Terms of Reference for the

Evaluation of the EU legislative Framework

in the Field of Cultivation of GMOs under Directive 2001/18/EC and Regulation(EC) No 1829/2003

and marketing of their other uses under Directive 2001/18/EC

1. BACKGROUND – A DESCRIPTION OF THE ACTIVITY TO BE EVALUATED

1.1. The regulatory framework that will be evaluated.

The present exercise aims at the evaluation of the regulatory framework of the cultivation of GMOs under Directive 2001/18/EC on the deliberate release into the environment of GMOs (hereinafter: the Directive)[1] and Regulation (EC) No 1829/2003 on GM food and feed (hereinafter: the Regulation)[2] and the marketing of their other uses under the Directive.

The aim of the evaluation is to assess to what extent the legislative framework on the cultivation and marketing of GMOs and its up to date implementation have achieved its objective of protecting human and animal health, the environment and consumers' interest, while ensuring the effective and efficient functioning of the internal market.

The evaluation will cover the provisions concerning risk assessment, authorisation procedures, post-marketing management, risk communication, national safeguard measures, confidentiality rules and zero-tolerance of unauthorised GM material in seeds.

Annex 3 offers an extended description of the provisions of the regulatory framework that will be evaluated.

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[1] Directive 2001/18/EC on the deliberate release into the environment of GMOs, entered into force on 17 October 2002

[2] Regulation(EC) No 1829/2003 on genetically modified food and feed, entered into force on 7 November 2003

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The present evaluation does not cover the EU legislative framework in the field of GM food and feed as this is covered by a parallel evaluation launched by the Commission. The medicinal uses of GMOs are regulated under a different regime[3] which falls outside the scope of this evaluation.

1.2. Implementation aspects: Authorised products, national safeguard measures and national transposition acts up to date.

Under the procedure of the Directive, the European Community authorised two GM oilseed rapes for import and processing, one GM carnation for import and four varieties of GM maize for import and feed uses[4].

No GMO has been authorised for cultivation under the current regulatory regime. The only GMO authorised under the old regime (Directive 90/220/EEC) and still actively cultivated in the EU is MON810. Three notifications for cultivation are pending under the Directive and ten under the Regulation. Two applications for renewal of authorisations (MON810 and T25) are also pending under the Regulation.

Three Member States (Austria, Hungary and Greece) have invoked the safeguard clause of the Directive and one Member State (France) has adopted an emergency measure under the Regulation against the cultivation of MON810. Austria has also invoked the safeguard clause of the Directive against the cultivation of T25, the feed uses of MON863 and the import and processing of two oilseed rapes (Ms8Rf3 and GT73).

None of the Commission proposals for the authorisation of a GMO for any use has received a favourable qualified majority at the Regulatory Committee or the Council under the applicable Committee procedure. This constitutes an exceptional case compared to the thousands of proposals submitted by the Commission every year in other policy areas and which receive favourable votes at the level of Regulatory Committees.

The Commission proposals for the repeal of national safeguard measures have also received no opinion at the Regulatory Committee and most of them have been rejected by qualified majority at the Council. A significant number of Member States usually abstain during the voting.

Finally it should be noted that all Member States have transposed the Directive into their national legislation. Member States have also adopted complementary decrees regulating further the cultivation and marketing of GMOs. All these national acts are not always in conformity with the Directive and the overall EU legislation and may introduce different approached to the cultivation of GMOs.

1.3. Reporting activities, meetings and studies.

[3] Regulation(EC) No 726/2004

[4] Notifications on feed uses have been submitted before the Regulation on GM food and feed entered into force

Experimental releases of GMOs into the environment are subject to the provisions of Part B of the Directive. Decision making on "Part B releases" takes place at the level of Member States. An analysis of field trials management in Member States and prevention of accidental entry of GMOs on the market has recently been carried out by CSL upon Commission's request[5] and is going to be published soon.

A specific study on the operation of the Directive was undertaken in 2004, identifying means to improve the consistency and efficiency of the legislative framework in the field of biotechnology[6]. The outcome of this study was incorporated in the 2004 Report from the Commission to the Council and the European Parliament on the experience of Member States with GMOs placed on the market under Directive 2001/18/EC[7]. The second implementation report from the Commission was published in 2007[8]. In 2006 the Commission also adopted the respective report about the implementation of the Regulation according to Article 46 of the Regulation itself.

As provided by the Directive and the Regulation, Member States and the Commission meet regularly to vote on Commission proposals and to exchange information on the experience acquired with regard to the release and marketing of GMOs. Ad hoc working groups have also elaborated issues such as the monitoring of the effects of GMO into the environment.

In view of the above it can be concluded that, a few years after the new regulatory framework entered fully into force, a significant amount of information is already available for evaluation by the contractor. A full list of the available material can be found in Chapter 5 and Annex 5. On the other hand, there is still limited practical experience in this area, since no GMO has been authorised for cultivation under the new regulatory regime.

2. OBJECTIVE AND SCOPE OF THE EVALUATION

The objective of the evaluation is to assess, on the basis of data and factual evidence, to what extent the legislative framework on marketing and cultivation of GMO and its implementation have proven capable to accomplish the objective of protecting human and animal health, the environment and consumers' interest, whilst ensuring the effective functioning of the internal market. The evaluation shall provide the Commission with key findings and lessons of experience from past and current implementation of EU legislation and will introduce prospective options for the future.

The report will be in particular designed to:

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[5] Report expected to be published before the end of 2008.

[6] http://ec.europa.eu/environment/biotechnology/pdf/background_study.pdf

[7] http://ec.europa.eu/environment/biotechnology/pdf/com_575_final.pdf

[8] http://ec.europa.eu/environment/biotechnology/pdf/com_2007_81.pdf

- provide the Commission's policymakers and managers with information on the implementation of the current legislation,

- identify problems in the design and implementation of the current legislation,

- recommend options for potential future action,

- identify, where available, the potential social, economic and environmental impacts of the current implementation and of recommended options for action,

- create the basis for the conduct of a possible impact assessment concerning the review of broader aspects of the GMO legislation.

