17025 **"may relate to individual tests or groups of tests"** is unclear.

Main comments from the MS and corresponding options:

The sentence needs to be clarified.

« Groups of tests » refers in particular to flexible scope accreditation. EA Guide – 2/15 on accreditation of flexible scopes needs to be clarified.

- ***Option: clarification of Article 12 of Regulation (EC) No 882/2004****: unless otherwise specified, the scope of accreditation shall include all methods used by the laboratory as official laboratory.*
- ***Option: clarification of EA Guide – 2/15 on accreditation of flexible scopes.***

2. Use of a method recently required in legislation

Issue 2:

The **use of a method is a recent/new requirement in Union legislation** and requires the validation of the new method and (in general) a new accreditation or an extension of accreditation of the laboratory.

General comments from MS and corresponding option:

Time is needed for the validation of the method and the accreditation of the laboratory. The use of a validated but « not (yet) accredited » method by an already ISO 17025 accredited official laboratory should be possible.

- ***Option: in this case, possibility for the CA to temporarily designate the laboratory*** *under specific conditions (alternative guarantees): the laboratory is already accredited according to ISO 17025 (i.e. a solid quality assurance system is already in place) to ensure sound and reliable results; analysis/diagnosis are carried out under the supervision of the CA or the national reference laboratory (NRL); the temporary designation shall not exceed one year renewable once –* ***Modification of Article 12 of Regulation (EC) N° 882/2004.***

3. Changes of a method already in use

Issue 3:

Changes of a method already in use require a new accreditation or an extension of the accreditation already obtained by the laboratory.

General comments from MS and corresponding option:

Time is needed for the validation of the method and the (extension of) accreditation of the laboratory. The use of a validated but « not (yet) accredited » method by an already ISO 17025 accredited laboratory should be possible.

- ***Option: in this case, possibility for the CA to temporarily designate the laboratory*** *under specific conditions (alternative guarantees): the laboratory is already accredited according to ISO 17025 (i.e. a solid quality assurance system is already in place) to ensure sound and reliable results; analysis/diagnosis are carried out under the supervision of the CA or the national reference laboratory (NRL); the temporary designation shall not exceed one year renewable once –* ***Modification of Article 12 of Regulation (EC) N° 882/2004.***

4. Emergency situations and emerging risks

Issue 4:

Emergency situations or cases of emerging risks where a **sudden increase of analytical needs** requires the use by official laboratories of a non standardised or non validated method or a standardised method which is not included in their scope of accreditation

General comment from MS and corresponding option:

The swift and efficient management of the situation/risk is the priority. The use of a validated but « not (yet) accredited » method by an already ISO 17025 accredited laboratory should be possible.

- ***Option: in this case, possibility for the CA to temporarily designate the laboratory*** *under specific conditions (alternative guarantees): the laboratory is already accredited according to ISO 17025 (i.e. a solid quality assurance system is already in place) to ensure sound and reliable results; analysis/diagnosis are carried out under the*

supervision of the CA or the national reference laboratory (NRL); the temporary designation shall not exceed one year renewable once – ***Modification of Article 12 of Regulation (EC) N° 882/2004.***

5. Small sized *Trichinella* laboratories

Issue 5:

Small sized *Trichinella* laboratories attached to slaughterhouses or game handling establishments have important difficulties to be accredited according to ISO 17025.

General comment from MS and corresponding option:

The requirement for these laboratories carrying out extremely basic tests, to be accredited according to ISO 17025 is disproportionate and not adapted.

↳ ***Option: modification of Article 12 of Regulation (EC) No 882/2004: possibility for the competent authority to permanently derogate small sized laboratories attached to food business operators' (FBOs) premises***

- *exclusively carrying out specific basic tests prescribed in Union legislation on a limited number of samples pertaining to the FBOs' process,*
- *using standardised/validated methods,*
- *having a quality assurance system in place,*
- *and operating under the supervision of an official laboratory accredited according to ISO 17025 or of the competent authority.*

6. Accreditation of plant health and plant reproductive material laboratories

Issue 6:

Currently official laboratories operating under the Plant Health and/or the Plant Reproductive Material regimes are not obliged to be accredited according to ISO 17025. There is a need to **improve reliability, soundness and uniformity of their results**. Weaknesses and problems as regards the performance of official Plant Health or Plant Reproductive Material laboratories have often been identified during FVO audits.

General comments from MS:

Worldwide, there is a strong trend towards accreditation of laboratories. The **move towards accreditation has to be supported** under **certain conditions**. Many official Plant Health or Plant Reproductive Material laboratories are already accredited.

↳ ***Option: modification of Article 12 of Regulation (EC) No 882/2004: extension of the mandatory accreditation:***

- to laboratories under the Plant Health and the Plant Reproductive Material regimes carrying out **plant (or seeds) health tests**,
- after a **transitional period,**
- with the possibility to:

- determine **exemptions to Article 12.3** taking into account the characteristics of the different sectors (e.g. accreditation at least for a single diagnostic protocol or a single protocol per taxonomic discipline),
- **permanently derogate** universities and research centres,
- **temporarily designate laboratories** (like foreseen for food/feed and animal health laboratories – see issues 2, 3 and 4)

7. Accreditation of animal health laboratories

Main comments from MS and corresponding option:

Accreditation is globally not a problem. Accreditation may however be difficult:

- for methods used in diagnosis of viral diseases because of the important resources needed for documentation and validation of the methods (solution: accreditation for types of methods or techniques?),
- for methods used in the diagnosis of parasitic diseases because of the multitude of parasitic diseases and the broad spectrum of diagnostic tests.

- ***Option: modification of Article 12 of Regulation (EC) No 882/2004:*** possibility to determine **exemptions** to Article 12.3 taking into account the characteristics of the different sectors.

8. Participation in proficiency tests (PTs) or comparative tests (CTs)

Issue 8:

ISO 17025 recommends the participation in PTs/CTs: "5.9 The laboratory shall ensure the quality of results by monitoring test and/or calibration results. This monitoring shall be planned and reviewed and **may** include, but not limited to the … participation in inter-laboratory comparison or **proficiency testing programmes**".

In some areas, like **residues of veterinary medicines and residues of pesticides**, EU legislation provides for the **mandatory participation in PTS/CTs.**

Interpretations of ISO 17025 on this point differ from one Member State to another. Different mandatory minimum frequencies of participation in PTs/CTs furthermore exist accross the EU. Finally, a **lack of participation of laboratories in PTs/CTs** and a **lack of PTs/CTs organised** are sometimes reported.

Main comments from the MS and corresponding option:

The frequent/regular participation in PTs/CTs relevant to the scope of accreditation of the laboratory and the satisfactory performance at these PTs/CTs are **absolutely necessary/ mandatory.**

The participation in PTs/CTs has to be verified during the assessment of the laboratory by the accreditation body. The lack of participation in PTs/CTs is sometimes/rarely due to high costs, more often to the unavailability of PTs/CTs.

To ensure a higher level of participation at PTs/CTs, the participation at PTs organised by the EU reference laboratories (EURLs) should be made possible for routine laboratories, as well as the possibility to participate at PTs/CTs organised by national reference laboratories

(NRLs) from other MS. Less limited/narrow scopes of accreditation according to ISO 17025 and "a more horizontal" organisation of PTs/CTs should also be considered.

↳ ***Option: modification of Article 12 of Regulation (EC) No 882/2004: mandatory participation of laboratories in PTs/CTs organised in their scope of accreditation by the EURL or the NRL on request by either of them.***

9. Validation of methods

Issue 9:

According to ISO 17025, the **laboratory has to use standardised methods or validated methods:**

- Requirement 5.4.5.1: « Validation is the confirmation by examination and the provision of effective evidence that the particular requirements for a specific intended use are fulfilled ».
- Requirement 5.4.5.2: « The laboratory shall validate non-standardised methods, laboratory designed/ developed methods, standardised methods used outside their intended range and amplifications of standardised methods to confirm that the methods are fit for the intended use".

Which methods can be given equivalent status to « standardised methods »?

Main comments from MS and corresponding option:

Methods validated by EURLs/NRLs should be given equivalent status to « standardised methods »:

- validated methods by EURLs: all EU accreditation bodies should deliver the accreditation for their use within the intended scope without requesting a supplementary internal validation by the laboratory (only a verification by the laboratory would be necessary);
- validated methods by the NRL in a MS: the national accreditation body of this MS should deliver the accreditation for their use within the intended scope without requesting a supplementary internal validation by the laboratory in the MS (only a verification by the laboratory would be necessary).

↳ ***Option: modification of Article 11 of Regulation (EC) No 882/2004****: methods validated by EURLs/NRLs are given equivalent status to « standardised methods » and are incorporated accordingly in the cascade of methods of Article 11.1 of Regulation (EC) No 882/2004.*

10. Specific mandatory methods in legislation

Issue 10:

There is a global lack of flexibility of the system (e.g. in case of changes of the method, emergency situations) due to too **specific** mandatory methods in EU legislation.

Proposal from several MS:

Mandatory method performance criteria should be preferred when establishing legislation (instead of mandatory specific methods) to ease/fasten the introduction and the use of the latest and most appropriate method.

11. Flexible scope / fixed scope accreditation

Issue 11:

There are **very different/diverging requirements in particular for flexible scope accreditation** (but also for fixed scope accreditation) **from one national accreditation body to another**.

Main comments from MS and corresponding option:

The EA Guide – 2/15 on accreditation of flexible scopes is too general. A harmonised interpretation of the accreditation of flexible scopes is absolutely needed across the EU. If not, huge differences in levels of difficulty, time needed and costs for laboratories will continue to exist.

The accreditation of flexible scopes is useful in particular when no specific assessment by accreditation body prior to the addition of the matrix/analyte/method to the scope is requested (e.g. in case of emergency situations and emerging risks).

Some examples of diverging interpretations between accreditation bodies are:

- In some Member States, a fixed scope accreditation can only cover the use of a specific method (to be followed very precisely by the laboratory) on a specific matrix in order to detect a specific substance, virus, bacteria, etc. The consequence is for instance that for each new use of the method (e.g. on another very similar matrix), the laboratory has to have a new accreditation. In other Member States, fixed scope accreditations are given for broader combinations method/analyte/matrix making it for instance possible for the laboratory to use the method on another similar matrix without undergoing a new accreditation procedure.
- In some Member States, the use of a slightly newer version of a method (on the same matrix in order to detect the same substance, virus, bacteria, etc) by an official laboratory being already accredited according to ISO 17025 for the use of the slightly older version is only possible when the laboratory has a flexible scope accreditation for the use the older version of the method. In other Member States, the use of the slightly newer version is possible for laboratories having only a fixed scope accreditation for the use of the older version of the method.
- When a new method is already covered by the flexible scope accreditation of the laboratory, then in some MS the accreditation body includes it automatically in the scope of accreditation without carrying out a specific assessment of the laboratory. In other Member States, the accreditation body first carries out a specific accreditation assessment.
- For some accreditation bodies but not for others, a flexible scope accreditation can cover the use of all methods using a same analytical technique (e.g. ELISA, LC-MS/MS).

↳ ***Option: additional EA guidance on pros and cons of flexible and fixed scopes, with examples, on what a flexible scope could cover and corresponding precise requirements, on degrees of flexibility of flexible scopes, on flexible scope accreditation assessments by Abs***

12. New laboratories/new personal

Issue 12: **New laboratories** have first to be accredited according to ISO 17025 before being able to be designated by the competent authority. The possibility to **use new staff** in already accredited laboratories is very difficult.

Main comments from MS and corresponding option:

The designation, by the competent authority, of the laboratory before its formal accreditation is risky (because the laboratory is not yet accredited for the use of any method), difficult and not necessary. It shouldn't be allowed.

ISO 17025 allows already touse new personal under the condition of their appropriate supervision and training.

↳ ***Option: no action.***

Annex XIX: LABORATORIES – Costs relating to the introduction of a mandatory accreditation of official laboratories carrying out plant health tests and to the creation of EU reference laboratories

1. Cost relating to the introduction of a mandatory accreditation of laboratories carrying out plant health tests

The inclusion of plant health and plant reproductive material regimes in the scope of Regulation (EC) N° 882/2004 would legally create the obligation for laboratories carrying out plant health tests to be accredited according to EN ISO/IEC 17025. Some flexibility would be foreseen as regards the scope of accreditation (laboratories would at least be accredited for a single diagnostic protocol or a single diagnostic protocol per taxonomic discipline) and the transitional period (five years). The costs for the initial accreditation (valid for four years) would be borne by the EU, the following accreditation costs (following accreditations are each time valid for five years) would be for the laboratories themselves and should be included in the cost-recovery based fees to the extent that a laboratory carries out official diagnoses.

Financial impact: accreditation according to EN ISO/IEC 17025 requires laboratories to set up a quality assurance system, including the appointment of a quality assurance officer (this may be an additional task for a staff member who is not actively involved in the diagnoses). Quality assurance should be good practice for any modern laboratory and the associated costs should therefore not be taken into account as additional. The transitional period of five years should normally be sufficient.

The additional costs relate to the formal accreditation itself, which depends on the size of the laboratory and the price level in the MS. Based on a survey of MS laboratories[146] and information available from different accreditation bodies, the average costs of the accreditation according to EN ISO/IEC 17025 are assumed to be €3,000 per laboratory per year.

1.1. Official laboratories performing plant health tests under the EU plant health regime

In some MS, the laboratories have already been accredited or largely so. In others, this is not yet the case. The number of laboratories per MS presumably ranges between one (for centralised MS)[147] and 26 (for MS with regional laboratories). In this study, it is assumed that 20 MS still have laboratories which need to apply for accreditation that this would concern on average six laboratories[148] per MS.

Based on these assumptions, the accreditation costs would be:

- for the Commission: 20 x 6 x € 3,000 x 4 years = € 1,44 million (total costs)

- for the MS: 20 x 6 x €3,000 = €360,000 per year

[146] Replies were received from AT, BE, CZ, DE, DK, ES, FR, IE, LV, NL, MT, PL, SE, SI, SK.
[147] One MS does not have any such laboratory at all but has contracted out all analyses to other MS.
[148] This is the average number of relevant laboratories in the 15 MS that replied to the consultation.

1.2. Official laboratories performing plant health tests under the EU plant reproductive material regime

Official laboratories under the EU plant reproductive materials regime would only be required to be accredited according to EN ISO/IEC 17025 when they carry out plant health (i.e. seed health) tests.

Specialised seed testing laboratories as well as laboratories charged with the testing of:

- seed potatoes,

- wine and fruit plant propagating material, vegetable young plants, forest reproductive material and propagating material of ornamental plants

would be concerned.

