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TECHNICAL SPECIFICATIONS

SANCO/2014/E1/024 - Technical study in the context of the assessment of the need for harmonisation of methods of sampling and analysis for GM material in food

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1. Purpose of the Contract

This contract aims to perform an ad-hoc study to contribute to the assessment of the need and the feasibility for harmonisation of methods of sampling and analysis for official controls at the EU level as regards the presence **in food** of genetically modified material, in particular for which an authorisation procedure is pending or the authorisation of which has expired.

The performance of an in-depth Impact assessment for a potential legislative proposal will be considered at a later stage.

1.1 Context of the study work

Currently, EU legislation does not set in all cases obligatory specific rules for the official control of material which contains, consists of or is produced from GMOs.

In the **feed sector**, Regulation (EC) No 152/2009, as amended by Regulation (EU) No 619/2013, lays down the methods of sampling and analysis for the official control of feed, including sampling methods for the control of GM material.

In the **food sector**, Recommendation 2004/787/EC provides technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms. However, this Recommendation is not binding for Member States and, due to its limited practicability on large product lots, it is not always implemented by Member States' Competent Authorities. Therefore, in a number of cases, enforcement authorities adopt alternative sampling strategies for the control of GM material in food (as pointed out in some FVO audit reports) and this results in a lack of harmonisation across the EU.

As regards method of analysis, Regulation (EC) No 1829/2003 requires that applicants provide methods for detection and identification of the transformation event when submitting a request for marketing authorisation. These methods are validated by the European Union Reference Laboratory on GM food and feed (EURL-GMFF) and made available to official laboratories. Although event-specific methods are harmonised at European level, **interpretation of relative results may differ among official control authorities when presence of GM material is at very low levels, close to the limit of detection of the method**. Experience has shown, for example, that some Member States decide that analytical results obtained below a certain level are not sufficiently reliable and reproducible between laboratories to take a decision regarding the compliance of a lot. This results in the fact that a product may be considered as compliant in one Member State and not in another.

It should be considered that this lack of harmonisation affects the official control in general terms. However divergences in the interpretation of analytical results are expected to have a marginal impact in the **enforcement of labelling requirements** set by the EU legislation. In fact in this case compliance is established with respect to the labelling threshold set at 0.9%, which, at least for raw material, is far above the limit of detection of the validated analytical methods currently used.

The impact is much higher in the **enforcement of the EU "zero tolerance policy"**[1] with non-authorised GMOs, since in many cases compliance must be evaluated for **trace levels which are**

[1] According to **Regulation (EC) No 1829/2003 on genetically modified food and feed**, GMOs can be placed on the EU market for food and feed use only after having been authorised on a case-by-case basis, following a stringent risk assessment by the European Food

close to the limit of detection of the methods, where a higher **analytical uncertainty** is expected. This is the reason why this study is focusing on non-authorised GM events.

This lack of harmonisation could bring two main effects: significant differences as regards decisions taken on compliance by competent authorities, and **legal uncertainty** along with the derived economic risk for food operators due to these differences.

The first effect would hinder the implementation of effective and harmonised measures to manage non-compliances across the EU, when different interpretations are provided by different laboratories, or by the enforcement laboratory and the laboratory carrying out the analysis for defence.

Concerning the second effect, **operators of the food and feed chain**, which are fully responsible at all stages of production, processing and distribution within the business under their control[2], **should apply internal quality systems and control procedures** to ensure the absence of non-authorised GMOs in a commodities' lot or in the food and feed chain. **In order to properly define their internal control systems, operators need to have clear and EU-wide understanding on required sampling and analysis protocols and on rules for the interpretation of the results of the analysis aiming at demonstrating the absence of GMOs**. They claim that absence of such clear and predictable criteria across the EU, as described above, make them face legal uncertainty and potential risk of economic damages for instance in the case of commodities supply disruption, and/or food and feed product recalls.