The evaluation will not cover all aspects of the legislation concerning cultivation and marketing of GMOs and will solely focus on selected key areas of the regulatory framework. An overall assessment of the entire scope of the respective legislation would follow, if deemed necessary, after the conclusion of this evaluation and within the framework of a potential impact assessment.

In this view the evaluation will focus on following topics:

- The risk assessment and risk management of GMOs under the Directive, and specifically for cultivation under the Regulation, including authorisation procedures;
- Risk communication;
- The national safeguard measures under Directive 2001/18/EC and emergency measures under the Regulation on the cultivation of GMOs;
- The applicable rules on confidentiality and data protection
- The zero-tolerance of unauthorised GM material in seeds;

The contractor should collect the available data and information in a form that could later on feed into a possible impact assessment[9]. These data should be analysed in order to identify impacts of different policy options to possible revise the existing legislation. The study shall also include an analysis of the limitations of available data, comparison against varied baselines and statistical significance of time series, which should allow assessing the conclusiveness of results. Areas requiring follow-up should be identified as well.

The evaluation shall encompass the timeframe since the entry into force of the Directive and the Regulation. The contractor shall analyse with a special regard to the focus areas as outlined above. He/she will also follow the most updated developments during the conduct of the evaluation (e.g. future submissions of proposals for authorisations or safeguard measures, EFSA Opinions, Committee and Council votes, etc).

[9] Details on Impact Assessments can be found at http://ec.europa.eu/governance/impact/index_en.htm

3. MAIN IDENTIFIED CHALLENGES

The regulatory framework has been subject to controversy between Member States, stakeholders and the general public. Its implementation has faced difficulties as well. More specifically:

a. *New techniques.*

Member States increasingly deal with questions from stakeholders whether newly applied techniques result in a GMO. In order to harmonise the approach of Member States in this issue, a Working Group has been established to address whether these techniques lead to GMOs as defined under Directive 2001/18/EC and also GMMs under Directive 90/219/EEC[10]. The terms of reference of this working group will be finalised after the meeting of Competent Authorities of 17 November 2008 and its works will commence on 15 December 2008. A document outlining the state of play of the work will be presented to the Competent Authorities as early as possible in 2009.

The scientific/technical aspects of these new techniques, including their environmental, health and socio-economic variables, will be examined by a separate expert study that will be requested by the Commission.

Taking into account the above, an evaluation is needed on the regulatory aspects concerning the available plant breeding techniques. Companies and other operators partly determine their strategy on the development and use of particular techniques on the basis of whether they are subject to the GMO legislation or not. It would be thus useful to understand to what extent the compatibility of these techniques with the current definition of GMOs has influenced the development of the biotechnology sector and has generated potential costs or benefits for the involved companies, plant breeders, other operators and consumers. In this view the socio-economic, environmental and health impacts of the inclusion or non-inclusion of these techniques under the GMO legislation should be examined.

b. Evaluation of environmental risk assessment.

Under both applicable procedures, national Competent Authorities are called to carry out the evaluation of environmental risk assessments. In the case of the Regulation, EFSA has to delegate the environmental risk assessment to a national Competent Authority. EFSA shall thereafter adopt overall opinions on which the Commission proposals are based. Under the Directive, EFSA is only involved after a Member State's or Commission's objection on the environmental risk assessment is maintained after a consultation period of a total of 105 days. Concerns have been expressed by Member States, EFSA and other stakeholders about the involvement of each side in the environmental risk assessment. Same concerns have been voiced during the assessment of scientific justifications of national safeguard measures. While the work of EFSA is subject to a different legislation and evaluation, the regulatory provisions about the role of each side in the environmental risk

[10] Working Group on the Establishment of a List of Techniques Falling under the Scope of Directive 2001/18/EC on the Deliberate Release of GMOs into the Environment and Directive 90/219/EEC on the Contained Use of GM Micro-organisms

assessment of GMOs remains an important topic of debating. Moreover, the environmental risk assessment of herbicide tolerant GMOs raises issues about the interplay with the legislation on plant protection products[11], since the risk assessment and authorisation of the concerned herbicides take place under the latter legislation.

c. Interplay of the two pieces of legislations on cultivation.

As outlined above, notifications for the cultivation of GMOs can also be submitted under the Regulation, together with the food/feed uses, under the "one-door-one-key" principle. This leads to the application of different procedures not only in terms of risk assessment, risk management and national safeguard measures for the same use of GMOs, but also in the responsibility of the Community Reference Laboratory (CRL) in its role as validator of the event specific methods to be supplied by the notifier. Indeed, whereas method validation by the CRL is mandatory under 1829/03 (and the notifier contributes to the costs incurred) this is not foreseen in the Directive, but has been done *de facto* for the most recent applications, without any financial contribution made by the notifier. In this view it is important to evaluate the appropriateness and implementation of this principle.

d. Centralised authorisation at Community level.