1.2.1. Official seed testing laboratories

According to the information available (in particular data from the International Seed Testing Association (ISTA) and information available on the websites of the laboratories), it is assumed that approximately 35 official seed testing laboratories in the EU carrying out plant health (i.e. seed health) tests are not yet accredited according to EN ISO/IEC 17025[149].

Based on these assumptions, the accreditation costs would be:

- for the Commission: 35 x € 3,000 x 4 years = € 420,000 (total costs),

- for the MS: 35 x €3,000 = €105,000 per year.

1.2.2. Official laboratories testing seed potatoes

Laboratories charged under the plant reproductive material regime with testing of seed potatoes (i.e., small potato tubers for planting) would in general not incur additional costs as, in principle, they also carry out the plant health tests under the EU plant health regime and any supplementary accreditation costs are covered above under that regime.

1.2.3. Official laboratories testing wine and fruit plant propagating material, vegetable young plants, forest reproductive material and propagating material of ornamental plants

The number of laboratories concerned not yet accredited according to EN ISO/IEC 17025 is estimated to be 70.

Based on these assumptions, the accreditation costs would be:

- for the Commission: 70 x € 3,000 x 4 years = € 840,000 (total costs),

- for the MS: 70 x €3,000 = €210,000 per year.

In total:

- the total costs for the Commission (financing of the initial accreditations valid for four years) would be: 1,440,000+ 420,000 + 840,000= €2,700,000

[149] Most of these laboratories are accredited according to and by ISTA which does not comply with the requirements for national accreditation bodies and the operation of accreditation of Regulation (EC) N° 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

- the yearly costs for the MS for the accreditation according to EN ISO/IEC 17025 of official laboratories carrying out plant health tests would amount to 360,000 + 105,000 + 210,000 = €675,000

2. Cost relating to the creation of EU Reference Laboratories (EURLs) for plant health diagnosis

The inclusion of plant health and plant reproductive material regimes in the scope of Regulation (EC) N° 882/2004 would legally create the possibility to set up EURLs in the these areas and support these financially from the EU budget.

Financial impact: it is estimated that in due course EURLs would be set up for circa ten to twelve priority pests. At present, the EU supports 44 EU Reference Laboratories in the food, feed and animal health areas covered by Regulation (EC) N° 882/2004 for a total annual sum of €14.2 millions (figure for 2010/2011); the average EU support thus amounts to €323,000. This implies that the annual costs for EURLs in the plant health and plant reproductive material areas would be €3.2 millions to €3.9 millions (based on this our assumption is €4 millions).

Annex XX: DIRECTIVE 96/23/EC - Consultation of the competent authorities in the MS on the impacts of the different options regarding the revision of Directive 96/23/EC – Questionnaire and results of the consultations

The questionnaire addressed to the Member States is made of parts 1, 2, 3 and 4 hereafter. Part 5 presents the results of the consultations carried out.

1. About the consultation

1.1. Background of the consultation

Pharmacologically active substances administered to animals both intentionally and non-intentionally, may result in the presence of residues in the food obtained from such animals. Whereas animals need to be treated for animal health and welfare reasons, the intake of residues in the food can be harmful to the consumers.

The adoption of Directive 96/23/EC aimed at increasing consumer protection by establishing harmonised rules for the controls to be carried out by Member States on residues of veterinary medicines in live animals and foodstuffs of animal origin produced in the EU and imported. The first objective of this Directive was the fight against the illegal use of growth promoters in livestock. The second was to ensure that consumers are exposed neither to harmful residues of veterinary medicinal products and pesticides, nor to contaminants, at levels above those established by the legislation.

In 2003, the Commission launched a broad consultation process to review the legislation on residues of pharmacologically active substances used for the treatment of animals *(Reflection Paper on residues in foodstuffs of animal origin)*[150]. The main purpose of the exercise was to eliminate inconsistencies between different legal instruments and to replace them with a single act.

Indeed, at that time, the following legislative acts were in force:

1. Regulation (EC) No 2377/90[151] laying down Community procedures for the establishment of maximum residues limits (MRLs) of pharmacologically active substances in foodstuffs of animal origin ("*MRLs regulation*"),
2. Council Directive 96/22/EC[152] concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (ban on the use of hormones for growth promotion - "*Hormone Directive*"),
3. Council Directive 96/23/EC[153] on measures to monitor certain substances and residues thereof in live animals and animal products ("*Residue Control Directive*").

Member States (MS), Third Countries (TC) and stakeholders provided substantive encouraging feedback during the abovementioned process[154] and Regulation (EC) No 2377/90

[150] Reflection Paper on residues in foodstuffs of animal origin
[151] OJ L 224, 18.8.1990, p. 1.
[152] OJ L 125, 23.5.1996, p. 3
[153] OJ L 125, 23.05.1996, p. 10
[154] Comments to the Reflection paper-29.6.2004

as well as Directive 96/22/EC were amended. Indeed some of the issues identified by the consultation process were addressed through the adoption of the following acts:

1. Regulation (EC) No 470/2009[155] laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin

   The aim of this new Regulation is to limit the exposure of consumers to pharmacologically active substances and at the same time to enhance the availability of veterinary medicinal products in the European Union (EU).

2. Directive 2008/97/EC[156] amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists

   This act introduced two main modifications of Directive 96/22/EC: the limitation of the scope of Directive to food-producing animals only and the total prohibition of the use of 17 beta-oestradiol in food producing animals.

Directive 96/23/EC was not revised.

In 2004, with the adoption of Regulation (EC) No 882/2004[157] on official controls performed to ensure the verification of the compliance with feed and food law, animal health and animal welfare rules, a general framework for the performance of official controls along the food chain was established. The "*Official Controls Regulation*" created an integrated approach to official controls in all areas related to the food chain. Considering that during the abovementioned exercise of review of the rules on veterinary medicines was ongoing, controls on residues covered by Directive 96/23/EC were excluded from the scope of Regulation (EC) No 882/2004.

In July 2009, the Commission transmitted a Report to the European Parliament and the Council on the implementation of Regulation (EC) No 882/2004 since 1st January 2006, reporting on the first years' experience of enforcement and pointing at some necessary reviews to be considered. The Report indicated the need to consider the possibility of integrating the rules currently applicable to official controls on pesticides, contaminants and residues of pharmacologically active substances in food into the framework of Regulation (EC) No 882/2004, so as to rationalise and simplify the overall legislative framework whilst allowing the Member States to integrate controls on residues in food in their multi-annual control plans (MANCPs). This would also allow a more consistent approach on controls of residues of veterinary medicines in food produced or imported to the EU.

1.2. Purpose of the consultation

This consultation is part of the exercise aiming to review Directive 96/23/EC. A roadmap for the exercise is published at:

http://ec.europa.eu/governance/impact/planned_ia/docs/418_sanco_rev_dir_substances_animals_en.pdf.

In order to align the legislative framework applicable to official controls on residues of veterinary medicinal products with the more modern principles established in Regulation

[155] OJ L 152, 16.6.2009, p. 11
[156] OJ L 318, 28.11.2008, p. 9
[157] OJ L 165, 30.04.2004, p. 1

(EC) No 178/2002[158] as well as with the provisions of Regulation (EC) No 882/2004 and, notably, with the need to plan and carry out control activities on the basis of risks, the extensive material collected in the framework of the evaluation started in 2003 will be considered, insofar as it is still relevant after the adoption of Regulation (EC) No 470/2009, and complemented with fresher input and additional feedback from MS and stakeholders to specifically address the issues related to the alignment of the veterinary medicines' residues controls with the requirements of Regulation (EC) No 882/2004.

Therefore the purpose of this consultation is twofold:

1. to update (relevant) information gathered during the consultations carried out in the past,
2. to collect additional data to be used to assess the impact of the options available: MS are requested to provide as detailed information as possible to allow the evaluation of the impacts of the different options proposed.

The information collected through this questionnaire will be used to assess the potential impacts of the main options possible to reach the objective stated, consideration being given also to possible synergies and trade-offs.

1.3. Who is consulted and how to submit contributions

This questionnaire is addressed to the Competent Authorities (CA) of the Member States (MS) responsible for the management of official controls in the food, feed and animal health sectors (members of the "Working group on the general application of Regulation (EC) No 882/2004"), to the Chief Veterinary Officers (CVOs) of the Member States as well as to officials in the MS in particular responsible for the management of residues of veterinary medicinal products control plans in the Member States (members of the "Residue expert working group"). The questionnaire can be shared with other departments concerned.

For the purpose of consolidating the responses, only one contribution per Member State should be sent to the Commission per email to Alexander Rogge at alexander.rogge@ec.europa.eu .

An acknowledgement of receipt will be issued for each contribution received within five working days.

1.4. Timetable

All contributions should be submitted to the Commission by the 1st April 2011 latest (the ones received before this deadline being of course warmly welcomed).

1.5. Next steps

All contributions will be carefully analysed. A summary of the outcome of the consultation will be published on the website of the European Commission and also sent directly to all contributors. The results of the consultation will be used for the impact assessment report on the revision of the Directive 96/23/EC.

[158] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety – OJ L 31, 01.02.2002, p. 1

2. Problem definition and objective

Directive 96/23/EC brought about a significant degree of harmonisation of controls on residues of veterinary medicinal products and contaminants in the MS. The act provides for a minimum number of samples to be taken for each type of live animal or product per group or sub-group of substances according to the animal production as listed in the Annexes.

While harmonisation clearly has the advantage of ensuring a uniform approach to enforcement actions performed to fight against the use of illegal substances and to control compliance with levels of residues of authorised veterinary medicinal products, the lack of flexibility, which is the consequence of the detailed and over prescriptive nature of the Directive, may result in a reduced efficiency of the controls carried out. In fact, this rigidity:

- limits the possibility to establish control priorities and to allocate controls resources on the basis of risks (other than the size of the animal production),
- does only permit very limited risk based changes to frequencies and methods of controls.

The general objective of the current exercise is therefore to assess the possibility of aligning the rules applicable to official controls on residues of veterinary medicines to the principles and rules on which the system of official controls is based following the adoption of Regulation (EC) No 882/2004, so as to rationalise and simplify the overall legislative framework and to allow MS more flexibility necessary to ensure the integration of residues controls into their MANCPs.

More specifically the objective announced above would require the following to be achieved:

- simplify existing rules and eliminate overlaps which may result from the implementation of Directive No 96/23/EC and other legislation, in particular, on contaminants (Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food and Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs) and plant protection products (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 and amending Council Directive 91/414/EEC);
- ensure that official controls on residues of veterinary medicinal products are carried out with a frequency established on the basis of risk and taking into account past records of compliance, any indication of non-compliance and reliability of own checks;
- if necessary, ensure a minimum level of control of certain substances whose illegal or non-compliant use would represent a particularly serious health risk (e.g. growth promoters or antibiotics);
- reduce the burden resulting from redundant or unnecessary procedures, in particular those laid down in Directive 96/23/EC for the approval of the control plans, and eliminate overlapping requirements on the MS;
- in line with EU's international obligations under WTO SPS Agreement, increase transparency vis-à-vis Third Countries by simplifying import requirements and making them clearer (increased transparency facilitating also EU's exports due to a better understanding of Third Countries of EU's control system(s)).

3. Data needs

A significant amount of information is already available in the Residues Application in particular in terms of number of samples analysed and results of analysis. However, the Commission is lacking important data on the cost of the residues controls which is indispensable to evaluate the impacts of the different options proposed.

Therefore, the following data would be necessary:

- total annual cost of implementing the national residue control plan (NRCP) referred to in Chapter II of Directive 96/23/EC including all expenses: staff, laboratories, consumables, overheads, etc.,
- average total cost per sample, including all expenses,
- average cost per sample for laboratory analysis only,

Data on number of samples and on results of analysis will be taken from submissions to the Residues Application. Please provide the following data only if figures differ from those recorded in the Residues Application, stating the reasons for this difference (e.g. additional control system in place):

- number of samples taken for residue controls per year under Directive 96/23/EC (please provide the average figure per year for the last two years),
- number of non-compliant samples.

4. Key issues

4.1. Key issue 1- List of substances in Annex I

Annex I of Directive 96/23/EC provides for two groups of substances to be investigated:

- Group A "substances having anabolic effect and unauthorised substances" whose use is partly or entirely explicitly prohibited in food producing animals,
- Group B "veterinary drugs and contaminants":
    - B1 and B2 substances that may be authorised for use in veterinary medicinal products for food producing animals,
    - B3 "other substances and environmental contaminants" (organochlorine compounds, organophosphorus compounds, chemical elements, mycotoxins, dyes and "others").

Minimum sampling levels depending on type of animals (bovine, porcine, ovine, caprine and equine animals, poultry) or animal products (aquaculture products, milk, eggs, honey, rabbit meat, meat of wild and farmed game) are required for the groups and sub-groups of substances.

Specific enforcement measures to be taken in case of non-compliance depend on the classification of the substance: non-compliance with Group A substances is reckoned as more severe than exceeding MRLs for an authorised substance of Sub-Group B1 or B2.

Finally, unlike substances of Groups A, B1 and B2, the presence of the substances and contaminants referred to in Sub-Group B3 (e.g. cadmium, lead, mercury, PCBs and dioxins, aflatoxin B1, ochratoxin A) is in general not due to intentional use.

4.1.1. Contaminants

Issue

According to Article 2 of Regulation (EC) No 315/93 laying down Community procedures for contaminants in food, foodstuffs shall not be placed on the market when they contain a contaminant exceeding a maximum level set in the relevant legislation. Commission Regulation (EC) No 1881/2006 sets the maximum levels for certain contaminants listed in its Annex: nitrate, mycotoxins, metals (lead, cadmium, mercury, inorganic tin), 3-monochloropropane-1,2-diol (3-MCPD), dioxins and PCBs, and Polycyclic Aromatic Hydrocarbons (PAHs), in food of animal origin (e.g. milk, eggs, fish, meat of bovine animals, sheep, pig and poultry). Unlike Directive 96/23/EC, the Regulation does not provide for the mandatory establishment and approval of a control plan, nor for a minimum number of samples to be planned and analysed each year: Member States carry out control activities on the basis of their own risk assessment.

Article 9 of Commission Regulation (EC) No 1881/2006 furthermore requires Member States to report to the Commission findings from official controls on most of the mycotoxins, as well as on dioxins, PCBs, acrylamide and furan, whereas according to Article 8 of Directive 96/23/EC, MS have to forward annually to the Commission the results of their monitoring plans comprising all substances listed in its Annex.

