European Commission

ROADMAP			
TITLE OF THE INITIATIVE	**Review of Regulation (EC) No 882/2004 on official controls on food and feed safety, animal health and animal welfare**		
LEAD DG – RESPONSIBLE UNIT	DG SANCO/ E5	DATE OF ROADMAP	10 / 2012

This indicative roadmap is provided for information purposes only and is subject to change. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.

A. Context and problem definition

(1) What is the political context of the initiative?

(2) How does it relate to past and possible future initiatives, and to other EU policies?

(3) What ex-post analysis of existing policy has been carried out? What results are relevant for this initiative?

Regulation (EC) No 882/2004 on official controls was part of a wider initiative of 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 in 2004, with the aim of establishing an integrated approach to official controls in all areas related to the food chain (in its broadest meaning, that is covering in principle official controls carried out by Member States in all the above mentioned areas).

Regulation (EC) No 882/2004 has been in application since 1 January 2006. In July 2009 the Commission transmitted a Report on its implementation to the European Parliament and the Council, reporting on the first years' experience of enforcement.

As mentioned in the report, the new rules have indeed introduced important changes to the way competent authorities organize and carry out official controls along the food chain, establishing the basis for a more integrated and horizontal approach.

However, evaluations carried out in order to understand the state of implementation of the existing legislation as well as feedback from Member States competent authorities and Food Veterinary Office (FVO) mission reports (in particular its General Audits Reports) have shown that in a number of areas, some adjustments are now necessary in order to simplify, clarify the legal framework related to official controls, and consolidate the integrated approach in all areas related to the food chain.

In particular:

- **the financing of official controls**. The rules governing the establishment and application of inspection fees (i.e. of fees paid by business operators to finance inspection costs incurred by the competent authorities), which are laid down in Articles 26 to 29 of the Regulation, are being reviewed on the basis of external studies carried out in 2008 and 2011 which point to several problem issues which need to be addressed. In particular, the evaluation highlighted the need to provide the necessary staff and other resources for official controls.
- the official **controls on residues of veterinary medicines**. The specific rules laid down in Directive 96/23/EC are being reviewed in order to fully integrate the related provisions within the framework of the revised Regulation (EC) No 882/2004, so as to eliminate redundant control requirements, the rigidity of control requirements not based on risk assessment, and to provide competent authorities, operators and exporting third countries with a simpler and more transparent framework for controls on residues of veterinary medicines. The possibility of repealing the complex and overly prescriptive framework currently included in Directive 96/23/EC and derogating from Regulation (EC) No 882/2004, has been considered.
- the rules on **veterinary controls on import of live animals and products of animal origin**, currently laid down in Council Directive 91/496/EEC and 97/78/EC respectively, are also undergoing review. The current system of veterinary border checks has proved to be working well, so the review will not impact substantially on the overall organisation and functioning modalities of the existing Border Inspection Posts (BIPs), nor on the two core principles of import controls, namely that products entering the EU from third countries must comply with EU legislation and offer the same level of safety as domestic products, and that controls on imported products must be risk based. On the other hand, the review of veterinary border controls will contribute to marking the existing import control system more transparent, up-to-date and effective, along the lines of the Report from the Commission to the Council and the European Parliament on the effectiveness and consistency of sanitary and phytosanitary controls on imports of food, feed, animals and plants, by taking into account technological developments (e.g.

electronic certification) and by using fully existing data collection and handling tools to operate a risk-based approach to physical inspections. The review will also seek to eliminate the fragmentation of the current legislative framework, by fully integrating the rules on veterinary border controls into the general framework of the Regulation, which indeed recognises that certain commodities, for which specific risks are identified, require specific controls prior to their introduction into the EU. An impact assessment of the changes that will be needed as a result of the review is not foreseen as the exercise aims at simplifying existing legislation while keeping unchanged the general principles on which the system of import controls is built.

- In addition to the review mentioned above, some other simplification and clarification might need to be introduced into the Regulation to **appropriately complement the work being carried out in the context of three broad and ambitious reviews which are currently looking at modernising respectively the Animal Health and the Plant Health *acquis* and the rules on Plant Reproductive material**:

  - the animal health sector is undergoing a major review aimed at modernizing the overall legal framework:

    http://ec.europa.eu/governance/impact/planned_ia/docs/2010_sanco_015_animal_health_en.pdf).