As outlined in Annex 2, Member States have no margin to deviate, on grounds of environmental and health protection, from the terms of the consent or authorisation adopted at Community level. In case new scientific information or re-assessment of existing information becomes available that give detailed grounds for considering that a GMO constitutes a risk for human health orthe environment, a Member State can adopt a safeguard measure or initiate the procedure for the termination or amendment of the consent. Up to date Member States have only adopted safeguard measures and have not asked for amendments of consents. Under the special procedure of the EC Treaty[12] the Commission has rejected the draft measures of Austria (Upper Austria) and Poland thus denying the possibility of regional bans. Member States have sought several different ways to regulate cultivation of GMOs through the transposition acts of the Directive, additional acts, or safeguard measures. These measures provide a wide array of manners to regulate cultivation, such as:

(i) additional authorisation procedures at national or regional level;

(ii) regional or general prohibitions of GMO cultivation;

(iii) establishment of GM-free zones, either through administrative acts or through the voluntary agreements of concerned farmers;

(iv) isolation distances from ecologically sensitive areas; ,

v) monitoring of environmental effects of GMO cultivation, even if this is not foreseen by the Community consent (case of MON810)

[11] Directive 91/414/EEC

[12] Art. 95(5) EC Treaty

Therefore it is important that the Commission obtains a comprehensive overview of the legislative methods applied by Member States to regulate the cultivation of GMOs and their potential social, economic and environmental effects.

e. "Zero-tolerance" for unauthorised GM material in seeds.

Under both pieces of legislation the presence of unauthorised GMOs in any product, such as seeds, cannot be tolerated. A recent report by DG AGRI[13] analysed the question how severely imports of animal feed could be affected by the presence of non-approved GMOs in maize and soybean products. Such a study does not exist for the presence of traces of unauthorised GM material in seeds, thus it would be useful to receive an input by the concerned shareholders on the matter.

f. Inspections and controls of seeds.

Article 4(5) of the Directive allows Member States to carry out their inspections and controls without specifying further the manner and the scope of these inspections. The FVO reports have indicated that the controls of the presence of unauthorised GMOs in seeds have been uneven per Member State. It remains therefore questionable whether further harmonisation, through the introduction of more specific provisions for controls and inspections, would be appropriate to ensure the same level of environmental protection and functioning of the internal market throughout the EU..

g. Safeguard and emergency measures.

As outlined with more details in Annex 3, several Member States have used safeguard measures to prohibit the cultivation and marketing of certain GMOs. Some of these prohibitions have lasted for many years and the Commission proposals to repeal them have never received any favourable opinion under the Comitology procedure. It remains also questionable whether the application of the emergency procedures of the Regulation is suitable for the examination of national measures on the cultivation of GMOs.

h. Confidentiality and data protection.

Given the up to date experience, it is deemed important to assess several aspects concerning the clauses on confidentiality and data protection, and their consistency with other pieces of legislation, such as Regulation (EC) No 1049/2001 on access to documents.

4. THE EVALUATION QUESTIONS

The evaluation questions are intended to steer and facilitate the work of the contractors. Replying to these questions on the basis of factual evidence and

[13] "Economic impact of un approved GMOs on EU feed imports and livestock production", http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf

founded analysis is considered the core activity of the evaluator and the basis for the recommendations required.

The answer to each question shall include the following elements:

a. interpretation and comprehension of the key terms of the question;

b. indication of the judgement criteria allowing to answer the question;

c. indication of the quantitative and qualitative information needed/collected/used

d. description of the evaluation methods used (including their possible limitations)

e. detailed description of the reasoning followed in the analysis

f. conclusions directly drawn from the analysis, founded on the data and referred to the judgement criteria

1. whether the current objectives and scope of the GMO legislation are in line with the needs of society, and especially the biotechnology operators and consumers. The contractor must evaluate in particular:

- Which plant breeding techniques are already applicable or in the pipeline for commercial uses, in the EU and elsewhere;
- The socio-economic, environmental and health effects that the exclusion or inclusion of each technique into the GMO legislation may have on the biotechnology sector and other segments of the society;
- Options for future policies with regard to these techniques and the potential health, environmental and socio-economic impacts of each option.

This evaluation must take into account the scientific/technical aspects that will be addressed by the Working Group and the commissioned study (see chapter 3 a.), whose work the contractor should take into account as background information together with other relevant information.

2. whether the procedures for the risk assessment of GMOs and their implementation up to date, are efficient, time-limited and transparent The contractor will also analyse whether the procedures are capable to accomplish the objective of the existing legislation, namely to protect human and animal health, the environment and consumers' interest, whilst ensuring the effective functioning of the internal market

3. more specifically, and in the context of the above:

- the co-operation between national Competent Authorities and EFSA, as well as the role of each of them in the environmental risk assessment; the contractor should analyse *inter alia* the comments of MS, their inclusion in the EFSA opinions, the co-operation between EFSA, Competent Authorities and notifiers, the completeness and quality of the application dossiers and the possible need for additional information during the risk assessment , and the applicable timelines;

- the existence of two separate procedures for the authorisation of GMOs for cultivation as well as the application of the "one-door-one-key" principle under the Regulation for cultivation files. The contractor must compare the two procedures (under the Directive and the Regulation), analyse their impact on the environmental risk assessment and on the assessment of the validity of the detection methods to be provided for traceability and labelling, and evaluate whether the "one-door-one-key" principle for cultivation properly fulfils the objectives of the legislation;

4. the interplay between the environmental risk assessment of herbicide tolerant GMOs under Directive 2001/18/EC and the environmental risk assessment for the use of the respective herbicides under Directive 91/414/EC (Directive on Plant Protection Products); the evaluation should in particular consider whether there are any loopholes, overlaps or lack of co-ordination in the system as it has been applied so far.

5. on the basis of the upcoming study on field trials (shortly to be published by DG ENV), the way in which MS implement the provisions of Part B of Directive 2001/18/EC. In particular, the contractor will analyse the extent to which the Part B provisions and their implementation by the Member States have affected the risk assessment and authorisation procedure of GMOs for later commercial use, and whether they have fulfilled the objectives of the legislation.

6. the effect that national measures on GMO cultivation (apart from co-existence measures) have on the internal market, environmental and health protection, and possible options for future action. This evaluation has to be kept separate from the socio-economic aspects of the cultivation of GM crops, which are dealt with by national co-existence rules. The Commission is going to produce a Communication in 2009 on this issue and the contractor should take it into account as background information.