Finally, methods for sampling and analysis for contaminants are laid down in different specific legislation and the approaches for the validation of analytical methods and the establishment of measurement uncertainty differ between both (on one hand, Commission Regulations (EC) No 333/2007 (lead, cadmium, mercury, inorganic tin, 3-MCPD, benzo(a)pyrene), No 1882/2006 (nitrates), No 401/2006 (mycotoxins), No 1883/2006 (dioxins and dioxins-like PCBs) and, on the other hand, Commission Decision 2002/657/EC implementing Directive 96/23/EC).

Against this background, several Member States suggested in their answers to the Reflection Paper, contaminants to be taken out of the scope of this Directive 96/23/EC and the intensity of official controls to be based on each Member State's risk assessment.

Number of samples and results:

In 2009, **45 014** samples were analysed in the EU under Directive 96/23/EC for substances in group B3 of which 487 samples were found to be non-compliant (1.08 %).

The highest percentage of non-compliant samples in almost all species was found for chemical elements (B3c) (2.25 %). Cadmium, lead and mercury were the most frequently reported elements. Instances of non-compliance for organochlorine compounds (B3a) and organophosphorus compounds (B3b) were much lower: 0.19 % and 0.04 %, respectively. For mycotoxins (B3d), nine non-compliant samples for ochratoxin A in pigs, one for aflatoxin B1 in sheep and goats, and five for aflatoxin M1 in milk were reported. Dyes (B3e) were reported in aquaculture (1.6 %). Substances found were malachite green and leuco-malachite-green[159].

There is no overview of the number of samples analysed for control of contaminants in food of animal origin in the EU under the contaminants legislation.

[159] EFSA Report for 2009 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products

Questions (1)

Evaluation of potential impacts of repealing the requirements on official controls on contaminants currently laid down in Directive 96/23/EC (so that Regulation (EC) No 882/2004 and the existing specific EU contaminants legislation would only apply)

1. Do you agree with the description of the issue?

Yes

No

Comments

2. Socio economic impacts

2.1. How many samples are taken for Subgroup B3 per year in your Member State? (please provide data if different from the information submitted to the Residues Application and exclude pesticide residues as they are treated in 4.1.2 hereafter)

2.2. Do you consider that the number of samples taken to test for the presence of contaminants would have been globally lower in your country, had you been allowed to establish the frequency of sampling only on the basis of risk assessments?

If yes,

- would you be able to give an indication of the impact of the reduction (in %, both in relation to the number of samples and to the overall costs)?
- would you expect the sampling capacity that would be freed to be used to increase sampling on other substances?

If not,

- would you expect an increase of the number of samples taken for contaminants?

or

- would you expect the level to remain more or less the same?

3. Public Health impacts

Would an exclusively risk based system of controls for contaminants (and thus the repeal of the requirements on official controls on contaminants currently laid down in Directive 96/23/EC) improve consumer protection?

Yes. Please substantiate your answer.

No. Please substantiate your answer.

Other comments:

4. Administrative burden impacts

What would be the effect on administrative burden on national Competent Authorities if the requirements on official controls on contaminants currently laid down in Directive 96/23/EC were repealed so that Regulation (EC) No 882/2004 and the existing specific EU contaminants legislation would only apply?

Administrative burden would increase. Please substantiate your answer.

Administrative burden would decrease. Please substantiate your answer.

Administrative burden would not change. Please substantiate your answer.

Other comments:

5. Other impacts

Please indicate any other impact that you consider relevant.

4.1.2. Pesticide residues

Issue

Directive 96/23/EC determines minimum sampling levels to be respected in the national monitoring plans depending on type of animals or products for the following subgroups of pesticides:

- carbamates and pyrethroids (B2c),
- organochlorine compounds (B3a),
- organophosphorus compounds (B3b),
- others (B3f).

Following the entry into application of Regulation (EC) No 396/2005 on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin, Member States are required to carry out official controls on pesticide residues in accordance with the relevant provisions of Regulations (EC) N° 178/2002 and 882/2004. Annex I of Regulation (EC) No 396/2005 establishes a list of 315 products (animal products included) to which MRLs apply. Article 29 requires the Commission to prepare a coordinated multi-annual Community control programme with a view to assessing consumer exposure and the application of current legislation and Article 30 requires Members States to establish risk based multi-annual national control programmes.

Thus, in each MS several plans or programmes for testing pesticide residues in food and feed are currently in place:

1. the EU coordinated programme under Regulation (EC) No 396/2005: the lots sampled are chosen without any particular suspicion towards a specific operator and/or consignment and the results obtained are considered as an indicator of MRL compliance in food placed on the market and of consumer exposure (statistical approach);
2. the risk based national controls programmes under Regulation (EC) No 396/2005 based on past records and focused on food and feed with higher probability for non compliance;
3. the control plan under Directive 96/23/EC with its targeted approach.

Each year, the two programmes and the plan as well as the results thereof are communicated to the Commission.

The evident overlap of the two sets of rules also implies that methods of analysis and corresponding validation requirements can differ for the same substance and matrix depending on which rules are applied: whereas laboratories carrying out analysis under Directive 96/23/EC follow Commission Decision 2002/657, laboratories carrying out analysis under Regulation (EC) No 396/2005 apply the "Method Validation and Quality Control Procedures for Pesticide Residues (Doc. SANCO/2007/3131), 31 October 2007".

One important difference results from the different rationale of the two sets of rules: whereas each year, carbamates, pyrethroids, organochlorine compounds and organophosphorus compounds are analysed in the live animals and the products mentioned in the Annex of Directive 96/23/EC, the product-pesticide combinations selected in the EU coordinated and national control programmes under Regulation (EC) No 396/2005 may vary from one year to another, depending on risk prioritisation.

Number of samples and results:

According to the European Food Safety Authority (EFSA) report for 2009 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products, 32 796 targeted samples were taken for groups B3a, B3b and B2c under Directive 96/23/EC in animals and products of animal origin. Instances of non-compliance for organochlorine compounds (B3a) and organophosphorus compounds (B3b) were 0.19 % and 0.04 %, respectively.

EFSA publishes also annual reports on the EU coordinated programme and the national control programmes of pesticides residues according to Article 32 of Regulation (CE) No 396/2005. The last report presented the results of the analyses in food commodities sampled during 2008 in the 27 EU Member States as well as in Norway and Iceland (two EFTA (European Free Trade Association) states). More than 70 000 samples of nearly 200 different types of food were analysed. 96.5% of the samples complied with the MRLs of pesticides.

11 610 samples of nine different commodities (of plant origin only) were taken in the 2008 EU coordinated programme where the overall MRL exceedance rate was 2.3%. The 70 143 samples analysed in the context of the national control programmes in 2008 included 67 887 surveillance samples and 2 256 enforcement samples (N.B.: these figures do also comprise the number of samples taken for the EU coordinated programme). The majority of samples taken originated from the European reporting countries (77%), while 20% of the samples were taken from imported consignments or lots. For 3 % of the samples the origin was not reported.

Data on controls in food of animal origin will only be available in the 2009 report.

Questions (2)

Evaluation of potential impacts of repealing the requirements on official controls on pesticides B3a, B3b, B3f and B2c currently laid down in Directive 96/23/EC (other than authorised veterinary medicines) (so that Regulation (EC) No 882/2004 and the existing specific EU pesticides legislation would only apply)

1. Do you agree with the description of the issue?

Yes

No

Comments

2. Socio economic impacts.

2.1. How many samples are taken for the analysis of pesticides residues under Directive 96/23/EC per year? (please provide data if different from the information submitted to the Residues Application)

2.2. Do you consider that the number of samples taken to test pesticides residues would have been globally lower in your country, had you been allowed to establish the frequency of sampling only on the basis of risk assessments?

If yes,

- would you be able to give an indication of the impact of the reduction (in % points, both in relation to the number of samples and to the overall costs)?
- would you expect the sampling capacity that would be freed to be used to increase sampling on other substances?

If not,

- would you expect an increase of the number of samples taken for pesticides residues?

or

- would you expect the level to remain more or less the same?

3. Public Health impacts

Would an exclusively risk based system of national controls for pesticides residues (and thus the repeal of the requirements on official controls on pesticides currently laid down in Directive 96/23/EC) improve consumer protection? (Please do not consider the EU coordinated programme in your answer)

Yes. Please substantiate your answer.

No. Please substantiate your answer.

Other comments:

4. Administrative burden impacts

What would be the effect on administrative burden on national Competent Authorities if the requirements on official controls on pesticides currently laid down in Directive 96/23/EC were repealed so that Regulation (EC) No 882/2004 and the existing specific EU pesticides legislation would only apply?

Administrative burden would increase. Please substantiate your answer.

Administrative burden would decrease. Please substantiate your answer.

Administrative burden would not change. Please substantiate your answer.

Other comments:

5. Other impacts

Please indicate any other impact that you consider relevant.

4.2. Key issue 2 - National residues monitoring plans

Issue

Council Directive 96/23/EC requires Member States to submit annual national residues monitoring plans to the Commission respecting the minimum number of samples per type of animal or product and (sub)group of substances combinations laid down in Annex IV of the Directive as well as in the Decision 97/747/EC.

As the number of samples is linked to the individual Member States' animal production in the preceding years, this can result in very small numbers of samples being taken in those MS where there is limited production of certain species and the relevance of taking one or two

samples is questionable. On the other hand, in countries with larger animal productions, the numbers of samples specified by the Directive are much greater than if a statistically based sampling approach (e.g. the one advocated by the Codex Alimentarius[160]) is followed.

Furthermore the current rigid framework of Directive 96/23/EC militates against the application of a risk-based approach as laid down in Article 3 of Regulation (EC) No 882/2004 which states that official controls shall be carried out regularly, on a risk basis, with appropriate frequency and taking into account identified risks, past records, reliability of own checks and any indication of non-compliance (risk approach). Whilst some degree of risk-based approach is possible under the current Directive (for example MS are free to prioritise certain substances within specific substance groups and the minimum sample numbers specified in the Directive can be exceeded), the fact remains that MS are forced to test for certain substances and substance groups where there has been little evidence of a residues problem for many years (e.g. Group A1 – stilbenes).

Moreover, the approval of the national monitoring plans involves a long and heavy administrative procedure including notification, formal examination and approval by the Commission to be carried out every year and no clear indication is given of the possible consequences of not approving a national plan.

Against this background, MS expressed during the consultations their view that the requirements for the national monitoring plans under Directive 96/23/EC were not providing satisfactory results in relation to the resources invested. They suggested that (part of) the samples should be selected in accordance to the principles in Regulation (EC) No 882/2004 (*i.e.* on a risk basis) while considering the opportunity to give some priority to the detection of the use of prohibited substances presenting a serious health risk for consumers.

Number of samples and results:

A total of **445 968** targeted samples and 38 119 suspect samples were reported under the Directive 96/23/EC in 2009. There were 1 342 non-compliant samples (0.30 %) out of the total targeted samples. From the total of collected targeted samples, 40.9 % were analysed for substances having anabolic effect and prohibited substances (group A) and 63.1 % for veterinary drugs and contaminants (group B).

Questions (3)

Evaluation of potential impacts of:

Option 1: repealing the current prescriptive harmonisation of the modalities for control planning laid down in Directive 96/23/EC and allowing Member States to plan controls according to their own risk assessments and to integrate these controls in their MANCP;

Option 2: option 1 combined with EU harmonised uniform control modalities for certain substances or groups of substances and/or certain combinations animal(s) or product(s) and substance(s) established in case of specific "intrinsic" risks (e.g. growth promoters) or other risks that would justify the introduction of minimum control frequencies at EU level under certain conditions and for certain combinations animal(s) or product(s) and substance(s).

Please do not consider contaminants (treated in 4.1.1.) and pesticides residues (treated in 4.1.2.) when answering to the following questions.

[160] http://www.codexalimentarius.net/download/standards/11252/CXG_071e.pdf

1. **Do you agree with the description of the issue?**

   Yes

   No

   Comments

2. **Socio economic impacts**

   2.1. Do you consider that the number of samples taken would have been lower in your country, had you been allowed to plan controls only on the basis of your risk assessments (as in option 1)?

   (a) If yes:

   (i) would you be able to give an indication of the impact of the reduction (in % points, both in relation to the number of samples and to the overall costs)?

   (ii) would you expect the sampling capacity that will be freed to be used to increase sampling on other substances or for a monitoring programme to assess consumer exposure?

   (b) If not:

   (i) would you expect an increase of the number of samples taken?

   or

   (ii) would you expect the level to remain more or less the same?

   2.2. Would you be able to estimate any impact of EU harmonised uniform control modalities for certain (groups) substances and/or certain combinations animal(s) or product(s) and substance(s) (as in option 2) on the number of samples taken in your country?

   Yes. Please substantiate your answer.

   No, I'm not able to estimate any difference between options 1 and 2. Please substantiate your answer

   Other comments:

3. **Public Health impacts**

   3.1. Would a system of controls exclusively based on your own risk assessments (as in option 1) improve consumer protection?

   Yes. Please substantiate your answer.

   No. Please substantiate your answer.

   Other comments

   3.2. Would you be able to estimate any impact of EU harmonised uniform control modalities for certain (groups) substances and/or certain combinations animal(s) or product(s) and substance(s) (as in option 2) in regard to consumer protection?

   Yes. Please substantiate your answer.

   No. Please substantiate your answer.

   Other comments

4. Administrative burden impacts

Option 1 and option 2 would require the MS to draft the national residues control programmes according to its own risk assessments but they would no longer require each MS to submit its national control plan and its results for specific approval (each MS would include its plan in the MANCP).

4.1. What would be the effect of option 1 on the administrative burden for the national Competent Authority?

Administrative burden would be increased. Please substantiate your answer.

Administrative burden would be decreased. Please substantiate your answer.

Administrative burden would not change. Please substantiate your answer.

Other comments:

4.2. Would you be able to estimate any impact of EU harmonised uniform control modalities for certain (groups) substances and/or certain combinations animal(s) or product(s) / substance(s) (as in option 2) on the administrative burden of the Competent Authority?

Yes. Please substantiate your answer.

No. Please substantiate your answer.

Other comments

5. Other impacts

Please indicate any other impact that you consider relevant.

4.3. Key issue 3 - Requirements for Third Countries on residues controls/imports

Issue

Article 29 of Directive 96/23/EC requires that Third Countries (TCs) provide "guarantees" that have an "effect at least equivalent" to the measures that are to be implemented by Member States (MS) according to the Directive. In particular, TCs have to submit on an annual basis a residues monitoring plan, the requirements being very prescriptive and essentially the same as for the Member States' plans (minimum sampling frequencies, etc.), and to provide details on their control system. According to this article, TCs with an approved residues monitoring plan appear on a list from which MS are authorised to import (Commission Decision 2004/432/EC).