The EU imports significant quantities of commodities produced in third countries, where GMO cultivation is widespread, for use in the food and feed chain. For example, about 80% of the vegetable proteins (mainly soybean and soymeal) used for feed in the EU are imported, and it is estimated that 75% is GM[3]. However the EU authorisation's timeframe[4] differs from those of its trading partners. This issue was emphasized in the Evaluation of the EU legislative framework in the field of GM food and feed[5], published in 2011.

The EU established legal clarity and predictability to operators as regards the issue of the presence of **asynchronous** and **obsolete** GM material in **feed**[6]. Regulation (EC) No 619/2011 harmonises the implementation of the zero-tolerance policy on non-authorised GM material in feed, by establishing harmonised methods of sampling and analysis for the official controls performed by Member States and setting up a Minimum Required Performance Limit (MRPL) for detection of asynchronous and obsolete GM material in feed. These harmonised rules are based on Article 11(4) of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

Several publications, including a report from the Commission Joint Research Center (JRC)[7], highlight that in the coming years the number of GMO authorisations is expected to steeply increase worldwide.

Since the adoption of Regulation (EC) No 619/2011, crops traders, grain processors, the food industry and retailers, and agricultural commodities exporting countries as well, have been **calling for an**

Safety Authority (EFSA) having demonstrated their safety for human and animal health and for the environment. In other words, the EU applies a **"zero tolerance policy"** as regards the presence of non-authorised GMOs on its territory.

[2] Regulation (EC) No 178/2002 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

[3] Proceedings of a workshop on "market for non-genetically modified identity preserved crops and derived products" organised by the Commission Joint Research Center http://ftp.jrc.es/EURdoc/JRC76117.pdf

[4] The EU does not recognise the risk assessments performed and authorisations granted by third countries. There are three situations where GMOs produced in third countries are not authorised in the EU: i) **asymmetric** authorisation, when a GMO approved in (a) third country(ies) is not intended to be authorised in the EU as no application was made by the operator, who e.g. has no intention to market this product in the EU, or could not file an application compliant with the EU criteria; ii) **asynchronous** authorisation, when due to differences in authorisation criteria and procedures, but also agricultural or trade policy choices, a GMO may be already authorised in third countries, while in the EU the application file has been submitted and declared valid by EFSA, but the authorisation procedure is still pending.; and iii) **obsolete** authorisation, when the authorisation may have expired in the EU due to the phasing-out/non-renewal of the product by the marketing authorisation holder.

[5] http://ec.europa.eu/food/food/biotechnology/evaluation/index_en.htm

[6] The scope of the Regulation was limited to feed on the grounds that while imported commodities can be used both in the production of food and feed, the vast majority of imported commodities likely to contain GMOs are destined to the feed sector, thereby entailing a higher risk of trade disruption for that sector.

[7] The global pipeline of new GM crops. Implications of asynchronous approval for international trade. 2009 J. Stein, E. Rodriguez-Cerezo.

harmonisation of methods of sampling and analysis for food, on the grounds that they would keep facing legal and economic uncertainties when handling commodities for food use in the EU, and/or when marketing food products derived from these commodities, due to the existing variation in GMO official controls for food in the Member States. The food and feed **Industry** claims also that, considering the interconnectedness of food and feed sectors (e.g. soya beans are used for both food (oil) and feed (meal)), the lack of harmonisation in the food sector makes Regulation (EC) No 619/2011 not fully effective in a number of cases, and therefore advocate for an extension of its scope to food.

On the contrary, a **non-industry** and **non-trader stakeholder** has contended that Regulation (EC) No 619/2011, and any extension of its scope to food, would fail to deliver legal certainty for operators and could even result in increasing costs and administrative burdens for both operators and Member States' control authorities. According to this opinion, it would be easier for food operators to check whether or not raw materials are contaminated with non-authorised GMOs, rather than to determine the exact level of any contamination.