7. the current provisions for the risk management of GMO marketing and their implementation up to date. The contractor must analyse whether the respective provisions, as well as their implementation, are efficient transparent and in line with the general objectives of our legislation; special emphasis to be placed on the applicable provisions for inspections, controls, monitoring and special protection of eco-systems, environments and geographical areas.

8. the inspections and controls of the presence of unauthorised GM material in seeds as carried out by the Member States. The contractor must review *inter alia* the respective FVO reports, their findings and their recommendations, evaluate the current legislation and its implementation and present options, if necessary, for potential improvements.

9. the communication of risk concerning the release of GMOs into the environment and the manner in which it has been implemented so far by the Commission, EFSA, national Competent Authorities, the industry and other stakeholders. The contractor will analyse *inter alia* press releases, publications, scientific events and websites of the above authorities, as well as opinion polls related to the perception of risk by the public and involved stakeholders. The evaluation will not cover communications on GM feed and food which fall outside the scope of the current evaluation.

10. whether the procedures on national safeguard / emergency measures on cultivation under the Directive and the Regulation are efficient, effective, time-limited and transparent, the role of the Commission, Member States and EFSA in the procedure and whether there are any loopholes in the system;

11. whether the provisions related to national safeguard measures under the Directive and the Regulation are coherent (e.g. consideration of safeguard measures on cultivation under the emergency procedures of the general food law);

12. whether the applicable rules on confidentiality and data protection of the Directive are consistent with those of the Regulation and Regulation(EC) No 1049/2001(e.g. whether the scope and the categories of protected information are different between the two legislative tools), whilst the different concepts of data protection and confidentiality shall at all times be kept seperate; it should also be assessed whether they are efficient enough so as to sufficiently protect confidential information and intellectual property rights, while ensuring the maximum possible transparency with regards to the deliberate release of GMOs into the environment and in particular the associated risk assessment;

13. the effect of zero – tolerance policy on unauthorised seeds in the EU, with specific reference to the impact of this policy on imports of seeds and on related seed prices.

14. Where available, the answer to the above questions must also indicate social, economic and environmental impacts of the current implementation and of the suggested future options. The contractor is also invited to identify any other issues not addressed by the above questions; this could include conclusions as to whether the current legal framework has contributed to achieve its key objectives.

5. DOCUMENTS AND DATA SOURCES

The contractor shall conduct interviews with the involved stakeholders and shall analyse with a special regard to the identified areas of the regulatory framework as outlined above:

- the provisions of the EU legislation on the marketing and cultivation of GMOs (see Annex 5 for more details);
- EU legislation on relative topics, such as plant protection products[14], and access to documents[15];
- the Commission reports on the implementation of GMO legislation (reports on the implementation of the Directive (2004 and 2007),

[14] Directive 91/414/EEC

[15] Regulation(EC) No 1049/2001

Regulation (2006) and Regulation 1830/2003 on traceability and labelling of GMOs (2006 and 2008);

- the conclusions of meetings of Regulatory Committees, Competent Authorities, and thematic Working Groups;
- background documents on each individual case of product authorisation or national safeguard measure;
- Council conclusions on specific areas of GMO policy;
- EFSA guideline documents to applicants for the risk assessment of GMOs;
- Commission requests to EFSA to develop guidelines on environmental risk assessment and issue opinions on the safety of individual products;
- the Commission action plan to improve the implementation of EU legislation on GMOs
- the transposition acts of the Directive and the respective conformity checks;
- the applications of Austria and Poland under Art. 95(5) EC Treaty, the respective Commission decisions and the following court cases;
- inputs and recommendations provided by the interviewed stakeholders, including the 27 Competent Authorities designated under the Directive, professional associations and NGOs dealing with environmental and biotechnology affairs.
- the mid-term review of the Strategy on Life Sciences and Biotechnology

A full compilation of the above documents will be provided at a later stage and before the commencement of the evaluation.

The contractor is invited to propose approaches and solutions based on time and resources available.

6. THE ORGANISATION OF THE EVALUATION AND BUDGET AVAILABLE

The project will be conducted under the supervision of Unit B3 (Biotechnology, Pesticides and Health) within the European Commission's Directorate-General Environment. The contractor will provide regular progress reports to the Unit and will inform it about any important issue that may arise.

It is important to note that DG SANCO is parallel launching a study to assess the EU legislative framework in the field of GM food and feed in order to identify existing challenges in its implementation and to ensure its relevance for the current needs. The contractor will therefore seek to avoid overlapping with this exercise and consult for this purpose, as appropriate, DG ENV.

The planned assignment should be carried out in close co-operation with the Steering Committee. In this Steering Committee, other DGs and services participating in the EU GMO policy-making (DG SANCO, AGRI, TRADE, ENTR, RTD, BUDG, JRC, SG) shall be represented in order to ensure a wide viewpoint across the Commission as well as EFSA for the issues directly related to its competence as risk assessor.

The various non-institutional stakeholders will be involved in the process of evaluation but will not be part of the Steering Committee.

The maximum budget allocation for this contract is fixed at the amount of 360,000 euros.