During the consultation, a simpler and more transparent framework as well as the definition of criteria to assess the effective equivalence of monitoring plans and control systems were requested and to a certain extent, this has been delivered already with the publication of the Commission's Third Country residues web page in which the provision of guarantees equivalent to those provided for by Directive 96/23/EC are described[161].

In 2004, the entry into force of Regulation (EC) No. 882/2004 has created a more horizontal approach to the establishment of import requirements. In particular:

[161] http://ec.europa.eu/comm/food/food/chemicalsafety/residues/third_countries_en.htm

1. Article 47 of the Regulation requires TCs to provide accurate and up-to-date information on the general organisation and the management of their sanitary control systems, sanitary regulations, control and inspection procedures, risk assessment procedures and the factors taken into consideration, results of their controls, their follow up to the recommendations made pursuant to FVO missions, changes of the structure and functioning of the relevant control systems, etc.;

2. Article 48 gives the possibility to lay down if necessary specific import conditions and detailed procedures which may include the establishment of a list of Third Countries from which specific products may be imported and the definition of specific import conditions depending on the type of animal or product and the possible risks associated therewith.

3. Article 46 requires FVO controls to be carried out in TCs in order to verify, on the basis of the information referred to in Article 47, the compliance or equivalence of TCs legislation and systems with EU feed and food law and animal health legislation.

   These controls shall have particular regard to the legislation of the TC, the organisation of the its competent authorities, their supervision, powers and independence, the training of their staff, their resources including diagnostic facilities, the existence and operation of documented and adequate control procedures and systems as well as the assurances which the Third Country can give regarding compliance with, or equivalence to, EU requirements.

Approximately 80 countries are listed in Commission Decision 2004/432/EC for animals and food from animal origin for which a residues monitoring plan has been submitted and positively assessed by the Commission. FVO missions are furthermore carried out to check the effective implementation of the plans.

Questions (4)

Evaluation of potential impacts of:

<u>Option 1</u>: repealing the current prescriptive modalities for TCs' residues monitoring plans in Directive 96/23/EC and replacing them by a set of minimum specific guarantees as regards equivalence or compliance of the control system and programme of veterinary medicines' residues of the TC (legislation, authorisation, control of production and use of veterinary medicines, identification of prohibited substances, control programme for testing residues in animals and food from animal origin) which shall be provided by the Third Country in order for it to be inscribed in the list established under Article 48 of Regulation (EC) No 882/2004 and which shall be controlled during FVO missions at frequencies determined in accordance with prescriptions of Article 46 of Regulation (EC) No 882/2004;

<u>Option 2</u>: option 1 combined with mandatory minimum control frequencies in the TC's control programme for certain substances or groups of substances whose illegal use would represent a particularly serious violation and/or health risk for the consumers (e.g. growth promoters or certain antibiotics) and which require a specific approach (special import conditions).

Impacts:

1. Do you agree with the description of the issue?

Yes

No

Comments

2. Socio economic impacts

2.1. Would you be able to estimate any socio-economic impact of option 1 on your national Competent Authority (human resources, controls, etc.)?

Yes. Please substantiate your answer.

No. Please substantiate your answer.

Other comments

2.2. Comparing option 1 with option 2, would you be able to estimate any difference in the socio-economic impact on your national Competent Authority (human resources, controls, etc.)?

Yes. Please substantiate your answer.

No. Please substantiate your answer.

Other comments:

3. Public health impacts

3.1. Would option 1 improve consumer protection?

Yes. Please substantiate your answer.

No. Please substantiate your answer.

Other comments

3.2. Comparing option 1 with option 2, would you be able to estimate any impact of mandatory minimum control frequencies in the TCs' control programmes (for certain substances or groups of substances whose illegal use would represent a particularly serious violation and/or health risk for the consumers) on consumer protection?

Yes. Please substantiate your answer.

No. Please substantiate your answer.

Other comments

4. Administrative burden

4.1. What would be the effect of option 1 on the administrative burden for your national Competent Authority?

Administrative burden would be increased. Please substantiate your answer.

Administrative burden would be decreased. Please substantiate your answer.

Administrative burden would not change. Please substantiate your answer.

Other comments:

4.2. Comparing option 1 with option 2, would you be able to estimate any impact of mandatory minimum control frequencies in the TCs' control programmes (for certain substances or groups of substances whose illegal use would represent a particularly serious violation and/or health risk for the consumers) on the administrative burden of your Competent Authority?

Yes. Please substantiate your answer.

No. Please substantiate your answer.

Other comments.

5. Other impacts

Please indicate any other impact that you consider relevant.

4.4. Key issue 4 - Enforcement measures

Articles 13, 16, 17 and 18 as well as Articles 22, 23, 24 and 25 of Directive 96/23/EC provide very precise and specific enforcement measures to be taken by Member States in case of illegal treatment, use of unauthorised substances or presence of their residues, levels exceeding the maximum limit for residues, repeated infringements of MRLs, etc. (e.g. immediate slaughter of all animals in case of confirmation of illegal treatment). The very detailed and over prescriptive nature of the Directive may result in some confusion for the Competent Authorities and their enforcement officers as well as in a reduced flexibility as regards of the possible enforcement actions in a given situation.

Regulation (EC) No 882/2004 has a more flexible and rationalised approach: Article 54 of the Regulation requires that actions taken by the Competent Authority shall ensure that the operator remedies the situation and that they take account of the nature of the non-compliance as well as the operator's past record with regard to the non compliance. It furthermore lists the possible measures without linking them rigidly to specific non-compliances:

- imposition of sanitation procedures or any other action deemed necessary to ensure the safety of feed or food or compliance with law;
- restriction or prohibition of the placing on the market, import or export of feed, food or animals;
- monitoring and, if necessary, ordering the recall, withdrawal and/or destruction of feed or food;
- authorisation to use feed or food for purposes other than those for which they were originally intended;
- suspension of operation or closure of all or part of the business concerned for an appropriate period of time;
- suspension or withdrawal of the establishment's approval;
- any other measure the competent authority deems appropriate (for instance slaughter of animals).

Article 54 finally requires that all expenditure incurred shall be borne by the responsible feed and food business operator.

The alignment of the rules applicable for residues of veterinary medicines controls with the ones of Regulation (EC) No 882/2004 would thus allow specific case by case adapted

measures remedying the situation without preventing Competent Authorities to take, if needed, the same enforcement measure than the one they would have taken under Directive 96/23/EC.

Questions (5)

Evaluation of potential impacts of repealing the requirements on enforcement measures currently laid down in Directive 96/23/EC (Articles 13, 16, 17, 18, 22, 23, 24 and 25) so that Article 54 of Regulation (EC) No 882/2004 would only apply

1. Do you agree with the description of the issue?

Yes

No

Comments

2. Socio economic impacts

2.1. Do you consider that, in general, you would have taken the same enforcement measures, had current provisions in Article 54 of Regulation (EC) No 882/2004 been applicable?

Yes. Please substantiate your answer.

No. Please substantiate your answer.

Other comments.

2.2. Do you consider that your enforcement actions would have been better targeted and/or adapted, had current provisions in Article 54 of Regulation (EC) No 882/2004 been applicable?

Yes. Please substantiate your answer.

No. Please substantiate your answer.

Other comments.

3. Public Health impacts

Would the repeal of the rigid requirements on enforcement measures currently laid down in Directive 96/23/EC and the application of current provisions in Article 54 of Regulation (EC) No 882/2004 improve consumer protection?

Yes. Please substantiate your answer.

No. Please substantiate your answer.

Other answer:

4. Administrative burden impacts

What would be the effect on administrative burden on national Competent Authorities in case of repeal of the rigid requirements on enforcement measures currently laid down in Directive 96/23/EC and the application of current provisions in Article 54 of Regulation (EC) No 882/2004?

Administrative burden would increase. Please substantiate your answer.

Administrative burden would decrease. Please substantiate your answer.

Administrative burden would not change. Please substantiate your answer.

Other comments:

5. Other impacts

Please indicate any other impact that you consider relevant.

5. Results of the consultation

All 27 Member States (MS) and Norway **answered** to the questionnaire.

5.1. *Overlaps resulting from the implementation of Directive 96/23/EC and the specific EU contaminants legislation (Regulations (EC) N° 315/93 and N° 1881/2006)*

The option considered was to repeal the requirements on official controls on contaminants currently laid down in Directive 96/23/EC so that Regulation (EC) No 882/2004 and the existing specific EU contaminants legislation would only apply.

26 MS agreed with the description of the issue (1 disagreed). No MS was opposed to the option.

General comments from the MS

Some MS underlined the specific case of dyes (malachite green and leucomalachite green used for the illegal treatment of farmed fish) which should be considered separately.

Others called for the inclusion in EU legislation of an EU coordinated programme for at least some priority environmental contaminants which should be reviewed regularly or annually.

Several MS stressed the need to ensure future the financing of official controls on contaminants through fees paid by industry and some were of the opinion that private controls carried out by food business operators (FBOs) should be more taken into account.

Some MS focussed on the possible consequences of this option on EU exports: export possibilities would have to be re-negotiated with each third country (TC) and new specific requests from TCs (e.g. analyses of consignments) could be possible.

Member States' perception of the potential impacts of the option

1. Socio-economic impacts

The **majority of the MS** (18) considered that the **number of samples** taken to test for the presence of contaminants **would have been globally lower** in their country, if the frequency of sampling was only on the basis of risk assessments. 7 MS mentioned reductions of the number of samples (globally or for one or several group(s) of substances) between – 10 % and – 60 %.

The majority of these MS (11/18) expected the sampling capacity that would be freed to be used to increase the sampling of other substances and/or on other matrices (in general if justified by risk assessments). Several MS noticed however that any increase of the number of samples is difficult in the current situation of public deficits and scarce public budgets.

6 MS felt that the number of samples would remain unchanged (they would be distributed differently) and 3 MS didn't or couldn't answer.

2. Public health impacts

For the **majority of MS** (17), an exclusively risk based system of controls for contaminants **would improve consumer protection** (sampling better focussed and more efficient, better allocation of resources, local specificities better taken into account). Some MS proposed a rolling program based on risk assessments with more or less intensive samplings from one year to another.

2 MS felt that the level of consumer protection would remain the same (because of very few samples concerned). All other MS having answered explained that an exclusively risk based system would not or not necessarily improve consumer protection unless it comprises also a monitoring programme of low risk or low occurrence substances in order to observe medium and long term trends, to keep track of consumer exposure and to identify incidents.

3. Administrative burden impacts on national competent authorities

The **majority of Member States** (15) answered that the **burden would decrease** (10) after perhaps an initial increase (due to the reduced number of samples and an optimum allocation of resources, the repeal of the annual submission and approval by the Commission, as well as of the double reporting) **or** that it **would not change globally** (5). 9 MS estimated that the burden would increase at least initially (because of risk assessments to be carried out, plans to be reviewed on a regular basis/every year). 3 MS didn't or couldn't answer.

5.2. *Overlaps resulting from the implementation of Directive 96/23/EC and the specific EU pesticides residues legislation (Regulation (EC) N°396/2005)*

The option considered was to repeal the requirements on official controls on pesticides B3a, B3b, B3f and B2c currently laid down in Directive 96/23/EC (other than authorised veterinary medicines) so that Regulation (EC) No 882/2004 and the existing specific EU pesticides legislation would only apply.

26 MS agreed with the description of the issue (1 disagreed). No MS was opposed to the option.

General comments from the MS

6 MS underlined that some group B2c pesticides were pharmacologically active substances for which a MRL was set up in accordance with Regulation (EC) No 470/2009 and which were used as VMPs (ecto-parasitics). These pesticides should be treated as VMPs.

Several MS were of the opinion that a broader monitoring of pesticides residues in animals and their products was needed in order to observe medium and long term trends, to keep track of consumer exposure and to identify incidents and requested that animals and food of animal origin should be better represented in the current EU coordinated (monitoring) programme on pesticides residues.

Some MS proposed that requirements concerning methods of analysis should also be aligned.

Several MS stressed the need to ensure the future financing of official controls on pesticides residues through fees paid by industry.

Member States' perception of the potential impacts of the option

1. Socio-economic impacts

The **majority of the MS** (17) considered that the **number of samples** taken to test for the presence of pesticides residues **would have been globally lower** in their country, if the frequency of sampling was only determined on the basis of risk assessments. More than half of them (9/17) expected the sampling capacity that would be freed to be used to increase the sampling of other substances and/or on other matrices (in general if justified by risk assessments) or to use more efficient and expensive methods. 7 MS mentioned reductions of the number of samples between – 2 % and – 100 % depending on the type of animals or animal products and the substance or group of substances. Only 6 MS estimated that the number of samples would remain more or less unchanged (different distribution of samples or very few samples concerned) and 4 didn't or couldn't answer.

2. Public health impacts

For the **majority of MS** (16), an exclusively risk based system of national controls for pesticides residues **would improve consumer protection** (sampling better focussed and more efficient, better allocation of resources, local specificities better taken into account). Some MS proposed a rolling program based on risk assessments with more or less intensive samplings from one year to another.

3 MS felt that the level of consumer protection would remain the same (*inter alia* because of very few samples concerned). All other MS having expressed an opinion (4) answered that an exclusively risk based system would not or not necessarily improve consumer protection unless it comprises also a monitoring programme of low risk/low occurrence substances in order to observe medium/long term trends, to keep track of consumer exposure and to identify incidents.

3. Administrative burden impacts on national competent authorities

The **majority of Member States** (15) answered that the **burden would decrease** (9) after perhaps an initial increase (because of less samples, no annual submission and approval by the Commission, no double reporting, etc.) **or** that it **would not change** (6). 7 MS estimated that the burden would increase at least initially (because of risk assessments to be carried out, plans to be reviewed on a regular basis/every year). 5 MS didn't or couldn't answer.

5.3. Enforcement measures

The option considered was to repeal the requirements on enforcement measures currently laid down in Directive 96/23/EC (Articles 13, 16, 17, 18, 22, 23, 24 and 25) so that Article 54 of Regulation (EC) No 882/2004 would only apply.

25 MS agreed with the description of the issue (2 disagreed).

General comments from the MS

Some MS were of the opinion that Article 54 would be sufficient while others were opposed to the option and requested the current measures to be kept.