In light of the abundant, but sometimes contradictory and incomplete elements of information described above, the **Commission wants to collect from all relevant sources, and to analyse in further details, data concerning the impacts of the current situation on national official control authorities, food business operators and other relevant stakeholders, where methods of sampling and analysis of asynchronous and obsolete GM material in food are not harmonised at EU level**.

1.2 Objectives and general approach of the study

The aim of the study is to collect and analyse **data** and **information** allowing to draw an extensive and clear picture of the **current** and **forthcoming situation** linked to the **lack of harmonisation** of methods of sampling and analysis for official controls at the EU level as regards the presence **in food** of non-authorised **asynchronous** and **obsolete** GM material. The data and information will be collected from EU Member States' Competent Authorities and official control services and from actors along the whole food supply chain. The findings will help the Commission to identify and scrutinize possible problems linked to this situation, in particular as regards the implementation of the zero tolerance policy in food, and to assess whether a policy action is needed to address them.

Two overall policy objectives have to be taken in account while performing the study: fostering the **internal market** and **safeguarding consumer choice and welfare**.

These activities will be performed with a unique set of tools and methods, from extensive literature review, surveys and interviews, to cost assessment and market analysis.

1.3 Sponsor and user of the contract

Technical unit in charge is SANCO unit E1.

2. Task to be performed by the contractor

The successful tenderer will be asked to perform the following tasks which also form the basis of the indicators of achievement and assessment of deliverables:

2.1 Scope of the study

2.1.1 Time frame

The time period 2009 - 2014 should be covered by the Study.

2.1.2. Geographical coverage

This study should cover the EU28 and relevant third countries growing GM-crops and exporting crops and derived products to the EU, such as Argentina, Brazil, Canada and United States.

2.1.3 Actors

The **EU Member States Competent Authorities and official control services** are affected by the current situation and should be consulted.

The following **stakeholders in the food chain** are also concerned: Agricultural commodities exporting countries (regulatory authorities and relevant operators); Crops traders; Transporters; EU grain crushers/processors (for food and feed uses); EU food sector, including SMEs; EU retailing sector.

Organisations dealing with **consumer protection and rights, environmental protection etc**, should also be consulted.

In order to perform the study, the contractor should collect data and views from the abovementioned actors **(including individual companies and/or professional organisations)**.

An **indicative list** of relevant stakeholders to consider is provided in annex I.

2.2 Study Questions

This study should bring data and information allowing answering the following set of **indicative** questions:

A. Lack of harmonisation of methods of sampling and analysis for the official control of asynchronous and obsolete GMOs/ Definition of a MRPL:

A.1. How many official food **samples** are tested annually for presence of asynchronous and obsolete GM material in the Member States? Which asynchronous and obsolete GMO events are tested?

A.2. What **sampling** procedures are implemented for the presence of asynchronous and obsolete GM material in food in the Member States?

A.3. Does the lack of harmonisation of **sampling** procedures have any impact on the reproducibility of testing results (within Member States and between Member States)? Have Member States ever had practical experience on that?

A.4. What **testing** procedures are implemented in the Member States regarding the control of the presence of asynchronous and obsolete GM material in food (qualitative, quantitative, MRPLs,…)?

A.5. Does the lack of harmonisation in the interpretation of **testing results** have an impact on compliance assessment (within Member States and between Member States)? Have Member States ever had practical experience on that?

A.6. Would the definition of a **Minimum Required Performance Limit** affect protocols of **testing**?

A.7. Are there any beneficial or negative effects deriving from the harmonisation of sampling and analysis and the introduction of a Minimum Required Performance Limit for food as it already exists for feed? What are these effects?

B. Impacts on operators and on the market

B.1. What are the **sampling, analysis** and **risk management strategies and protocols** applied **by food business operators** regarding asynchronous and obsolete GMOs? How many and what kind of samples are taken and what types of tests are performed on an annual basis in the framework of the own check controls?

B.2. For food **business** operators also involved in feed activities (i.e. crops growers and traders, crushers), what are the strategies and measures adopted and implemented to manage the two products flows for which different sampling and analysis procedures apply?