7. THE TIMETABLE

0 month	Signature of contract
2 weeks	Kick-off meeting with Steering Group. The meeting will discuss the basic outline of the inception report and will set the platform for its preparation.
6 weeks	Inception Report. This report will describe the intervention, providing the current intervention logic. It will describe the evaluators' understanding of the evaluation objectives, issues and questions. This document will present in detail the evaluators' methodology, how it is going to be implemented and in particular how the method will provide an answer to each evaluation question. The inception report will describe the way the evaluators intend to structure their activities, the number of human resources involved in the exercise, their background and the number of meetings they propose to have with the steering group. It will include the draft questionnaires which the evaluators will use to obtain information from the different stakeholders, for approval by the steering group. This document will provide the steering group with the opportunity to make a final check of the feasibility of the methodology proposed and the extent to which it corresponds with the information needs outlined in the terms of reference.
5,5 month	Interim report. This report will provide information about initial analyses of data collected. The evaluator may already be in a position to provide preliminary

	answers to some of the evaluation questions. This report will provide the steering group with the opportunity to check whether the evaluation is on schedule and whether the evaluation has actually focused correctly on the specified information needs.
9 months	Draft final Report. This document will provide the conclusions of the evaluator in respect to the evaluation questions in the terms of reference. These conclusions will be clearly based on evidence generated through the evaluation. Judgements provided should be clear and explicit. The draft final report will also contain some exploratory recommendations developed on the basis of the conclusions reached by the evaluator. The structure of the draft final report will respect the structure set up by common Evaluation Standards and include an executive summary (synthesis of main analyses and conclusions, added value of the proposals including cost/benefits), main report (presenting in full the results of the analyses, conclusions and recommendations), technical annexes (one of which will be the Task Specification), and a draft one-page summary on the Key Messages of the evaluation.
12 month	Final Report. It will take into account the results of quality assessment and discussions with the steering group about the draft final report insofar as they do not interfere with the autonomy of the evaluators in respect to their conclusions. The final executive summary and Key Messages page will be part of it.

Several meetings between the contractor and DG ENV/B.3 will be arranged in between to ensure constructive cooperation and a common understanding of the evaluated topics.

8. GEOGRAPHICAL SCOPE

The evaluation shall cover the 27 Member States of the European Union. To the limit of the data collection/creation, the evaluator could make reference to the situation of the specific Member States. In this case the consultant will collect a robust and representative sample of stakeholders' assessments of the issues in scope of this evaluation across all the 27 Member States. By doing so, the regional specifics resulting from cultural, traditional or organisational differences should be considered in order to reach the important actors in all the Member States.

9. STRUCTURE AND QUALITY CONTROL OF THE FINAL REPORT

The final report should be structured as indicated in Annex 1. In order to check whether the draft report adequately covers the subject and scope of work as outlined in the Terms of Reference and that data within the report is consistent and accurate the Quality Control Checklist (Annex 2) will be used.

10. PREFERRED EXPERTISE

The core team proposed by the tenderer should have well established and proven experience in the areas appropriate to this evaluation, including experience in biotechnology, economy, policy making and evaluating similar evaluation assignments.

Furthermore, the team proposed by the tenderer must be able to carry out the work in English.

11. DURATION OF THE CONTRACT.

The task will be completed within 12 months of the signature of the contract. The execution of the tasks may not start before the contract has been signed. The contract is not renewable.

12. VALIDITY OF THE OFFER

The validity of the offer should be indicated here.

13. SUBCONTRACTING

Subcontracting is permitted up to a maximum of 20%, subject to the following conditions:

- the subcontractor is the sole responsibility of the main contractor;
- the Contractor shall not subcontract without prior written authorisation from the Commission nor cause the Contract to be performed in fact by third parties, unless it was approved of by the Commission.

- even where the Commission authorises the Contractor to subcontract to third parties, he shall none the less remain bound by his obligations to the Commission under the Contract.
- the Contractor shall make sure that the subcontract does not affect rights and guarantees to which the Commission is entitled by virtue of the Contract.

14. BUDGET AND METHOD OF PAYMENT

The maximum available budget is 360,000 euros.

This contract will be paid on a lump sum basis.

A pre-financing payment of 30% will be paid upon signature of the contract.

An interim payment of 40% will be paid upon acceptance by the Commission of the interim report.

A final payment of *30%* will be paid upon acceptance by the Commission of the final report.

The Commission is exempt from all taxes and dues, including value added tax, pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Communities with regard to its financial contribution under the contract.

15. ASSESSMENT OF THE QUALITY OF THE WORK OF THE CONTRACTOR

The quality of the evaluation report will be assessed by the Commission's departments based on the criteria set out in Annex 2. The Commission will publish (at its own costs) the report together with the assessment.

ANNEX 1

Structure of the Final Report

Title page:
_ title and nature of evaluation (e.g. ex post)
_ title of programme, generation, duration
_ identification of author, date of submission, commissioning department

Table of contents:
_ main headings and sub-headings
_ index of tables of figures and graphs

Executive summary:
_ an overview of the entire report in no more than five pages
_ a discussion of the strengths and weaknesses of the chosen evaluation design

Introduction:
_ description of the programme in terms of needs, objectives, delivery systems etc.
_ the context in which the programme operates
_ purpose of the evaluation in terms of scope and main evaluation questions.
_ description of other similar studies which have been done

Research methodology:
_ design of research
_ implementation of research and collection of data
_ analysis of data

Evaluation results:
_ findings, with specific elaboration of the questions asked in chapter 4;
_ conclusions, following up to the questions asked in chapter 4;
_ recommendations

Annexes:
_ terms of reference
_ additional tables
_ references and source
_ glossary of terms

ANNEX 2

Summary table for assessing the quality of work (Source – Evaluating EU Activities – a practical guide for the Commission Services – November 2003)