  The rules of Regulation (EC) No 882/2004 already apply to official controls carried out to verify compliance with the requirements of animal health rules. However at the time of its drafting, Regulation (EC) No 882/2004 had its greater focus on food and feed products. For this reason the wording of Regulation (EC) No 882/2004 is not always consistent when it comes to its applicability to animal health issues. There is therefore the need for some language adjustments, clarifications and updates of certain definitions in Regulation (EC) No 882/2004. This will promote better coordination and alignment with the on-going review of animal health rules.

  - the plant health sector fully includes a major review of the related framework:
    http://ec.europa.eu/governance/impact/planned_ia/docs/2013_sanco_002_plant_health_law_en.pdf)
    .

  This sector was only partially included (with reference to the multiannual control plans and Community inspections) under the remit of Regulation (EC) No 882/2004 due to the fact that official controls in this area were already covered by the specific legislation (Directive 2000/29/EC). However, the two control regimes are very similar and in the context of the on-going review of the plant health sector it appears clear that it is now possible to have only one official controls regime, the one designed in Regulation (EC) No 882/2004, to cover also official controls in the plant health area. To this end, some adjustments in Regulation (EC) No 882/2004 are necessary to fully include the plant health sector under the official controls regime set up by this Regulation.

  - the plant reproductive material sector is also undergoing a review, in close coordination with the plant health sector with which it partly overlaps:

    http://ec.europa.eu/governance/impact/planned_ia/docs50_sanco_marketing_seed_and_propagating_material_en.pdf

- Finally, but equally important, the on-going work offers the opportunity to address those **weaknesses of the system of official controls which are of horizontal nature** (which result for instance from duplicated or overlapping reporting and planning requirements or from unclear or inconsistent language). This will be done by a recast exercise which will consolidate the integrated approach to official controls along the food chain so as to simplify the framework for enforcement cooperation between the Commission and the Member States and to ensure better consistency in implementation across the EU. It is assumed that the resulting more efficient framework for enforcement will result in a substantial reduction of administrative burden and in a more efficient allocation of control resources.

The current legislative framework established by Regulation (EC) No 882/2004 has proved to be a solid and innovative system able to support an integrated approach towards the performance of official controls along the food and feed chain. The current exercise will therefore aim at consolidating and strengthening the benefits resulting from such integrated approach, while at the same time looking at possible improvements.

It was therefore decided to merge into a single exercise all the changes that the various initiatives mentioned above will require to be made to the relevant provisions of the Regulation (EC) No 882/2004 and to address the issues of clarifying the scope of the Regulation

What are the main problems which this initiative will address?

The review of Regulation (EC) No 882/2004 will address in a single legal proposal all the issues identified within the on-going reviews of the legislation as outlined above.

It will draw on these independent reviews and subsequent impact assessment projects (where relevant) which address specific issues of the areas in question. A single, global Impact Assessment has been prepared to address these issues with regard to the review of Regulation 882/2004. (The impact of the major reviews of the Animal Health, Plant Health and Plant Reproductive Materials sectors are addressed separately in sector specific impact assessments).

On a horizontal level, the review of Regulation (EC) No 882/2004 will also seek to recast the provisions of Regulation (EC) No 882/2004 to achieve an overall simplification. Issues to be addressed include:

- inconsistencies and legal gaps, in particular as regards controls carried out for plant health. In addition, ambiguity in relation to its scope for products of relevance for the food chain which are not food (e.g. food contact materials, animal by-products, plant reproductive material, etc.);

- inefficiencies (or lack of implementation in some cases) resulting from the lack of uniform implementing rules in some areas;

- difficulties faced by Member States in using some of the mechanism for the cooperation of competent authorities in and between Member States when an enforcement action is required in more than one Member State;

- the administrative burden resulting for the Commission and the Member States authorities from some of the planning and reporting requirements introduced by the Regulation, which could be simplified and rationalised without missing any of the objectives of the Regulation. In addition, while requiring official laboratories to be accredited in accordance with EN ISO/IEC 17025, 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.