B.3. Does the lack of harmonisation of sampling and analysis for official controls for the presence of asynchronous and obsolete GM material affect food **business** operators at EU level? If so, what are these impacts?

B.4. What would be the potential consequences for food **business** operators under a scenario where the current lack of harmonisation of sampling and analysis for official controls would remain unchanged? How would this affect their risk management strategies?

B.5. What would be the expected impact of harmonisation of sampling and the definition of a **MRPL** for food tests as regards asynchronous and obsolete GM material?

B.6. Does the harmonisation of testing and sampling, or the lack of harmonisation thereof, affect **consumers** in the EU? If so, how?

2.3 Tasks

The Commission expects the contractor to perform the following tasks:

2.2.1 Task 1: Structuring and methodology

The contractor has to establish a **general work plan** and methodology based on the objectives and tasks in order to collect data and views of interest and process and analyse them, providing an overview over the task to be considered.

The contractor should **identify the main food sectors and products, such as soya,** on which the study needs to focus and **map relevant competent authorities and official control services, stakeholders** and other sources (scientific literature, databases, etc.) most relevant for the collection of data.

Based on the findings of the **mapping**, and in order to respond to the study questions outlined in point 2.2, the contractor has to **prepare a questionnaire** to conduct **surveys towards Member States' authorities and relevant European and international stakeholders** in order to perform task 2. The questionnaire will be fine-tuned with and validated by the Commission within one month following the kick off meeting.

The contractor will propose a list of relevant Member States (such as Germany, Netherlands, Spain, Belgium, France, Austria and Hungary) where to perform an in-depth analysis providing insight of the different approaches adopted as regards methods of sampling and analysis.

The contractor will have to gather the findings of the data collection (task 2) and analysis process (task 3) into a synthetic format to be agreed with the Commission.

2.3.2 Task 2: Observing

- Description of national authorities and stakeholders' approaches to handle the lack of harmonised methods for sampling and analysis for pending and obsolete GM material in food in the EU

The contractor is expected to organise and conduct a **survey** towards national authorities, food **business** operators (including those involved in both food and feed related activities) and relevant stakeholders in order to collect data and views allowing to answer to the questions mentioned in section 2.2. of the terms of reference.

- Description of market's and supply chain's specifications and trends for the identified main products

The contractor should provide a **comprehensive description** of the concerned markets sizes (value and volume) and temporal evolution (past, present, future), and about structures and functioning of supply chains from fields to consumers, in the EU and worldwide; this **market study** should in particular investigate main factors influencing variations in supply and demand, with a particular focus on adventitious presence of asynchronous and obsolete GMOs in traded commodities.

The contractor will have to develop a methodology allowing to collect appropriate data and views via desk research and survey (questionnaire and telephone/face to face interviews) towards the regulatory authorities/stakeholders.

2.3.3 Task 3: Analysing

Based on the information collected during task 2, the contractor is expected to provide answers to the questions listed in section 2.2 and to make suggestions on **approaches to address the possible identified problems**.

The collected data should be assessed along the criteria referred in section 1.2 (functioning of the Internal Market and consumer welfare).

3. Description of Experts and additional information

The contractor should possess a proven level of knowledge in official control procedures (with notions in sampling and detection), economics and market analysis in the food and feed sector, public policy and agrofood policy analysis, as well as in data collection, analysis and policy development.

The contractor should:

- Indicate profile, background and categories of the experts of the contractor's team.
- Designate the expert to be team leader for the study to be carried out. The team leader should have at least 15 years of professional experience of which at least 7 must be relevant to the sectors concerned and the type of tasks to be performed under the contract.

  The team leader should ensure uninterrupted coordination with the European Commission.
- Designate the members of the team according to the necessary knowledge and skills for performing the various tasks and subtasks required.
- Good English language skills are required, both written and spoken.
- Demonstrated capability to access documents and interact with informants as necessary for the completion of the tasks.