As regards this criterion, the evaluation report is:	**Unacceptable**	**Poor**	**Satisfactory**	**Good**	**Excellent**
1. Meeting needs: Does the evaluation deal adequately with requests for information from the Commission and is it in line with the specifications?					
2. Relevant scope: Have the rationale of the intervention, its outcomes, outputs, impacts, interactions with other policies and unexpected effects been studied in full?					
3. Appropriate methodology: Is the design of the evaluation adequate and suitable for providing the findings required (within time limits) to answer the main evaluation questions?					
4. Reliable data: Are the primary and secondary data collected or selected suitable? Are they sufficiently reliable in the light of the expected use?					
5. Sound analysis: Does the analysis of the quantitative and qualitative data comply with established rules, and is it complete and appropriate for answering the evaluation questions correctly?					
6. Credible results: Are the results logical and justified by the analysis of the data and by interpretations based on carefully presented explanatory hypotheses?					
7. Valuable conclusions: Are the conclusions just, and are they unbiased by personal or partisan considerations?					
8. Useful recommendations: Are the recommendations comprehensible, useful, applicable and detailed enough to be put into practical effect?					
9. Clarity: Does the report describe the context and goal of the intervention evaluated and also the organisation and results in such a way that the information provided is easily understood?					
Bearing in mind the specific constraints imposed on this evaluation by the background, the evaluation report is considered to be					

ANNEX 3

Regulatory framework on marketing and cultivation of GMOs in the EU

The Directive and the Regulation lay down the framework for regulating the cultivation of GMOs in the Community. The Directive also regulates the placing on the market of GMOs for other uses. Specific uses such as food/feed are regulated by the Regulation and medicinal products are regulated by Regulation (EC) No 726/2004. This framework pursues the global objective of ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to the cultivation of GMOs, whilst ensuring the effective functioning of the internal market.

The Directive is the basic legal act for the authorisation of GMOs for marketing throughout the EU, including commercial cultivation. It repealed and replaced Directive 90/220/EEC aiming at strengthening the controls of risks from the deliberate release of GMOs into the environment. The key features of the Directive include a harmonised approach to risk assessment, post-market monitoring, phasing out of antibiotic-resistance marker genes, traceability and labelling, consultation with and information to the public, predictability and transparency of decision-making and time limited consents.

Notifications for the cultivation of GMOs are submitted under the Directive. However they can also be submitted under the Regulation, together with their corresponding food/feed uses, under the "one-door-one-key" principle[16]. As a result, as of to date the majority of notifications for cultivation have been submitted under the Regulation, given their close link to the following use of crops for the production of animal feed and – at a lesser extent- of human foods. However, the provisions of the Regulation about the risk assessment, authorisation and national measures concerning cultivation of GMOs differ in some areas from the ones of the Directive.

A. Authorisation procedures.

In accordance with the Directive, a notification for the authorisation of the marketing of a GMO is submitted to one of the Competent Authorities designated under the Directive. The Competent Authority (CA) adopts an assessment report indicating and notifies it to the Commission and the other CAs. If an objection is raised and maintained by the Commission or another CA regarding the risks of GMOs to human health or to the environment, then the Commission consults EFSA. On the basis of EFSA opinion, the Commission initiates the general Committee ("Comitology") procedure[17] by submitting a proposal for an authorisation decision to the Regulatory Committee. In case a favourable decision is finally adopted, the CA which received the notification and prepared the assessment report gives a written consent for the placing on the market of the product.

The Regulation. The procedure under the Regulation is more centralised. An application for authorisation of cultivation must be submitted to one of the national

[16] Art. 2(8) and Art. 3(1)/15(1), applying also to GMOs that may be used as food/feed material for the production of food/feed. In this view the scope of the Regulation contains also seeds or other material for cultivation.

[17] In accordance with Council Decision 468/1999/EC

CAs which automatically forwards it to EFSA. Contrary to the system established by the Directive, the receiving CAs does not carry out its own assessment and the other CAs cannot make any input before EFSA receives the application. EFSA is required to adopt an opinion within 6 months. In the meantime, it must ask a CA designated under the Directive to carry out the environmental risk assessment. The other CAs of the Directive are also consulted by EFSA and can submit their opinions within 3 months. On the basis of the EFSA opinion the Commission initiates the general Comitology procedure by submitting a proposal for an authorisation decision to the Standing Committee. The product can be marketed directly on the basis of the decision adopted under the Comitology procedure.

Under the provisions of the Directive the authorisation of a GMO for any use takes place solely on the basis of an environmental and health risk assessment, while other aspects (such as socio-economic variables, effects on non-GM productions, costs and benefits, etc) are not considered. In accordance with the Regulation a decision must take into account the opinion of EFSA, any relevant provisions of the Community law and other legitimate factors relevant to the matter under consideration. While there is no specification about the precise content of these "legitimate factors", the wording of the Regulation definitely goes further than the one of the Directive concerning the basis for the approval of a GMO.

B. Content of authorisations and post-marketing management of GMO cultivation.

Community level. Under both the Directive and the Regulation, the authorisation of a GMO for marketing, including cultivation, is valid at EU level. On the basis of a written consent/authorisation a GMO may be used without any further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to. Member States may not prohibit, restrict or impede the placing on the market of GMOs which are marketed under the requirements of the Directive or the Regulation. A consent/authorisation decision may contain detailed risk management and monitoring measures depending on the potential risks indicated by the environmental risk assessment of the notifier, the CA and EFSA. Member States cannot add to or deviate from these measures. These measures must contain the conditions for the placing on the market (including the conditions for the protection of particular ecosystems/environments and/or geographical areas) and labelling requirements.

Member States. Under the Directive, Member States may take appropriate measures to avoid the unintended presence of GMOs in other products[18]. This refers to the right of Member States to regulate the co-existence of GM with non-GM crops through the establishment of measures such as isolation distances, buffer zones, rotation schemes, etc. These measures must address only the economic aspects of co-existence, namely to avoid the presence of GMOs in other products above the applicable labelling thresholds.[19] Therefore Member States have no margin to

[18] Article 26a

[19] The labelling threshold for the presence of GMOs in food, feed and products intended for industrial processing is 0,9%. Currently there are no thresholds for the presence of GMOs in seeds.

deviate from the central Community consent / authorisation on grounds relating to environmental and health protection. For instance, and unless the Community authorisation would allow them to do so, they cannot introduce regional or seasonal bans on GMO cultivation, they cannot exclude GMOs from areas of special environmental interest, they cannot establish isolation distances from particular natural sites or adapt the cultivation to the needs of their particular ecosystems. On the other hand, under the current legislation Member States are free to organise their inspection and control activities upon their discretion[20].