Several MS differentiated between minor and major infringements: in their opinion, Article 54 seemed sufficient for group B substances and simple cases of exceeded MRLs, where

more flexibility was necessary, whereas for group A substances (non authorised substances, growth promoters), stronger and more uniform enforcement measures more adapted to animals (than those in Article 54) were needed because of the use of illegal substances being related to (organised) criminal activities. Others thought that, if enforcement measures in Directive 96/23/EC were to be deleted then measures not explicitly covered by Article 54 of Regulation 882/2004 should be "transferred" to the Regulation (this concerned in particular movement restrictions on livestock and destruction of livestock)

Finally, some MS underlined that enforcement measures would probably be more questioned/contested by concerned FBOs.

Member States' perception of the potential impacts of the option

1. Socio-economic impacts

1.1 The majority of the MS (14) considered that, in general, they **wouldn't have taken the same enforcement measures**, had current provisions in Article 54 of Regulation (EC) No 882/2004 been applicable. The reasons were following:

- a more flexible individual case by case approach as well as better targeted and easier measures were needed,
- in some cases concerning non authorised substances or growth promoters, measures would have been less drastic and in others more and/or profounder investigations would have been necessary,
- in cases of first non conformity concerning an authorised substance, measures would have been essentially administrative and the focus would be more on repeated offenders,
- if several different measures were possible, the national approach would be to start with less harmful measure.

10 MS estimated that they would have taken more or less the same enforcement measures. 3 MS didn't or couldn't answer.

1.2. The **majority of the MS** (16) considered that **their enforcement actions would have been better targeted and/or adapted**, had current provisions in Article 54 of Regulation (EC) No 882/2004 been applicable. The reasons were globally the same as those described under point 1.1. For 1 MS, they would have been the same.

7 MS only answered that their enforcement actions would not have been better targeted and/or adapted. 3 didn't or couldn't answer.

2. Public health impacts

For a **majority of MS** (17), the repeal of the rigid requirements on enforcement measures currently laid down in Directive 96/23/EC and the application of current provisions in Article 54 of Regulation (EC) No 882/2004 **would *per se* not improve consumer protection** (the reason often specified being that the repeal **would have no significant impact on consumer protection**). 9 MS were of the opinion that it would improve consumer protection. 1 MS didn't answer.

3. Administrative burden impacts on national competent authorities

The **majority of the MS** (17) estimated that the **burden would not change** (14) (because of the few cases concerned, the fact that enforcement measures would remain similar, the better allocation of time and resources) or that it would decrease (2).

6 MS were however of the opinion that the burden would increase (mainly because of a more complicated decision process and an increased number of measures contested by the concerned FBOs). 4 MS didn't or couldn't answer.

5.4. *National residues monitoring plans*

The options considered were:

Option 1: repeal the current prescriptive harmonisation of the modalities for control planning laid down in Directive 96/23/EC and allow MS to plan controls according to their own risk assessments and to integrate these controls in their multi-annual control plan (MANCP)

Option 2: option 1 combined with EU harmonised uniform control modalities for certain substances or groups of substances and/or certain combinations animal(s) or product(s) and substance(s) established in case of specific "intrinsic" risks (e.g. growth promoters) or other risks that would justify the introduction of minimum control frequencies at EU level under certain conditions and for certain combinations animal(s) or product(s) and substance(s)

24 MS agreed with the description of the issue (2 disagreed). Option 2 was supported by most of the MS.

General comments from the MS

Option 1 was in general not supported by the MS (the main reason mentioned was the risk of a non harmonised approach between the MS with potential impacts on the internal market and on bilateral agreements with TCs).

Option 2 was supported by most of the MS (18). A lot of MS indeed underlined the need for a mandatory (if possible EU coordinated) monitoring plan of at least group A substances (non authorised substances and growth promoters) and antibiotics (justified by the growing antimicrobial resistance) as well as dyes, in order to assess consumer exposure to their residues, to generate sufficient data for the risk assessments, to establish common guarantees for EU exports towards TCs and to maintain the preventive effect of such a monitoring. Most MS mentioned that this plan should be revised regularly and some that it could comprise minimum numbers of samples in accordance with *Codex alimentarius* rules (significantly less samples than currently). A lot of MS underlined that this EU coordinated monitoring plan should be complemented by national plans based on MS' own risk assessments. Some MS mentioned the proposal made during the previous consultation on this issue: 60 % of samples for the EU coordinated plan and 40 % for the national plan.

Some MS requested common principles or guidelines or procedures for the elaboration of the plans based on risk assessments, others proposed a common set of criteria or the use of internationally recognised criteria for the risk assessments to ensure a harmonised approach.

Finally, several MS underlined also:

- the need to ensure the financing of at least a part of the controls trough fees paid by FBOs,

- the importance of the data on the distribution and use of VMPs (seen as essential for the risk assessments by some MS),
- the possibility to extend the range of substances analysed through the use of multi-residue methods,
- the possibility to carry out rolling programmes based on risk assessments with more or less intensive samplings from one year to another.

Member States' perception of the potential impacts of the options

1. Socio-economic impacts

1.1. The **majority of MS** (15) considered that the **number of samples taken would have been lower** in their country, had they been allowed to plan controls only on the basis of their risk assessments (as in option 1). For several MS, the current number of mandatory samples was indeed excessive and very few non compliant samples for group A substances were detected. 13 MS expected the sampling capacity that would be freed to be used to increase the sampling of other substances and/or on other matrices (in general if this was justified by corresponding risk assessments) or to use more efficient and expensive methods. 7 MS mentioned reductions of the number of samples between – 10 % and – 75 % depending on the type of animals or animal products and the substance or group of substances.

4 MS estimated the number of samples would be more or less unchanged (the distribution only of the samples would be different), 1 MS that the number would not decrease and 7 MS didn't or couldn't answer.

1.2. 12 MS were able to estimate an impact of EU harmonised uniform control modalities for certain (groups) substances and/or certain combinations animal(s) or product(s) and substance(s) (as in option 2) on the number of samples taken in their country. They mostly mentioned a **decrease of the number of samples compared to the current system which wouldn't be as significant as for option 1**.

2. Public health impacts

2.1. For **a majority of MS** (15), a system of controls exclusively based on their own risk assessments (as in **option 1**) **would improve consumer protection** (as the sampling would be better targeted/focussed, local specificities taken into account and resources better allocated). 1 MS estimated that the level of consumer protection would remain unchanged.

7 MS however were of the opinion that it would not or not necessarily improve consumer protection (*inter alia* because a real monitoring of group A substances and antibiotics would not be guaranteed). 4 MS didn't or couldn't answer.

2.2. Most of the MS (21) were able to estimate an impact of EU harmonised uniform control modalities for certain (groups) substances and/or certain combinations animal(s) or product(s) and substance(s) (as in option 2) in regard to consumer protection. Nearly all of them thought that **option 2 would have the most favourable impact on consumer protection**.

3. Administrative burden impacts on national competent authorities

3.1. 10 MS estimated that option 1 would increase the burden at least at the beginning (because of the establishment of new plans based on own risk assessments and the regular review of them) and 6 MS answered that the burden would not change (after an initial increase for some of them). 5 MS were of the opinion that the burden would decrease

(because of less samples to be taken, the better allocation of resources, the absence of the annual submission and approval of plans, etc.) and 6 MS didn't or couldn't answer.

3.2. Only 12 MS were able to estimate the impact of option 2 on the administrative burden of their CA. Views were rather varied however most of the MS thought the **burden would increase at the beginning and then decrease**.

5.5. Requirements for third countries (TCs) from which products may be imported

The options considered were:

Option 1: to repeal the current prescriptive modalities for TCs' residues monitoring plans in Directive 96/23/EC and replace them by a set of minimum specific guarantees as regards equivalence or compliance of the control system and programme of veterinary medicines' residues of the TC (legislation, authorisation, control of production and use of veterinary medicines, identification of prohibited substances, control programme for testing residues in animals and food from animal origin) which shall be provided by the third country in order for it to be inscribed in the list established under Article 48 of Regulation (EC) No 882/2004 and which shall be controlled during missions of the Food and Veterinary Office (FVO) at frequencies determined in accordance with prescriptions of Article 46 of Regulation (EC) No 882/2004

Option 2: option 1 combined with mandatory minimum control frequencies in TCs' control programmes for certain substances or groups of substances whose illegal use would represent a particularly serious violation and/or health risk for the consumers (e.g. growth promoters or certain antibiotics) and which require a specific approach (special import conditions).

22 MS agreed with the description of the issue (3 disagreed).

General comments from the MS

MS often insisted on the **necessary equivalence of the system for MS with the system for TCs**.

Several MS expressed their clear preference for option 2 which should include mandatory minimum control frequencies at least for unauthorised substances (even more if these are authorised in the TC) and growth promoters as well as antibiotics. Other MS underlined that the submission of plans by TCs and their approval by the Commission should globally be kept (some adjustments were proposed).

Some MS were also of the opinion that:

- residue control plans of TCs should be based on risk assessments,
- common principles or guidelines or procedures for the elaboration of the plans based on risk assessments should be established to ensure a harmonised approach by MS and TCs,
- a harmonised approach for the controls and analyses of imports in the EU was also needed.

Member States' perception of the potential impacts of the options

1. Socio-economic impacts

1.1 17 MS were able to estimate a socio-economic impact of option 1 on their national CA (human resources, controls, etc.). For 7 MS of them, it shouldn't have a significant impact. The 10 other MS however estimated that option 1 may result in an increase of the controls at EU boarders (as well as in an increase of re-exports and alerts for some MS).

1.2 Comparing option 1 with option 2, 18 MS were able to estimate a difference in the socio-economic impact on their national CA. For 6 of them, there was no significant difference between option 1 and 2. 7 MS answered that the increase of controls on imports would be higher in option 1 than in option 2. 3 MS finally estimated that controls on imports would increase only if certain conditions are not fulfilled by the TC.

2. Public health impacts

2.1. 13 MS considered that option 1 would not improve consumer protection whereas 6 MS were of the opinion that it would. 8 MS didn't or couldn't answer.

2.2. Comparing option 1 with option 2, 20 MS were able to estimate an impact of mandatory minimum control frequencies in the TCs' control programmes on consumer protection. For the **majority of these MS** (18), **option 2 would result in a higher consumer protection**. For 1 MS, both options would increase consumer protection and for 1 MS both options were not sufficiently strong as regards consumer protection.

3. Administrative burden impacts on national competent authorities

3.1. 13 MS estimated that option 1 would increase the administrative burden for their national competent authority (mainly because of increased controls of imports at boarders/in MS). On the contrary 10 MS were of the opinion that the burden would not change. 4 MS didn't or couldn't answer.

3.2. Comparing option 1 with option 2, 18 MS were able to estimate an impact of mandatory minimum control frequencies in the TCs' control programmes on the administrative burden of their competent authority. For 8 of them, there would be no significant difference between options 1 and 2. 7 other MS estimated that the burden would be lower in case of option 2 (because of less controls and less non conformities detected).

Annex XXI: DIRECTIVE 96/23/EC - Costs reductions relating to the repeal of Directive 96/23/EC on controls of certain substances (veterinary medicinal products (VMPs), contaminants, residues of pesticides) and residues thereof in live animals and animal products

In the MS' replies to the consultation[162], the average cost per sample for laboratory analysis only ranged:

- from €41 to €265 when considering all 17 MS having transmitted exploitable data,
- from €120 to €210 when considering 12 out of the 17 MS having transmitted exploitable data.

In this study, it is thus assumed that the EU average cost per sample for laboratory analysis only is €165.

Furthermore, in their answers, the average total cost per sample including all expenses (staff, laboratories, consumables, overheads, etc.) ranged:

- from €62 to €436 when considering all 18 MS having transmitted exploitable data,
- from €150 to €350 when considering 16 out of the 18 MS having transmitted exploitable data.

In this study, it is thus assumed that the EU average total cost per sample for laboratory analysis is €250.

Changes under consideration:

(a) **Deletion of the overlaps resulting from the implementation of Directive 96/23/EC and the specific EU contaminants legislation (Regulations (EC) N°315/93 and N° 1881/2006) *i.e.* repeal of the requirements on official controls on contaminants currently laid down in Directive 96/23/EC so that Regulation (EC) No 882/2004 and the existing specific EU contaminants legislation would only apply (sampling only based on risk assessments)**

Financial impact:

Based on the results of the consultation of the Member States (MS), the decrease of the number of samples taken to test for the presence of contaminants is assumed to range between – 10 % and – 60 %. As in 2009 45 014 samples were analysed under Directive 96/23/EC for contaminants (*i.e.* for sub-groups B3a organochlorine compounds including PcBs, B3b organohosphorus compounds, B3c chemical elements, B3d mycotoxins, B3e dyes and B3f "others" of Annex I of the Directive), the decrease would range from 4 501 to 27 008 samples. Based on these assumptions, the decrease in costs would range:

- from €743 000 to €4 456 000 when considering the average cost per sample for laboratory analysis only,

[162] Revision of Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products: consultation of the competent authorities in the Member States on the impacts of the different options 08/02/2011

- from €1 125 000 to €6 752 000 when considering the average total cost per sample for laboratory analysis

(b) **Deletion of the overlaps resulting from the implementation of Directive 96/23/EC and the specific EU pesticide residues legislation (Regulation (EC) N°396/2005) *i.e.* repeal of the requirements on official controls on residues of pesticides currently laid down in Directive 96/23/EC so that Regulation (EC) No 882/2004 and the existing specific EU pesticides legislation would only apply (national sampling only based on risk assessments).**

Financial impact:

Based on the results of the consultation of the MS, the decrease of the number of samples taken to test for the presence of residues of pesticides is assumed to range between – 2 % and – 100 %. As in 2009 32 796 samples were analysed under Directive 96/23/EC for residues of pesticides (*i.e.* for sub-groups B2c carbamates and pyrethroids, B3a organochlorine compounds, B3b organophosphorus compounds and B3f "others" of Annex I of the Directive), the decrease would range from 655 to 32 796 samples. Based on these assumptions, the decrease in costs would range:

- from €108 000 to €5 411 000 when considering the average cost per sample for laboratory analysis only,
- from €164 000 to €8 199 000 when considering the average total cost per sample for laboratory analysis

(c) **Repeal the current prescriptive harmonisation of the modalities for control planning laid down in Directive 96/23/EC (mandatory minimum numbers of samples) and MS' controls (and sampling) according to their own risk assessments**

Financial impact:

Based on the results of the consultation of the MS, the decrease of the number of samples taken is assumed to range between – 10 % and – 75 %. As in 2009 a total of 445 968 samples were analysed under Directive 96/23/EC, the decrease would range from 44 597 to 334 476 samples. Based on these assumptions, the decrease in costs would range:

- from €7 358 000 to €55 188 000 when considering the average cost per sample for laboratory analysis only,
- from €11 149 000 to €83 619 000 when considering the average total cost per sample for laboratory analysis.