4. Organisation of the work

4.1 Budget allocated

A price band from 80.000 € up to a maximum of 100.000 €.

4.2 Overall management of the contract

The contractor is requested to produce records/minutes of each meeting with the Commission and to submit them to the Commission for approval the week following the meeting.

4.3 Deliverables & documentation

The study must be completed within **6 months** after the signature of the contract.

The present assignment includes the submission of a series of deliverables: reports and presentations. The contractor will deliver the following reports at key stages of the evaluation process: **inception report**, **interim report**, **draft final report** and **final report**. Each report should be written in English, and critically assessed as it provides the basis for tracking the quality of the work done by the evaluator. These reports will be submitted by the Commission to the established **steering group**, which may ask for complementary information or propose adjustments in order to redirect the work as necessary. Reports must be approved by the Commission. With work progressing and in the light of new findings, revisions of reports already approved may be necessary.

It is essential that all the reports be clear, concise, unambiguous and comprehensive. They should also be understandable for non-specialists. The presentation of the texts, tables and graphs has to be clear and complete and correspond to commonly recognised standards for studies to be published. A structured and precise elaboration of add-ons based on previous deliverables at every stage of the process is requested (for example, this could be done via colour-coding parts of the report developed at the offer, inception, interim and draft final stage). An indicative size of each report to be provided is (excluding annexes):

- inception report: up to 50 pages
- interim report: up to 100 pages
- final report: up to 200 pages

The reports should be provided to the Commission in both MS-Word and Adobe Acrobat (PDF) format with the charts in Excel. They should be accompanied, where requested, by appropriate annexes and delivered in accordance with the deadlines and requirements set out in the Terms of Reference and agreed with the Steering Group.

Every two weeks, the contractor should submit a **short progress note** to the Commission reporting on the state of execution of the tasks. Furthermore, the following reports and presentations shall be delivered:

Kick-off meeting report

After signature of the contract, the contractor will participate in a kick-off meeting with the Steering Group. The purpose of this meeting is to verify:

- the contractor's understanding of the Terms of Reference
- the proposed general approach to the work (methodology, planning, structure of deliverables etc.)
- the composition and eligibility of the contractor's team.

The stakeholder mapping will be discussed during that meeting.

Inception report *– within 1 month after the kick off meeting*

The inception report completes the **structuring phase** of the study. It aims at describing the organisation of the work, adapting and substantiating the overall approach, the methodology required for each evaluation question and/or specific task requested as well as the work plan outlined in the proposal. It should set out in detail how the proposed methodology will be implemented, and in particular lay out clearly in tabular form how the method allows each task to be answered via establishment of judgement criteria and within these, of evaluation indicators. A further column highlighting choice of relevant evaluation tools should complete the table. The inception report should develop such a chart to a level that allows the Steering Group to gain a good understanding of the evaluation tools and related methodological steps proposed.

The report may complete and/or suggest additional evaluation questions the contractors consider suitable. As such, this document will provide an opportunity to make a final check on the feasibility of the method proposed and the extent to which it corresponds with the task specifications.

The known sources of information, use of tracers (case studies), contact persons, as well as the way the contractor will interact with representatives will be fully clarified at this stage.

The inception report is submitted to the Commission, which will forward it to the Steering Group. On the basis of discussion, including with the contractor, changes and improvements may be requested. Final version of evaluation tasks/questions suggested by the contractor and evaluation indicators to be used will be validated by the Steering Group and the Commission at this stage. The contractor will submit a final version within two weeks.

Interim report *– within 4 months of the signature of the contract*

This report will provide information on the analysis of data collected. The evaluator should already be in a position to provide: a) **aggregated data**, and b) **preliminary findings and conclusions**.

The report will provide the Commission and the Steering Group with an opportunity to check whether the study is on track and whether it has focused on the specified information needs.