C. The national safeguard and emergency measures.

Under the Directive. In accordance with the safeguard clause of the Directive[21], a Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory. This prohibition must be based on new information made available since the date of the consent and must affect the environmental risk assessment. A decision shall be taken on the matter within 60 days, on the basis of an EFSA opinion and upon the Committee procedure ("Comitology"). The period of time needed for EFSA (60 days) and the Council (three months) to decide is not taken into account.

Under the Regulation. National safeguard measures against products whose applications for authorisation or re-authorisation are pending under the Regulation, are notified and proceeded under the specific provision of the Regulation on "emergency measures"[22]. According to this procedure, where it is evident that the concerned products are likely to constitute a serious risk to human health, animal health or the environment. In that case, the Member State officially informs the Commission, while it can adopt in the meantime interim protective measures. Within 10 working days, the Commission shall put the matter before the Standing Committee with a view to the extension, amendment or abrogation of the national interim measure[23]. The Member State may maintain its national interim measure until the Community measure has been adopted. Contrary to the provisions of the Directive, no consultation with EFSA is obligatory.

Although all these measures were intended to be provisional, they have not been repealed by the Member States, with the exception of Austria which had to comply with the respective Commission Decisions on its prohibition of import and processing of maizes MON810 and T25. In all above cases EFSA has issued opinions rejecting the national safeguard measures and their arguments about the potential risks of the concerned products. In several cases, the examined scientific evidence was not even considered as new or additional to the one considered for the

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[20] Article 4(5) of the Directive

[21] Article 23, in conjunction with Art. 28(1) and 30(2)

[22] Article 34 of the Regulation in conjunction with Art. 53 and 54 of Regulation(EC) No 178/2002.

[23] Article 54 of Regulation (EC) No 178/2002

issuance of the consents. Despite these opinions, Member States failed to reach qualified majorities in favour or against the Commission proposals when submitted before the Regulatory Committee. Moreover they voted by qualified majority against the Commission proposals at the Council in all cases but two[24]. Finally, it would be necessary to evaluate whether the existing regulatory framework is appropriate to deal with national safeguard measures on the cultivation of GMOs. This might also require the examination of complex and usually long-term effects.

D. The provisions on confidentiality and data protection.

Under the respective provisions of the Directive[25], the Commission and the competent authorities shall not divulge to third parties any confidential information notified or exchanged under the Directive and shall protect intellectual property rights relating to the data received. The notifier may indicate the information, the disclosure of which might harm his or her competitive position and which should therefore be treated as confidential. In doing so, the notifier must provide verifiable justification. The competent authority shall, after consultation with the notifier, decide which information will be kept confidential and shall inform the notifier of its decisions. The general description of the GMO, methods and plans for monitoring and the environmental risk assessment cannot be kept confidential.

Under the provisions of the Regulation,[26] the applicant may indicate which information should be treated as confidential on the ground that its disclosure might significantly harm its competitive position. As is also the case under the Directive, Verifiable justification must be given in such cases. The Commission shall determine, after consultation with the applicant, which information should be kept confidential and shall inform the applicant of its decision. Information relating *inter alia* to the description of the GMO, composition, physico-chemical characteristics, its effects on the environment and human and animal health, and methods for detection shall not be considered confidential.

ANNEX 4

Evaluation methodology and required tasks

[24] ENV Council, 30 October 2007: no opinion for the proposals on the Austrian prohibition of food/feed uses of MON810 and T25.

[25] Article 25

[26] Articles 30 and 31

Task 1: Structuring

With respect to structuring, the contractor will elaborate the following elements:

Task 1.1: **Draft a detailed schedule** for the evaluation work (respecting time constraints given hereinafter) and present it during the kick-off meeting.

Task 1.2: Establish the descriptive part as indicated in chapter 4.1

Task 1.3: Draft a model of the intervention logic showing the relationships between the instruments, the expected impacts and the objectives of the measure as a whole.

Task 1.4: **Define the key terms for each evaluation question**, (the evaluation terms as well as the technical terms), elaborate judgement criteria and indicators allowing answering each evaluation question.

Task 1.5: Identify information sources, quantitative and qualitative, for each evaluation question: databases, surveys, studies, persons in administrations, organisations, companies and institutes to be interviewed.

Task 1.6: Create the tools needed for the quantitative and qualitative analysis : interview guides, questionnaires, queries for extractions from databases and any other data collection and analysis instrument that the contractor deems appropriate.

NB : The tools needed for the analysis, i.e. draft guide for the planned interviews (list of the bodies and people to be contacted, questionnaires, subject to be broached during the interviews), proposal for cases study areas and guidelines for them will have to be validated by the Commission before data collection itself starts.

Task 1.7: **Compile the descriptive part**, according to the description of chapter 4.1. This part will serve as a basis and introduction to the evaluation part of the report.

Task 1.8: Draft a detailed plan for the preliminary draft final deliverable. The plan has to be agreed with the Steering Group.

The executions of the above-referred tasks (tasks from 1.1 to 1.8) will be addressed in an **inception report.**

This report will describe the intervention, providing the current intervention logic. It will describe the evaluators' understanding of the evaluation objectives, issues and questions. This document will present in detail the evaluators' methodology, how it is going to be implemented and in particular how the method will provide an answer to each evaluation

question. The inception report will describe the way the evaluators intend to structure their activities, the number of human resources involved in the exercise, their background and the number of meetings they propose to have with the steering group. It will include the draft questionnaires which the evaluators will use to obtain information from the different stakeholders, for approval by the steering group. This document will provide the steering group with the opportunity to make a final check of the feasibility of the methodology proposed and the extent to which it corresponds with the information needs outlined in the terms of reference.