(d) **Repeal the current prescriptive harmonisation of the modalities for control planning laid down in Directive 96/23/EC (mandatory minimum number of samples)**, **MS' controls (and samplings) according to their own risk assessments and definition of EU harmonised uniform control modalities for certain substances or groups of substances and/or certain combinations animal(s) or product(s) and substance(s) established in case of specific "intrinsic" risks (e.g.**

growth promoters) or other risks that would justify the introduction of minimum control frequencies (or minimum number of samples) at EU level under certain conditions and for certain combinations animal(s) or product(s) and substance(s)

According the answers of the MS to the consultation, the decrease of the number of samples taken compared to the current regime would be lower than the ones estimated under (c), as a consequence that the decrease in costs would be lower too.

Annex XXII: Directive 96/23/EC – Administrative burden reduction in relation to the repeal of the Directive

	Art. no.	Description of the Information Obligation (mainly juridical)	Target group(s) / segments	Total nbr of entities concerned	Frequency per year	Additional information on administrative cost imposed on public authorities by these information obligations
Directive 96/23/EC						
	5 (1)	By 31 March at the latest of the year of the update, Member States shall submit to the Commission any update of plans setting out the national measures to be implemented previously approved on the basis of the experience of the previous years.	Member States	27	Once a year	ACTIVITIES: Coordination and drafting of the changes to the previous plan, changes of the data in the application (addition of substances, methods, limits, levels, number of analyses, etc), uploading the data. STAFF REQUIERED: 3 legislators, senior officials, managers TIME SPENT: 20,000 minutes per MS; 540,000 minutes for the 27 MS COST: € 10,430 per MS; € 281,610 for the 27 MS
	8 (2)	Annual amendments to the initial plans communicated by the Member States shall be forwarded by the Commission to the other Member States once the Commission has established their conformity with this Directive.	Commission	1	Once a year	ACTIVITIES: a) Evaluation of the plan, b) Submission to the MS STAFF REQUIERED: several legislators, senior officials, managers TIME SPENT: 28 500 minutes COST: € 14,863

	8 (2)	If their are no comments from Member States (in 10 working days), the amendments to the plans should be deemed to be approved. The Commission shall inform the Member States of such approval immediately.	Commission and MS	28	Once a year	**MS** ACTIVITY: Drafting of comments STAFF REQUIERED: 1 legislator, senior official, manager TIME SPENT: 700 minutes per MS; 18 900 for the 27 MS COST: € 365 per MS; € 9,860 for the 27 MS **COMMISSION** ACTIVITY: Information of the MS STAFF REQUIERED: 1 legislator, senior official, manager TIME SPENT: 60 minutes COST: € 31
	8 (2)	Where there are comments from Member States or where the Commission deems the update not to be in conformity or to be insufficient, the Commission shall submit the updated plans to the Standing Veterinary Committee, which must act under the regulatory procedure referred to in Article 33 (3).	Commission	1	Once a year	ACTIVITY: Submission of the updated plans to the Standing Veterinary Committee STAFF REQUIERED: 1 legislator, senior official, manager TIME SPENT: 900 minutes COST: € 469

	8 (3)	Every six month, Member States shall inform the Commission and the other Member States of the implementation of plans approved or of the development of the situation.	Member States	27	Every six month	ACTIVITY: Creation of data, reportSTAFF REQUIERED: 1 academic legislator, senior official, managerTIME SPENT: 10,000 minutes per MS; 270,000 minutes for the 27 MSCOST: € 5,215 per MS; € 140,800 for the 27 MSACTIVITY: Transmission to the CommissionSTAFF REQUIERED: 1 technician, associate professionalTIME SPENT: 120 minutes per MS; 3,240 minutes for the 27 MSCOST: € 37 per MS; € 997 for the 27 MS
	8 (3)	By not later than 31 March each year, Member States shall forward to the Commission the results of their residue and substances detection plans and of their control measures.	Member States	27	Once a year	ACTIVITY: Creation of data, report STAFF REQUIERED: 2 legislators, senior officials, managers TIME SPENT: 10,000 minutes per MS; 270,000 minutes for the 27 MS COST: € 5,215 per MS; € 140,800 for the 27 MS ACTIVITY: Transmission to the Commission STAFF REQUIERED: 1 technician, associate professional TIME SPENT: 120 minutes per MS; 3,240 minutes for the 27 MS COST: € 37 per MS; € 997 for the 27 MS

	8 (3)	Member States shall make public the outcome of the implementation of the plans.	Member States	27	Once a year	ACTIVITY: Creation of data, report STAFF REQUIERED: 1 legislator, senior official, manager TIME SPENT: 3 300 minutes per MS; 89,100 minutes for the 27 MS COST: € 1,720 per MS; € 46,466 for the 27 MS ACTIVITY: Transmission to the Commission STAFF REQUIERED: 1 technician, associate professional TIME SPENT: 120 minutes per MS; 3240 minutes for the 27 MS COST: € 37 per MS; € 997 for the 27 MS
	8 (3)	The Commission shall inform Member States, within the Standing Veterinary Committee, of developments in the situation in the various regions of the Community.	Commission	1	Once a year	ACTIVITY: Information of the MS STAFF REQUIERED: legislators, senior officials, managers TIME SPENT:1 300 minutes COST: € 678

	8 (4)	Each year, or whenever it deems it necessary on public health grounds, the Commission shall report to Member States within the Standing Veterinary Committee on the outcome of the checks and surveys.	Commission	1	Once a year	ACTIVITY: Report to the MSSTAFF REQUIERED: 2 legislators, senior officials, managerTIME SPENT: 1 300 minutes COST: € 678
	8 (5)	The Commission shall send the European Parliament and the Council a communication each year on the results of the action taken at regional, national or Community level, bearing in mind the report and Member States' comments on it.	Commission and MS	28	Once a year	**MS** ACTIVITY: Drafting of comments STAFF REQUIERED: 1 legislator, senior officials, manager TIME SPENT: 900 minutes per MS; 24 300 for the 27 MS COST: € 469 per MS; € 12,673 for the 27 MS **EC** ACTIVITY: Preparation and sending of the report STAFF REQUIERED: 1 legislator, senior officials, manager TIME SPENT: 13 500 minutes COST: € 7,040
TOTAL COST (per year)		**COMMISSION:** € 23,759 **27 MS:** € 635,175 **per MS:** € 23,525				

Remarks

1) Source of the "Additional information" column:
- MS: informal consultation of the Austrian and UK competent authorities.
- EC: phone calls to the different EC officials involved in the process.

2) Method of calculation of the "COST": based on the Calculator of Administrative Costs (AC) & Administrative Burdens (AB) on Public Authorities
- types of obligation and main actions taken into account
- cost calculation based on the employee type and the corresponding employee tariff

3) The employee tariff are based on standardised ESTAT data. They cover both wages and non-wage labour costs for 9 different types of activities and for all 27 Member States.
They reflect 2006 prices and include a standard proportion of so-called overheads costs (i.e. 25%) linked with individual employees and borne by businesses but not included in their salaries (fixed administration costs such as premises, telephone, heating, electricity and IT equipment).

Annex XXIII: Main changes to the existing legislative framework under the options included in the analysis

This Annex gives an overview of the main changes to the existing legislative framework implied by each of the options included in the analysis of this IA.

As regards the **legislative technique**, while the changes under Option 1 will be introduced by a Regulation amending Regulation 882/2004, under Options 2 to 4, the changes would be introduced either through a legislative act amending Regulation 882/2004 and repealing relevant sectoral legislation or by an act which repeals and replaces Regulation 882/2004 and repeal relevant sectoral legislation.

Option 1A – Repeal Union rules on control fees

(Existing mandatory inspection fees are repealed (other provisions of the legislative framework remain unchanged)

The provisions of Articles 27-29 of Regulation 882/2004, which prescribe the scope and level of mandatory fees for official controls, will be repealed leaving only the requirement on MS that they ensure a level of resources necessary to allow the correct implementation of control requirements and efficient enforcement of EU law, currently laid down in Article 26 of the Regulation.

Option 1B - Mandatory exemption of micro-enterprises from the application of fees

(Existing mandatory inspection fees are maintained but not applied to micro-enterprises; other provisions of the legislative framework remain unchanged)

This Option would provide for the mandatory exemption of micro-enterprises from the application of mandatory fees and would require the breadth of operators upon which mandatory fees are levied to be appositely restricted. For the rest, Option 1B would maintain the current framework as it stands now.

Option 2 – Streamline

(The legislative framework is improved and streamlined, full cost recovery is ensured where mandatory fees are already provided)

Scope

(a) a new provision will be introduced to explicitly cover official activities performed by the competent authority not directly linked to ensuring compliance by operators (e.g. surveillance and monitoring of sanitary status, surveying in view of planning control activities);

(b) the definitions of 'surveillance', 'monitoring' and 'survey' currently laid down in Regulation 882/2004 will be aligned with those included in the sectoral legislation;

Language and terminology

The language and terminology used throughout the Regulation will be amended to fully account for all sectors included under its scope, including animal health and animal welfare

legislation, and specific food legislation such as the rules governing food contact material, and the ones governing the release in the environment of genetically modified organisms.

Methods of sampling and analysis

The cascade of methods currently in Article 11 of Regulation 882/2004 will be structured more clearly. It will also be clarified that business operators have the right to apply for a supplementary expert opinion which can take several forms, *inter alia,* where technically possible and relevant, the one of a second sampling (adjustments for sectoral specificities in the animal health areas will be provided).

Official laboratories

(a) The provisions currently laid down in Article 12 of Regulation 882/2004 will be clarified to clearly state that all the methods used for analysis or diagnosis by a laboratory when operating as an official laboratory shall be included in the scope of accreditation of this laboratory; and that the scope of accreditation can comprise one or several methods.

(b) The possibility of temporary designations by the competent authority of laboratories not yet having the required method in their scope of accreditation will be introduced for following cases:

- the use of the method is a recent requirement in Union legislation,
- changes of the method in use require a new accreditation or an extension of the scope of the accreditation of the laboratory,
- an emergency situation occurs and the sudden increase of analytical or diagnostic needs requires the urgent use of a validated or standardised method by official laboratories,
- an emerging risk requires the performance of analysis or diagnosis by official laboratories for which no standardised nor validated method exists (e.g. emerging risks).

(c) An empowerment for the Commission to grant permanent derogations to the mandatory accreditation according to EN ISO 17025 for small sized laboratories attached to business operator's premises will be introduced.

(d) In order to take into account specific characteristics of the animal health sector, an empowerment for the definition of exemptions to the general rule that all the methods or protocols used for analysis or diagnosis by an official laboratory shall be included in the scope of accreditation, will be created.

Official controls for animal health purposes

(a) Repeal of Directives 89/662, 90/425, 96/93, 89/609.

(b) Account in the Regulation for certain specificities of this sector that is:

- the delegation of official control tasks to individuals (i.e. approved veterinarians);
- the obligation for the MS competent authorities to ensure that animals and animal products and products of animal origin intended for dispatch to another Member State, and for which official certification is required by Animal Health Law, are controlled at the place of origin prior to dispatch to another Member State.

Border controls on goods from third countries

(a) Repeal Directives 97/78/EC and 91/496/EEC and Article 15(5) of Regulation (EC) No 882/2004.

(b) Establish a new set of rules to govern a single system of border controls capable of

handling live animals and their products, food and feed of non animal origin and other goods of relevance for the food chain (e.g. food contact materials). Such rules will be the result of streamlining existing legislation. The single and streamlined system of border controls will consist of the following elements (for which detailed uniform implementation modalities will be provided by the Commission through the use of implementing/delegated powers):

- the categories of goods that require controls prior to their entry into the EU are explicitly listed, with an empowerment to determine the specific goods which need to undergo border import controls (CN codes will be indicated as far as possible);
- the type and frequency of border controls are harmonised and based on risk criteria. The mechanism for the continuous adjustment of control rates are, on the basis of risk assessments, rates applied to specific commodities is established by delegated acts.
- the current Border Inspection Posts and Designated Points of Entry are replaced by border posts potentially capable of carrying out controls on all commodities. Such entities are subject to a single set of rules and requirements to ensure consistency of practices;
- similarly, the various health entry documents currently enshrined in legislation (e.g. Common Veterinary Entry Document, Common Entry Document) are replaced by a single harmonised model for all commodities (with necessary adjustments).

(c) Introduction of provisions to strengthen and specify the modalities of cooperation between competent sanitary authorities designated under Regulation 882, customs services and other relevant authorities. The objectives and minimum requirements of such cooperation will be established: e.g. type of information to be shared between sanitary and customs authorities, timing and modalities of it, possibility to delegate certain tasks etc, in view of optimising the synchronisation of parallel processes on the same goods and maximising efficiency gains. Similarly, the possibility of delegating certain tasks to non sanitary authorities will be introduced (e.g. controls on passengers' luggage[163]), and vice versa the possibility that controls on non food chain issues be delegated to staff of the sanitary authorities present at the borders (e.g. border controls for the presence of invasive alien species).

(d) Introduction of a provision for the competent authorities designated under Regulation 882 to be tasked by national authorities responsible for Invasive Alien Species (IAS) with carrying out border controls to verify the presence of IAS in the interest of efficiency, coherence and transparency with the border control system.

(e) Empowerments to adopt delegated / implementing acts to address technicalities of specific sectors are foreseen

Information management and handling system for official controls (TRACES+)

An empowerment to upgrade the IT tools at the disposal of the Commission and Member States would also appear necessary under this option in order to guarantee full efficiency gains. In particular, TRACES would need to be geared to deal with all commodities, including plants and plant products, and would be modified to deal with all import controls and documents, including the said harmonised entry document. Moreover, the interoperability and integration of TRACES with other Commission and Member State IT tools would need to be developed so as to ensure a proper and rapid exchange of information at defined levels with other competent authorities. Finally, in relation to TRACES itself, a legal basis would need to be foreseen for full electronic certification including the use of e-signatures so as to guarantee more efficient and safe import procedures.

[163] Currently, the possibility for sanitary authorities to delegate controls on passengers' luggage to customs services exists only in the animal health area.

Official certification

Streamline the requirements currently laid down in Article 30 of Regulation 882/2004 with those of Directive 96/93 and repeal the latter.

Empowerments

In addition to the empowerments mentioned in other sections, the review will seek to introduce appropriate delegated or implementing powers for the Commission in those cases where the absence of uniform modalities for the application of the Regulation's provision is a potential source of under enforcement. Examples are:

(a) Empowerments for the adoption of delegated/implementing acts establishing minimum requirements and mechanisms for cooperation amongst liaison bodies for the purpose of improving the administrative assistance and cooperation amongst MS.