The contractor will submit a revised interim report with the necessary updates of the report after Commission discussion with the Steering Group.

Draft final report *– within 6 months of the signature of the contract*

This document will provide the **draft final conclusions** of the contractor with respect to the tasks set in the present assignment. Any judgements provided should be clear and explicit. It will also provide a technical overview of the study process highlighting limitations and possible bias therein.

The draft final report should include an **executive summary** of not more than 5 pages (synthesis of analyses and conclusions), the main report (structure to be confirmed by the Commission services but planned to reflect the content of the assignment), technical annexes (inter alia the Task Specifications and a compilation of all requested country-based information) and a draft one-page summary of the Key Messages (conclusions in bullet form) of the evaluation. The latter should precede the executive summary. This executive summary report has to be in English and French.

Final report *- to be submitted within 15 days of communication of comments made by the Commission on the draft final report*

The final report should have the same structure as the draft final report. It will take account of the results of the comments and discussions with the Steering Group regarding the draft final report insofar as they do not interfere with the autonomy of the contractor in respect to the conclusions. The executive summary (including the Key Messages section preceding it) should be provided.

The copyright of the reports remains with the Commission.

4.4 Quality Assessment

The contractor will establish robust means to ensure the reliability, validity, and comparability of the information collected as well of its analysis and of its reporting.

The Steering Group will have to agree on a quality assessment of the final report.

For details on minimal requirements regarding quality assessment of the deliverables, please see Annex III.

In order to ensure the necessary quality for such work, contractors should be constantly minded that:

- the evaluation shall respond to the information needs, in particular as expressed in the terms of reference and following discussions with the steering group;
- the methodology and design shall be adequate for proceeding to the evaluation tasks and for obtaining the results needed to answer the evaluation questions;
- collected data must be adequate for their intended use and their reliability must be ascertained;
- data shall be analysed systematically to answer the evaluation questions and to cover all the information needs in a valid manner;
- findings shall follow logically from and be justified by the data/information analysis and by interpretations based on pre-established and rational criteria;
- conclusions for being valid shall be non-biased and fully based on findings.

5. Timetable and physical location

5.1 Timetable for the work and deliverables

The contractor is to start the desk-work in November 2014 and the contract should be completed within 6 months from the signature of the contract.

ANNEX I

Indicative list of relevant stakeholders

BEUC Bureau européen des unions de consommateurs

CELCAA Comité européen de liaison des commerces agroalimentaires

COCERAL Comité du commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures de l'Union européenne

COPA-Cogeca Comité des organisations professionnelles agricoles de l'Union européenne – Confédération générale des coopératives agricoles de l'Union européenne

ECVC European Coordination Via Campesina

ESA European Seed Association

EUROCOMMERCE European Representation of Retail, Wholesale and International Trade

EUROCOOP European Community of Consumer Cooperatives

EUROPABIO European Association of Bioindustries

EUVEPRO European Vegetable Protein Association

FEDIOL The EU Vegetable Oil and Proteinmeal Industry

FoEE Friends of the Earth Europe

FOODDRINKEUROPE Confederation of Food and Drink Industries

Greenpeace

PFP Primary Food Processors

UGAL Union des groupements de détaillants indépendants de l'Europe

ANNEX II
Existing data

- *EU supply and demand: crops, origins, challenges and current questions marks*. COCERAL, Presentation of COCERAL Annual General Meeting, 2014.

- Results of Member States' testing in the context of reporting obligations in Art. 6.2 of Regulation 619/2011.

- Multi-Annual National Control Plans

- GM crops in the pipeline: An Update for 2013/2014. C. Parisi, P. Tillie. European Commission, JRC-IPTS, 2013. Unpublished draft manuscript.

- *Upholding the principle of zero tolerance in GM food.* Letter from Friends of the Earth Europe, ARGE, Coop Italy, EuroCoop, Greenpeace EU and VLOG, 2013.