The inception report (in English and addressed to the steering group) will be submitted at the latest 6 weeks after the signature of the contract. A meeting for the presentation of the report to the steering group will be organised.

Task 2: Observing

With respect to observing, the contractor will elaborate the following elements:

Task 2.1: **Collect information and report about it**:

a) collect all the necessary data, including interviews (write detailed minutes of these), and collect the data necessary to feed the indicators defined under task 1.4;

b) assess the validity of the information used.

The output of task 2.1 will feed into task 3.

Task 2.2: **Draft an overview on the progress of the evaluation,** including the difficulties encountered in carrying out the evaluation and proposing solutions to solve them.

The execution of the above-referred tasks (2.1 and 2.2) will be addressed in an **interim report.**

This report will provide the steering group with the opportunity to check whether the evaluation is on schedule and whether the evaluation has actually focused correctly on the specified information needs.

The interim report (in English and addressed to the steering group) will be submitted at the latest 5.5 months after the signature of the contract. A meeting for the presentation of the report to the steering group will be organised.

Task 3: Analysing

With respect to analysing, the contractor will elaborate the following elements:

Task 3.1: Based on the output of task 2.1, **draft preliminary replies to the evaluation questions**.

The analysis must refer to the well established and acknowledged evaluation method or methods used and the limits thereof; the drafting must describe precisely the reasoning followed in the analysis, indicating among other things the underlying hypotheses of the reasoning and the validity limits of that reasoning.

Task 3.2: Revise the replies to evaluation questions in the light of the comments of the Steering Group.

Task 3.3: **Draft full replies to all evaluation questions**.

The analysis must refer to the well established and acknowledged evaluation method or methods used and the limits thereof; the drafting must describe precisely the reasoning followed in the analysis, indicating among other things the underlying hypotheses of the reasoning and the validity limits of that reasoning.

Task 4: Judging

With respect to judging, the contractor will elaborate the following elements:

Task 4.1: **Draft the conclusions and recommendations**: the contractor will have to provide a judgement covering the instruments studied. The judgement must be based on the findings. The limits and validity of the judgement will be specified. The recommendations have to be based on the findings and must be unbiased and realistic.

Task 4.2: **Draft a draft executive summary**, no longer than 25.000 characters (without spacing). It should include a very brief presentation of the evaluation work and the methods used, together with a summary of the conclusions and recommendations arising from the exercise

Task 4.3: **Compile the preliminary draft final deliverable.**

It should be presented in the form of the study report and structured as agreed with the steering group (task 1.8).

The report must be drafted in a clear and easily understandable language. The presentation of the texts, tables and graphs has to be clear and complete and correspond to commonly recognised standards for publication.

The general conclusions must include recommendations, which must be based strictly on the results of the analysis.

The volume of the report should not exceed 150 pages. The core text has to concentrate on the answers to the evaluation questions.

Statistical and background information shall be presented in the annexes of the report.

The draft final deliverable will be submitted at the latest 9 months after the signature of the contract.

Task 4.4: **Revise the draft executive summary,** incorporating all changes agreed with the steering group**, and provide it in English and French**.

The results of quality assessment and discussions with the steering group about the draft final report do not interfere with the autonomy of the evaluators in respect to their conclusions

Task 4.5: **Draft a synthetic summary** of no more than 15 000 characters (spaces not included). It should summarise the main results and recommendations arising from the evaluation questions. Additionally, a one-paged abstract with the Key Messages of the evaluation should be prepared.

Task 4.6: **Draft a PowerPoint presentation** (in English and French) of the evaluation work, of maximum 30 slides, highlighting the main findings.

Task 4.7: **Compile the draft final deliverable**

This deliverable will consist of:

1) Study report, which will be structured in the same way as the preliminary draft final deliverable, but incorporating all changes agreed with the steering group.

2) the executive summary in two languages (Task 4.4)

3) the synthetic summary (Task 4.5)

4) the PowerPoint Presentation (Task 4.6)

Task 5: Disseminating

- **Task 5.1: Assist the Commission for a period of 3 months in the dissemination of results** With respect to this task the evaluation will assist, for a period of three months, the Commission in the dissemination of results in the framework of meetings within the Commission

- seminars and meetings with stakeholders,

- meetings of regulatory committees,

This task will be performed according to a schedule to be agreed in the context of task 1.8.

– the composition of the evaluation team should be based on a mix of expertise, including at least an expert in biotechnology, an expert in the evaluation of the economic impact of policy and legislation and an expert in policy analysis in terms of consumers perception.

Annex 5

Legislative acts to be used for the evaluation

1. Directive 2001/18/EC on the deliberate release into the environment of GMOs

2. Regulation(EC) No 1829/2003 on GM food and feed

3. Regulation(EC) 1830/2003 on the traceability and labelling of GMOs

4. Council Decision 2002/623/EC with guidance notes on Annex II of Directive 2001/18/EC

5. Council Decision 2002/811/EC with guidance notes on Annex VII of Directive 2001/18/EC

6. Council Decision 2002/812/EC on the summary notification information format relating to the placing on the market of GMOs

7. Council Decision 2002/813/EC on the summary notification information format on "Part B" releases (other than placing on the market)

8. Commission Decision 2003/701/EC on a format for presenting the results of the deliberate release into the environment of GM higher plants for "Part B" releases (other than placing on the market)

9. Commission Decision 2004/204/EC on the operation of registers for recording information on genetic modifications in GMOs

10. Commission Regulation(EC) No 65/2004 on the unique identifiers for GMOs

11. Commission Recommendation establishing guidelines for sampling and detection of GMOs and material produced from GMOs