(b) Empowerment to introduce template for annual reports

(c) Empowerments to adopt delegated/implementing acts to provide for uniform minimum requirements of the transparency provisions.

Official controls on residues of veterinary medicines

Repeal Directive 96/23/EC so that:

- for environmental contaminants, only Regulation (EC) N° 882/2004 and the existing specific EU contaminants legislation would apply (sampling and testing of environmental contaminants only based on risk assessments),
- for residues of pesticides, only Regulation (EC) N° 882/2004 and the existing specific EU residues of pesticides legislation would apply (only the risk based national control programmes as well as the EU coordinated control programme under Regulation (EC) N° 396/2005 would exist),
- for residues of veterinary medicines, only Regulation (EC) N° 882/2004 as well as eventual implementing/delegated acts imposing minimum levels of mandatory controls in the MANCPs in cases where the nature of the risks involved requires a uniform minimum frequencies of controls across the EU would apply,
- only specific import conditions determined under the common regime of Regulation (EC) No 882/2004 would apply (third countries would have to provide information and data on legislation, control plans for testing residues of veterinary medicines providing guarantees at least equivalent to the ones provided by the minimum uniform frequencies of controls in the EU, etc.),
- only Article 54 of Regulation (EC) N° 882/2004 on enforcement measures would apply.

Financing of official controls

The list of mandatory fees currently laid down in Regulation 882/2004 will remain unchanged. Some changes will be introduced to improve the legislative framework.

(a) - Cost recovery

The following requirements will be introduced

1. where fees are mandatory Member States shall establish fees on the basis of costs incurred for the control activities;
2. fees shall be established at a level such that they enable CA to fully recover their costs;

3. where fees are levied on all operators irrespective of whether the operator receives an inspection during the reference period, Member States shall set up a system that, taking into account the record of compliance of each operator, establishes higher fee rates for less compliant businesses;
4. the Annexes IV and V to Regulation 882/2004, which currently set standard/minimum fees will be repealed.

(b) - Clearer costing

1. Control activities which an operator should be charged for will be specifically listed as follows:
   - controls on slaughter, cutting operations and cold storage of meat, production and placing on the market of fishery products, and milk production;
   - controls carried out to grant feed establishments approval;
   - controls carried out at a border on consignments of live animals and their products,; certain food and feed of non animal origin
2. The list of elements to be included in the calculation of overall costs will be better defined.

(c) Transparency

The requirements on MS to inform operators and the public of how control costs are established and fees calculated will be re-enforced by specifying the elements of information to be made publicly available. Such element shall include in particular:

- **Overall cost** of official control activity
- **Breakdown** per cost element (**direct and indirect**)
- **Level of fee** applied on operator
- **Reference period used for calculation of costs (e.g. in case of flat rate)**

(d) Micro-enterprises

MS will be provided with the possibility to (partly or totally) exempt micro-enterprises[164] from the payment of fees, provided that the exemption does not result in an equivalent cut in the resources necessary to CA for the performance of official controls. In other words, the exemption shall be compensated by the allocation to CA of additional resources equivalent to the difference between the cost of controls and the fees collected[165].

(e) A transition period of 2 years will be provided for the smooth introduction of the all provisions governing the financing of official controls.

[164] Enterprises with less than 10 employees and a turnover or balance sheet total equal or less than €2 million.

[165] The option of requiring MS to exempt all micro-businesses from payment of mandatory fees was discarded. See section 4.2. (*Discarded policy options*). With regard to Plant Health, exemptions for micro-enterprises will not apply given that most operators under these health regimes could qualify as micro-businesses; the new plant health legislation will foresee specific exemptions from plant passporting obligations for small companies operating exclusively on the local market (see Impact assessment report on "the proposal to revise the EU Plant Health Legislation"). With regards to plant reproductive material, whether or not exempting micro-business is still under consideration in the context of the ongoing IA.

Option 3 – Streamline + Integrate

(The legislative framework is improved and streamlined, plant health and plant reproductive material, and animal by-products are included in its scope, full cost recovery is ensured where mandatory fees are already provided)

In addition to changes described under option 2, option 3 would imply the following changes.

Scope

(a) the provision designing the scope of the Regulation will fully include plant health law, plant reproductive material and legislation governing animal by-products; as a consequence all provisions of the Regulation, streamlined and amended following option 2, will apply to official controls (including border controls and communication with customs) and other official activities not directly linked to ensuring compliance as regards these sectors unless otherwise provided.

(b) following the repeal of Directive 2000/29 and the 12 PRM marketing Directives, the new Regulations on plant health and plant reproductive material will no longer include horizontal issues covered under Regulation 882/2004

(c) repeal of official controls provisions laid down in Regulation 1069/2009 (animal by-products Regulation)

Language and terminology

The language and terminology used throughout the Regulation will be amended to fully account for the new sectors included under its scope.

Official laboratories carrying out plant health tests

(a) determine tailor-made obligations for the accreditation of official laboratories carrying out plant health tests (accreditation only for limited numbers of pests representative for pest groups);

(b) provide for a five years transitional period to allow smooth introduction of the obligation to accredit official laboratories in charge plant health tests;

(c) provide for a permanent derogation for universities and research centres in the plant health and plant reproductive material sectors;

(d) introduce the possibility to establish a system of EU and national reference laboratories.

Official certification

(a) amend the definition of 'official certification' to include the official certification issued by operators under the supervision of the competent authority;

(b) amend Article 30 of Regulation (EC) No 882/2004 to foresee the possibility for the operators to issue the certification under the supervision of the competent authority, without prejudice of more specific legislation;

(c) specificities of certification will be provided in the sectoral Regulations on plant health and plant reproductive material.

Financing of official controls

The list of mandatory fees will remain as under Option 2 with the only exceptions being in the field of plant health, where mandatory fees will be introduced for official controls linked to

plant passport obligations[166], and in the field of plant propagating material, where the principle of full cost recovery through fees will be established for certification and registration of varieties.[167]

Option 4 – Streamline + Integrate + Broader cost recovery

(The legislative framework is improved and streamlined, plant health and plant reproductive material, and animal by-products are included in its scope, and mandatory fees are extended to cover key areas of the food chain)

In addition to the elements of option 3, option 4 would imply the following changes.

(a) the list of mandatory fees will be expanded so as to also cover official controls carried out on activities for which an obligation for operators to be registered exists in accordance with Regulation (EC) No 852/2004 on the hygiene of foodstuffs and/or Regulation (EC) No 183/2005 laying down requirements for feed hygiene. In addition, a fee will be required for all border controls on goods from third countries carried out to ascertain compliance with EU food chain requirements.

This option would imply that, in addition to the list of mandatory fees under Option 3, Member States should ensure that a fee is collected to cover the costs generated by official controls in the following cases:

- **production** of food other than meat, fishery products and milk - these being already included; that is: **eggs and egg products, honey and all foods of non animal origin**.
- **distribution (including wholesale, retail and restaurants) of all food**;
- **production and distribution (including wholesale and retail) of feed**;
- **production and distribution of ABP** in so far as the concerned operators have to be registered under Regulation (EC) No 852/2004 or Regulation (EC) No 183/2005;
- **import of products originating from third countries that need to be checked at the border** other than those already covered by a mandatory fee (for example products subject to a safeguard measure).

(b) A transition period of 3 years will be provided for the smooth introduction of all provisions governing the financing of official controls.

[166] See Impact Assessment report on the proposal to revise the EU Plant Health Legislation.
[167] See Impact Assessment report on the placing on the market and production, with a view to placing on the market, of plant reproductive material

Annex XXIV- Simplification gains

	Title	Description	Expected impact
		Option 1	
1.	Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market	This Directive deals with official controls carried out to verify compliance with animal health requirements in intra- EU trade, with a view to the completion of the internal market.	Repealed because it overlaps with Regulation 882/2004
2.	Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra- Community trade in certain live animals and products with a view to the completion of the internal market	This Directive lays down rules relating to veterinary and zootechnical checks to be applied to live animals and products of animal origin for intra-Community trade. This legislation abolishes veterinary and zootechnical checks at the Union's internal borders and reinforces those carried out at the point of origin, during transit and at the place of destination.	Provisions for the application of the veterinary legislation will be repealed because they overlap with Regulation 882/2004. Provisions regarding the zootechnical aspects will remain untouched.
3.	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products	This Directive defines the prescriptions to be respected when drafting, submitting and executing national residue monitoring plans for live animals and products of animal origin as well as specific enforcement measures in case of non compliances by food businness operators, the requirements for third countries being essentially the same as for Member States. A principal objective of Council Directive 96/23/EC is to detect illegal use of substances in animal production as well as detecting the misuse of authorised veterinary medicinal products. Apart from residues of veterinary medicines, the Directive covers also several residues of pesticides and several environmental contaminants among the group of substances to be controlled within the framework of the national residues monitoring plans.	Repealed and streamlined with the pertinent provisions of Regulation 882/2004

	Title	Description	Expected impact
4.	Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters	This Directive establishes the modalities according to which Member States provide each other with mutual assistance to ensure that veterinary and zootechnical laws are properly applied.	Provisions for the application of the veterinary legislation will be repealed because they overlap with Regulation 882/2004. Provisions concerning the zootechnical aspects will remain untouched.
5.	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC	This Directive defines the prescriptions to be respected when drafting and executing national residue monitoring plans for live animals and products of animal origin. A principal objective of Council Directive 96/23/EC is to detect illegal use of substances in animal production as well as detecting the misuse of authorised veterinary medicinal products.	Repealed. Certain provisions will be streamlined into Regulation 882/2004.
6.	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	This Directive sets out the legal framework governing the checks to be carried out on products of animal origin from third countries at border inspection posts.	Repealed and replaced by the new chapter on import controls of Regulation 882/2004.
7.	Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organization of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC.	The Directive defines the arrangements for the external border checks and for the internal movement of live animals from third countries.	Repealed and replaced by the chapter on import conditions in Regulation (EC) No 882/2004. Delegated / Implementing acts
Option 2			

	Title	Description	Expected impact
8.	Council Directive 2000/29/EC of 8 May 2000 on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community	This Directive lays down measures designed to protect Member States against the introduction of organisms harmful to plants and plant products from other Member States or third countries. This Directive also lays down measures designed to protect Member States against the spread of harmful organisms within the European Union	Repealed. Regulation 882/2004 will apply for the aspects related to official controls. For the rest the new Plant Health Law will apply
9.	12 Directives on the marketing of plant reproductive material		
10.	Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation)	The purpose of the legislation is to safeguard public and human health by providing enforceable controls for the safe disposal of animal by-products.	Repealed because redundant General principles in Regulation 882/2004

Annex XXV: Exemptions and reductions for micro-enterprises

Regulation 882/2004 requires MS to account for the interests of low-throughput businesses when setting fees, as it can be expected that these establishments may be disproportionately affected by the charging of fees, by comparison with larger establishments. During the consultation process for the 2011 external study of inspection fees, the issue of whether sufficient consideration is currently given to the needs of SMEs was raised, and in particular, to the needs of micro-enterprises[168].

Summary of stakeholder opinions

Through the 2011 study, stakeholders (CAs and industry) were asked to consider the advantages and disadvantages of including fee exemptions or reductions in the revised legislation, impacts on the different stakeholder groups, and **whether the Regulation should provide a universal exemption for micro-enterprises under EU law** or provide the option for MS to implement reductions or exemptions as they choose.

For the purpose of the 2011 external study supporting the impact assessment[169], the definition of "micro-enterprise" applied is that set out in Commission Recommendation 2003/361/EC[170]. This states that a micro-enterprise is a business which has fewer than 10 employees and has:

- An annual turnover of not more than €2 million; and / or
- A balance sheet of not more than €2 million.

CA and industry respondents were clearly in favour of the option to have an exemption or reduction, or to have no special terms for micro-enterprises, rather than to introduce a universal exemption or reduction.

CAs and industry recognised that such an amendment would reduce the financial burden on micro-enterprises and help to encourage development of small businesses. Indeed exemptions are currently provided to micro-enterprises in 11 Member States (five Member States do not offer such reductions or exemptions and information is not available for the remaining 11 Member States[171]).

Industry noted that provisions to reduce the burden on micro-enterprises would be important if Regulation 882/2004 was to be amended to achieve full cost recovery (for example by better defining the activities subject to mandatory fees and the removal of minimum fees), and particularly in light of the possibility to expand the scope of mandatory fees to sectors not currently covered, whereby micro-enterprises in a number of sectors would be required to pay fees for the first time.

On the other hand, several industry respondents expressed concern that fee exemptions or reductions for micro-enterprises were unfair on those enterprises not subject to exemptions. It was suggested that an effective risk-based system might automatically reduce the costs for the best-performing micro-enterprises.

Both CAs and industry commented that a universal exemption / reduction for micro-enterprises would have a negative impact or, at best, no impact at all on the sustainable

[168] Annex X
[169] Annex XI
[170] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:124:0036:0041:en:PDF
[171] DG SANCO baseline and Eurostat 2008

performance of official controls. In particular, CAs voiced their concerns that a universal exemption / reduction would be likely to have a negative impact on resource mobilisation in situations where less fee revenue is collected but the number of controls remains the same, for example in MS with a large quota of micro-enterprises. CAs felt that the fees charged to micro-enterprises, if at a reduced rate, may not cover the cost of collection.

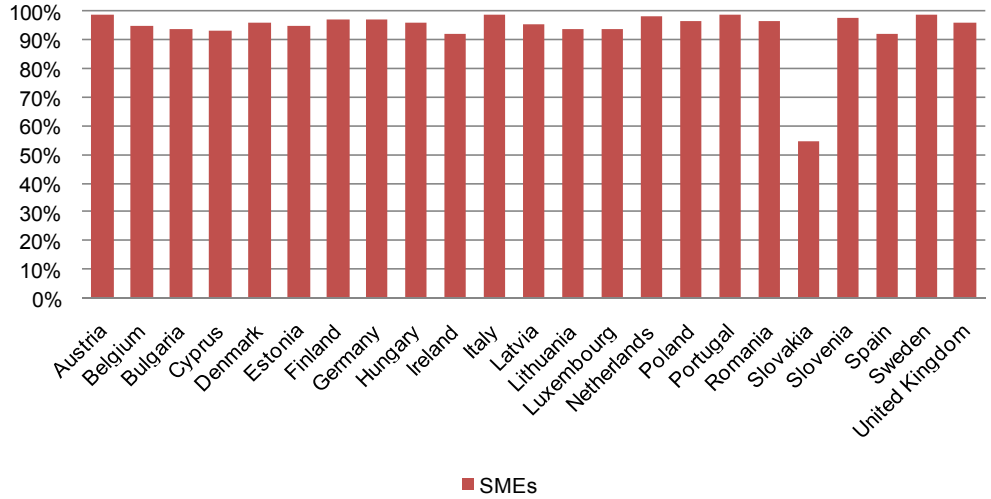
These views, expressed by stakeholders, are consistent with, and confirm the overall conclusion drawn in the Impact Assessment that it would not be appropriate to introduce a universal requirement for MS to exempt all micro-businesses from payment of mandatory fees as: (i) stakeholders (businesses and MSs) have opposed a rigidly established mandatory exemption (ii) such an exemption would have a disproportionate impact on competition and on cost recovery in MS with a large quota of micro-businesses.