- the full integration of tools being developed in recent years as in the case of Traces (Trade Control and Expert System) the trans-European network for veterinary health which notifies, certifies and monitors imports, exports and trade in animals and animal products.

With regard to the financing of official control activities, the Review of Regulation (EC) 882/2004 will seek to address the concern that the overall objective of ensuring Member States allocate adequate financial resources to official controls is not being met throughout the EU. Issues to be addressed include:

- the limited scope of mandatory fees and the lack of consistency and fairness between sectors. With the new framework or official controls established by the revised Regulation, and the requirement that MS carry out such controls at all stages of the food chain, the current list of mandatory fees no longer appears justified and fair.

- failure to achieve sustainable funding in the sectors subject to mandatory fees. 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 MS the choice between a cost based fee and standard, or minimum, fees which might in fact be lower or higher than the real cost of activities the are meant to remunerate.

- that a number of mechanisms included in Articles 26 to 29 with the aim of promoting efficiency of the fees system and compliance by operators fail to deliver.

Who will be affected by it?

Competent authorities and business operators. The initiative will bring benefits at all levels mainly through the simplification of the provisions of Regulation (EC) No 882/2004, clarification of its scope and field of application, consolidation of the provisions related to official controls in all areas and the reduction of the administrative burden. These improvements aim at ensuring a more efficient use of official control resources in the Member States and an increase in the added value that an efficient EU wide control system (and effective enforcement of rules) brings to food chain product.

Eventually benefits will be felt also at consumers' level with more efficient, risk based and fully integrated official controls along the entire food chain.

The new rules on financing through fees will impact on operators (as more of them will be asked to pay for the controls) and on competent authorities, as they intend to secure them a steady and stable influx of resources.

Is EU action justified on grounds of subsidiarity? Why can Member States not achieve the objectives of the proposed action sufficiently by themselves? Can the EU achieve the objectives better?

These issues were positively addressed at the time of proposing Regulation (EC) No 882/2004. The proposed review, a simplification and recast exercise, therefore does not put into question these issues.

However, in brief, it is clear that the high degree of harmonisation of legislation which exists in the sectors considered makes it necessary to set harmonised rules for the official controls related to the application of legislation. That would avoid the risk of having the same legal standards being applied very differently and without coherence in the different Member States and the related negative effects on the smooth functioning of the Single Market.

Official controls remain the responsibility of the Member States (as it is for the food business operators to ensure the respect of the legal standards applicable to their activities) but existence of a harmonized legal framework at EU level on the way official controls are organised and carried out ensures their uniform implementation across the Union.

Furthermore, the objective of increasing the efficiency of the EU control system as a whole through improved cooperation among Member States' competent authorities and with the Commission can clearly only be reached with action at European Union level.

The clarification on the scope of the Regulation regarding plant health and products of relevance for the food chain which are not food would facilitate the implementation of harmonised official controls in the areas concerned (food contact materials, reproductive material, etc.).

B. Objectives of the initiative

What are the main policy objectives?

The main purpose of this exercise is to reinforce the safety of the 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 food chain;
- maintain a high level of human, animal and plant health protection and animal welfare throughout the length of the food chain and prevent that this is undermined by potential non-implementation of EU legislation;

ensure proper and uniform implementation of EU legislation.

Do the objectives imply developing EU policy in new areas?

No

C. Options

(1) What are the policy options (including exemptions/adapted regimes e.g. for SMEs) being considered?
(2) What legislative or 'soft law' instruments could be considered?
(3) How do the options respect the proportionality principle?

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 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.

The resulting options are presented in the table below.

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

D. Initial assessment of impacts

What are the benefits and costs of each of the policy options?

Option 1A. The repeal of the existing EU framework on inspection fees is likely to result in an increased variance of national approaches, and in possible cuts in resources allocated to controls.

Option 1B. The mandatory exemption of micro-enterprises from the application of fees, while reducing the financial burden on micro-enterprises, would undermine the objective of ensuring the sustainability of the control system, and through it the safety of the food chain.