- *Low level presence of not yet EU authorized GM events. Impact assessment on the EU vegetable oil industry resulting from the absence of a Technical Solution (TS) applicable to food*. FEDIOL, 2011.

- *The Low Level Presence of not yet EU Authorised GM Events on the European Vegetable Protein Industry in the Absence of a Technical Solution (TS) Applicable to Food. Impact Assessmen*t. EUVEPRO, 2011.

- *GMO study: Imports of conventional and GM crops in the EU*. C. Freitag, K. Minol, A.J. Stein, Genius GmbH, FoodDrinkEurope, 2011.

- *Provisions concerning sampling and analysis of animal feed for genetically modified material on the basis of Regulation (EC) No 882/2004. Legal opinion on a proposal by the European Commission*. Anwaltsbüro Gaßner, Groth, Siederer & Coll, 2011.

- *Implications of Asynchronous GMO Approvals for EU Imports of Animal Feed Products*. European Commission, DG AGRI, 2010.
http://ec.europa.eu/agriculture/analysis/external/asynchronous-gmo-approvals/index_en.htm

- *Maintaining the EU's comprehensive and integrated approach on food and feed with regards to the low level presence (LLP) of genetically modified material in raw materials*. SOLAE, 2010.

- *The cost of low level presence of GMOs in food products in Europe. An impact assessment based on the recent RASFF 2009.1037 & 2009.1165*. Landmark Public Policy Advisers Europe, 2009.

- *The global pipeline of new GM crops: introduction to the database*. A.J. Stein, E. Rodríguez-Cerezo, European Commission, JRC-IPTS, 2009. http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=2199

- *Economic Impact of Unapproved GMOs on EU Feed Imports and Livestock Production*. European Commission, DG AGRI, 2007 http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf

- *Adventitious traces of genetically modified seeds in conventional seed lots: current situation in Member States.* Central Science Laboratory, 2007.

ANNEX III

Offer

The methodology of this study must be drawn by the tenderers taking into account the objectives and scope described above and existing good practice. The final methodology will be agreed by the Commission and the Contractor during the inception phase.

The tenderers are required to:

- prove understanding of the scope and objectives by drafting an intervention logic,
- prove ability to address the tasks envisaged by breaking them down as in the attached model (model - table n°1),
- clearly detail the different steps of the process specifying required resources (human and financial) and time (model - table n°2),
- present timetable of main milestones of the process

Table n°1

Evaluation task	Judgement criteria	Indicators	Data Sources

Table n°2

Task	Expert (name, category specialisation)	Time required

Tenderers are not expected to restrict themselves to listed minimum requirements. Proposals for additional methodological tools that may contribute to addressing the evaluation questions in a more satisfactory manner will be considered positively when evaluating the proposals.

Inception report

This report will describe in more detail the way the evaluation will be conducted and the methodology. It will provide proposed content of the questionnaires, interview questions, focus group outlines and the list of organisms and stakeholders to be consulted and also the number of interviewees and their positions and names (model - table n°3).

This document will provide the Commission with the opportunity to check the feasibility of the method proposed and the extent to which it corresponds with the needs outlined in the terms of reference.

Table n°3

Evaluation task	Judgement criteria	Indicators	Data Sources	**Survey questions, interview questions, focus group outlines**	**List of organisms to be consulted, interviewees, their positions and names**	**Timetable of consultations**

Interim Report

This report shall describe the work completed (most of the fieldwork should be finished):

- list of reviewed documents,
- number of questionnaire and interviews completed,
- summary of preliminary results of the investigation,
- validation of data,
- the way the contractor intends to make the results of interviews comparable,
- (if relevant) list of problems the contractor faced in his work in the framework of the specific contract,
- a process advancement table with critical analysis on the progress of the fieldwork.

Draft Final Report

Evidence from evaluation tools	**Findings:** factual statements derived from the available evidence	**Conclusions:** the evaluators' interpretation of the evidence, applying transparent judgment criteria	**Possible recommendations:** recommended changes or improvements