Measure of the impact of a universal exemption / reduction for micro-enterprises

As highlighted by CAs during consultation (see above) a universal exemption / reduction for micro-enterprises would have a disproportionate impact on cost recovery in MS with a large quota of micro-businesses.

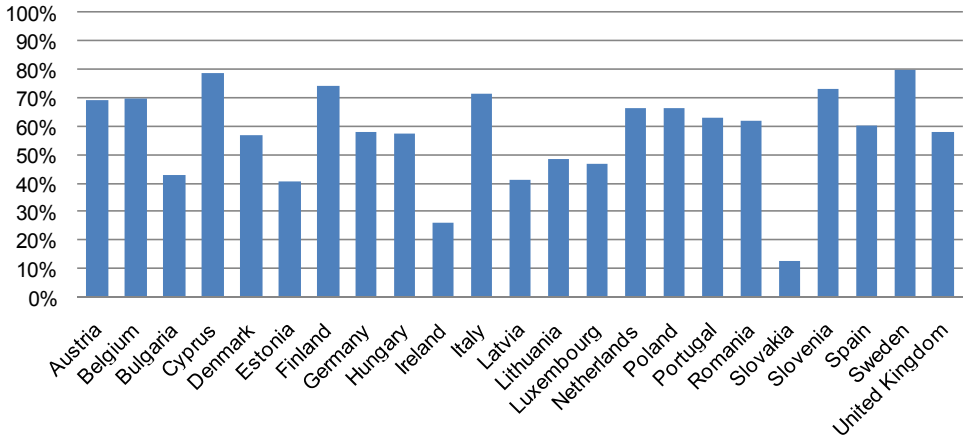
Figure 1 demonstrates the number of SMEs as a percentage of the total number of enterprises in the major industries affected by official control activities and it can be seen from Figure 2 (and broken down by industry in Table 2) that the large majority of these are micro-enterprises. Indeed, for 16 of the 23 Member States for which data are available, micro-enterprises represent more than half of all FBOs in the four major industries affected by official controls (for 9 of the 23[172], this figure rises to two thirds or more of all enterprises). Table 2 demonstrates that the strongest disruption to effective cost recovery would occur for official control in the dairy products industry where 72% of all operators are micro-enterprises. In Slovakia, only 13% of relevant enterprises are micro-enterprises and potential impact might be expected to be smaller, whereas in Sweden, the figure rises to 80% and potential impact would be expected to be much larger.

Figure 1. Share of SMEs in total number of enterprises in the four major European industries affected by official control activity (2008)*



[172] AT, BE, CY, FI, IT, NL, PL, SE, SI

Figure 2 Share of Micro-enterprises in total number of enterprises in the four major European industries affected by official control activity (2008)*



*Industry sectors include: processing and preserving of meat and production of meat products; processing and preserving of fish, crustaceans and molluscs; manufacture of dairy products; manufacture of prepared animal feeds. Greece and Malta are not included in Eurostat dataset. Data for the Czech Republic and France are not available.

Table 2 - Share of micro-enterprises in total number of enterprises in EU MS by sub-sectors (2008)

	Processing and preserving of meat and production of meat products			Processing and preserving of fish, crustaceans and molluscs			Manufacture of dairy products			Manufacture of prepared animal feeds			Total		
	Total	Micro	Share	Total	Micro	Share	Total	Micro	Share	Total	Micro	Share	Total	Micro	Share
AT	1,092	763	70%	6	2	33%	158	117	74%	56	25	45%	**1,312**	**907**	**69%**
BE	823	571	69%	56	:	:	442	373	84%	149	76	51%	**1,470**	**1,020**	**69%**
BG	475	201	42%	31	8	26%	273	125	46%	106	47	44%	**885**	**381**	**43%**
CY	71	46	65%	:	:	:	147	127	86%	38	28	74%	**256**	**201**	**79%**
CZ	1,467*	:	:	:	:	:	146	:	:	:	:	:	**1,613**	**:**	**:**
DK	147	89	61%	119	55	46%	75	49	65%	67	39	58%	**408**	**232**	**57%**
EE	53	20	38%	59	23	39%	31	11	35%	13	9	69%	**156**	**63**	**40%**
FI	204	142	70%	147	129	88%	52	29	56%	77	55	71%	**480**	**355**	**74%**
FR	10,410 *	:	:	496*	:	:	1,457	:	:	:	:	:	**12,363**	**:**	**:**
DE	11,044	6,558	59%	233	:	:	401	207	52%	420	263	63%	**12,098**	**7,028**	**58%**
HU	592	334	56%	13	11	85%	100	53	53%	196	119	61%	**901**	**517**	**57%**
IE	133	26	20%	68	15	22%	59	20	34%	58	22	38%	**318**	**83**	**26%**
IT	3,559	2,495	70%	442	277	63%	3,295	2,469	75%	579	365	63%	**7,875**	**5,606**	**71%**
LV	128	62	48%	108	36	33%	42	15	36%	16	8	50%	**294**	**121**	**41%**
LT	176	69	39%	66	37	56%	69	46	67%	25	10	40%	**336**	**162**	**48%**
LU	27	14	52%	0	0	0%	5	1	20%	0	0	0%	**32**	**15**	**47%**
NL	491	325	66%	115	64	56%	258	206	80%	182	96	53%	**1,046**	**691**	**66%**
PL	3,283	2,134	65%	410	280	68%	718	467	65%	461	343	74%	**4,872**	**3,224**	**66%**
PT	633	382	60%	211	112	53%	439	345	79%	128	52	41%	**1,411**	**891**	**63%**
RO	909	532	59%	41	25	61%	633	413	65%	128	88	69%	**1,711**	**1,058**	**62%**
SK	72	17	24%	8	3	38%	38	3	8%	60	:	:	**178**	**23**	**13%**
SI	163	110	67%	5	2	40%	87	77	89%	16	9	56%	**271**	**198**	**73%**
ES	4,153	2,771	67%	689	356	52%	1,462	1,168	80%	837	:	:	**7,141**	**4,295**	**60%**
SE	494	367	74%	214	180	84%	127	108	85%	100	91	91%	**935**	**746**	**80%**
UK	1,035	545	53%	343	189	55%	543	357	66%	426	263	62%	**2,347**	**1,354**	**58%**
Total	**29,757 ****	**18,573**	**62%**	**3,095* ****	**1,804**	**58%**	**9,454* ***	**6,786**	**72%**	**3,241**	**2,008**	**62%**	**60,709**	**29.171**	**48%**

*Source: Eurostat. *2007 figure ** Sum does not include CZ and FR. *** Sum does not include BE, FR, DE*
GR and MT are not included in Eurostat dataset
Figures in Total column includes all available data

Despite the large share of total enterprises attributed to micro-enterprises within the sectors most affected by official control activities, their share of the total turn-over within their respective MS is, by comparison, low. Table 3 illustrates that in all but one MS (Cyprus) share of total turn-over attributed to micro-enterprises is less than 10% (and for 17 MS it is 5% or less). This re-enforces the fact that a very low turn-over of individual micro-

enterprises by comparison with larger operators in these sectors, makes the relative impact of fees for official controls disproportionately greater.

Table 3 Share of micro-enterprises' sectoral turnover in total sectoral turnover in EU MS (2008) (absolute figures in millions of euros)

	Processing and preserving of meat and production of meat products			Processing and preserving of fish, crustaceans and molluscs			Manufacture of dairy products			Manufacture of prepared animal feeds			Total*		
	Total	Micro	Share	Total	Micro	Share	Total	Micro	Share	Total	Micro	Share	Total	Micro	Share
AT	3,276	244	7%	32	:	:	2,394	61	3%	900	:	:	**6,602**	**305**	**5%**
BE	5,267	454	9%	482	0	:	4,241	153	4%	3,259	297	9%	**13,248**	**904**	**7%**
BG	897	33	4%	30	1	2%	372	:	:	147	6	4%	**1,445**	**40**	**3%**
CY	325	26	8%	:	:	:	234	27	11%	136	68	50%	**695**	**121**	**17%**
CZ	:	:	:	:	:	:	:	:	:	:	:	:	**:**	**:**	**:**
DK	5,374	76	1%	1,761	51	3%	0	:	:	2,973	59	2%	**10,109**	**185**	**2%**
EE	246	10	4%	124	15	12%	383	:	:	67	4	7%	**820**	**30**	**4%**
FI	2,499	49	2%	160	33	20%	0	:	:	439	36	8%	**3,098**	**117**	**4%**
FR	35,750	3,597	10%	3,140	:	:	26,780	2,907	11%	11,978	812	7%	**77,648**	**7,316**	**9%**
DE	39,522	1,720	4%	2,533	:	:	27,593	69	0%	8,882	158	2%	**78,529**	**1,946**	**2%**
HU	2,645	109	4%	3	1	32%	1,106	11	1%	926	47	5%	**4,680**	**168**	**4%**
IE	4,275	31	1%	373	14	4%	3,556	32	1%	1,082	53	5%	**9,287**	**129**	**1%**
IT	19,153	1,251	7%	2,114	309	15%	17,423	1,589	9%	6,000	579	10%	**44,691**	**3,728**	**8%**
LV	375	9	2%	218	3	1%	349	2	1%	51	:	:	**993**	**13**	**1%**
LT	615	9	1%	232	5	2%	856	1	0%	339	:	:	**2,042**	**14**	**1%**
LU	116	4	3%	0	0	:	0	:	:	0	0	:	**116**	**4**	**3%**
NL	8,248	267	3%	:	:	:	9,642	95	1%	7,219	222	3%	**25,109**	**584**	**2%**
PL	11,800	487	4%	1,442	52	4%	6,064	96	2%	2,947	117	4%	**22,253**	**752**	**3%**
PT	2,199	94	4%	1,093	:	:	1,703	58	3%	:	98	:	**4,995**	**249**	**5%**
RO	2,481	63	3%	68	2	3%	1,053	33	3%	233	2	1%	**3,834**	**101**	**3%**
SK	703	16	2%	56	1	2%	585	:	:	233	:	:	**1,576**	**17**	**1%**
SI	670	30	5%	15	:	:	316	6	2%	98	:	:	**1,099**	**36**	**3%**
ES	19,637	1,414	7%	4,160	178	4%	10,659	817	8%	9,852	:	:	**44,308**	**2,408**	**5%**
SE	3,502	218	6%	:	89	:	2,752	53	2%	698	77	11%	**6,951**	**438**	**6%**
UK	16,624	276	2%	2,981	64	2%	9,609	144	1%	5,880	247	4%	**35,092**	**731**	**2%**
Total	**186,197**	**10,484**	**6%**	**13,722**	**729**	**5%**	**126,913**	**6,151**	**5%**	**52,865**	**2,784**	**5%**	**399,220**	**20,335**	**5%**

*Figures in Total column includes all available data

Annex XXVI: The development of an EU dedicated legislative instrument to tackle Invasive Alien Species – potential synergies with the revision of the rules on border control

Invasive alien species (IAS) are animals and plants that are introduced accidentally or deliberately outside of their natural past or present distribution. They represent a serious threat to biodiversity in Europe, as well as to plant health (e.g. agricultural weeds), to animal and human health (e.g. disease transmitting insects, allergenic weeds, poisonous species) and to the economy (e.g. blocking drainage systems), causing millions of euro worth of damage every year.

The Commission published a Communication[173] "Towards an EU Strategy on Invasive Species" in December 2008 and noted that there is currently no comprehensive instrument at EU level to tackle IAS, except for some aspects of the problem which are addressed by the plant and animal health regimes.

As announced in its EU 2020 biodiversity strategy[174], the European Commission is currently developing a dedicated legislative instrument to tackle outstanding challenges relating to IAS prevention, early detection and rapid response and containment and management, beside seeking to streamline biodiversity concerns into the existing legal instruments of the animal and plant health regimes. The dedicated instrument on IAS is expected to close the policy gaps, not yet addressed by the EU animal and plant health regimes, including a mechanism to control the import of listed IAS.

Possible synergies between Regulation 882 and the forthcoming IAS legal instrument

In the interest of efficiency and clarity, border controls on the import of listed IAS could be performed at the same entry points designated for other EU official border controls as established by Regulation 882, carried out to apply the plant and animal health legislation. This would avoid creating a parallel system of border controls but would take advantage of a well functioning system with limited extra investment, mainly limited to extra staff resources and training, as well as increased collaboration with the designated competent authorities.

A provision in Regulation 882 could allow that the competent authorities designated by Regulation 882 can be tasked by the IAS relevant competent authorities to carry out the necessary border controls to verify the presence of IAS. This is expected to create efficiency gains as well as avoiding the creation of a confusing legal framework for importers, through the establishment of a parallel system of border controls. The impacts and benefits of such possibility will be fully described and analysed in the Impact Assessment accompanying the legislative proposal on IAS.

Consultations and finding

Within the framework of the work on the forthcoming proposal for a dedicated legislative instrument on IAS, an intensive consultation exercise was held between 2010 and 2011. A crucial element of discussion was how to prevent the entry of new IAS into the territory of the

[173] http://ec.europa.eu/environment/nature/invasivealien/docs/1_EN_ACT_part1_v6.pdf
[174] http://ec.europa.eu/environment/nature/biodiversity/comm2006/pdf/2020/1_EN_ACT_part1_v7%5b1%5d.pdf

EU: it was generally recognised that prevention is a much more cost-effective way of dealing with IAS, rather than reacting to established species or after the onset of an invasion.

Border controls done according to harmonised EU rules were strongly supported as an appropriate means to avoid new invasions. There were calls to streamline as much as possible the border control with existing EU instruments in order to on the one hand ensure an efficient and cost effective use of resources and on the other hand to avoid creating an overly complex system by creating a parallel system of controls. The need to create synergies with existing and well-functioning systems was often stressed. This lends support to the mechanism whereby border controls on IAS could be delegated to the competent authorities established by Regulation 882, with a view to increasing efficiency and maintaining the system of border control as simple and streamlined as possible.