Option 2. Proposed amendments would increase 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 food chain. 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.

Option 3. In addition to the impacts identified for Option 2, A fully integrated system of controls along the food chain would maximise efficiency of enforcement through simplification and synergy gains, facilitating the fulfilment of the objectives of food chain legislation.

Option 4. In addition to the impacts identified for Options 2 and 3, by broadening the collection of mandatory fees to key activities of the 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. Option 4 would result in limited additional administrative burdens for CAs to establish a fees collecting system. Such costs would decrease over time.

Could any or all of the options have significant impacts on (i) simplification, (ii) administrative burden and (iii) on relations with other countries, (iv) implementation arrangements? And (v) could any be difficult to transpose for certain Member States?

See above

(1) Will an IA be carried out for this initiative and/or possible follow-up initiatives?

(2) When will the IA work start?

(3) When will you set up the IA Steering Group and how often will it meet?

(4) What DGs will be invited?

The Services have produced and plan to publish a single Impact Assessment report to justify the proposed changes to Regulation 882 as a package, and to explain their anticipated significant impacts.

A DG SANCO task force coordinated the different initiatives with reference to the necessary changes to be made to Regulation (EC) No 882/2004. All concerned DGs (Agriculture and Rural Development, Budget, Environment, Enterprise and Industry, Research and Innovation, Taxation and Customs Union, Trade, Development and Cooperation, Maritime Affairs and Fisheries, Legal Service, Justice, and the Secretariat

General) were regularly invited to discuss the overall review of Regulation (EC) No 882/2004.

(1) Is any option likely to have impacts on the EU budget above € 5m?

(2) If so, will this IA serve also as an ex-ante evaluation, as required by the Financial Regulation? If not, provide information about the timing of the ex-ante evaluation.

No

E. Evidence base, planning of further work and consultation

(1) What information and data are already available? Will existing IA and evaluation work be used?

(2) What further information needs to be gathered, how will this be done (e.g. internally or by an external contractor), and by when?

(3) What is the timing for the procurement process & the contract for any external contracts that you are planning (e.g. for analytical studies, information gathering, etc.)?

(4) Is any particular communication or information activity foreseen? If so, what, and by when?

Data from the following evaluations, studies, reviews and reports was considered:

1. Externally contracted evaluations

Supporting formal external evaluations for the cited OCR review are:
-the 2009 external evaluation of Community Reference Laboratories in the field of animal health and live animals (functioning, performance and fulfilment of obligations and duties of 12 CRLs for a period of 15 years),
-the - 2010 interim evaluation of Better Training for Safer Food in Africa
-the 2011 external evaluation of EU Reference Laboratories in the field of food and feed and animal health (functioning, performance and fulfilment of obligations and duties of 2 EU RLs in the animal health field and 26 EU RLs in food and feed safety for a period of 5 years),
-the externally contracted 2011 Better Training for Safer Food (BTSF) evaluation (on-going),
-the 2012 evaluation of the EU rapid response network, crisis management and communication capacity regarding certain transmissible animal diseases (on-going).

2. Further externally contracted studies (para-evaluation)

Supporting studies focusing on the specific issue of fees for controls (Art 26-29 of OCR):
-the external 2009 study to assess the fees or charges collected by MS for official controls (external contractor FCEC) and
-the Impact Assessment study on the same issue (external contractor: GHK).

Other externally contracted supporting studies are: BTSF in Africa (2010), Study on high quality control posts (2010), Best Practices in sanitary and Phytosanitary Training Activities (2010).

3. Other supporting studies (not externally contracted)

On the issue of official controls on residues of veterinary medicines (Directive 96/23), an internal review of a stakeholder consultation is being carried out. General Audits Reports from FVO also contain important assessment elements of compliance with the provisions of Regulation 882/2004.

A general communication initiative is being developed on the changes to be considered for Regulation (EC) No 882/2004.

Which stakeholders & experts have been or will be consulted, how, and at what stage?

These issues are specific to each of the mentioned initiatives. The changes to be included in Regulation (EC) No 882/2004 will be discussed with the Member States and the other stakeholders during dedicated working groups meetings.