EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Safety of the food chain
E1 - Biotechnology and plant health

EVALUATION OF THE EU LEGISLATIVE FRAMEWORK IN THE FIELD OF GM FOOD AND FEED

1. CONTEXT OF THE ASSIGNMENT

1.1. Background/Description of the policy area to be evaluated

Regulation (EC) N° 1829/2003 on genetically modified food and feed[1] lays down the general framework for regulating genetically modified (GM) food and feed in the Community. 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 genetically modified food and feed, whilst ensuring the effective functioning of the internal market. The Regulation is complemented by Regulation (EC) N° 1830/2003[2] that ensures traceability and labelling of GMOs at all stages of placing on the market, including the possibility of establishing thresholds.

Previously GM foods were regulated under the Novel Food Regulation 258/97[3], whilst GM feeds were partially regulated under Directive 2001/18 on the deliberate release of GMOs into the environment[4]. The main new features introduced with the new regulatory framework in comparison to the previous one were:

- A single scientific evaluation undertaken by the European Food Safety Authority (EFSA). Under the former legislative framework, i.e. the Novel Food Regulation and Directive 2001/18/EC, the scientific evaluation was carried out by the

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1 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed

2 Regulation (EC) No 1839/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

3 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients

4 Directive 2001/18/EC of the European Parliament and of the Council of 21 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L106, 17.4.2001, p.1

competent authority of one Member State but, as it was constantly objected by other Member States, had to be completed systematically by the Scientific Committee for Food established at Community level.

- A centralised Community procedure for the authorisation of GM food and feed (under the former legislative framework, the authorisation procedure was only partly centralised).

- A temporary threshold of 0,5% for the adventitious and technically unavoidable presence of unapproved GM material in food and feed which had received a positive evaluation by the relevant Scientific Committee[5] (this was not foreseen in the former legislative framework).

- New labelling requirements regarding in particular food and feed produced from GMOs (under the Novel Food Regulation, foods consisting of or containing GMO had to be labelled, but not foods produced from GMOs; there were no specific GM labelling requirements for feed).

- GM food and GM feed were put on the same footing (feed consisting of or containing a GMO were previously regulated under Directive 2001/18 on the deliberate release of GMOs into the environment, while feed produced from GMOs such as feed materials and feed additives was not subject to the GM legislation).

The new regulatory framework was adopted at a time where the authorisation process of GMOs and GM food and feed had come to a halt. In fact, between 1998 and 2004, no new authorisations had been granted. With the entry into force of the new legislative framework, the regulatory approval process for GM food and feed has been re-launched. Nevertheless the authorisation of GM food and feed remains a very sensitive issue. None of the authorisations granted has been supported by a qualified majority of Member States, neither in the Regulatory Committee nor in the Council. The Commission thus adopted the authorisation Decisions according to Article 5.6 last paragraph of the Comitology Decision[6].

In 2006, the Commission has reported according to Article 46 of the Regulation to the European Parliament and to the Council about the implementation of the Regulation. Among the conclusions was indicated that as a result of consumer demand and the policies of food producers and retailers, few food products labelled as "genetically modified" are at the present time on the Community market. The situation is completely different for the GM feed which is at present predominant on the EU market.

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[5] Article 47 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed

[6] Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission

With respect to the transitional measures for the adventitious and technically unavoidable presence of unapproved GM material in food and feed[7], this measure expired as of the 18th of April 2007.

1.2. Specific and operational objectives of the policy

The main specific objectives pursued with Regulation (EC) N° 1829/2003 were:

- To protect human and animal health and the environment by introducing a safety assessment at Community level based on a scientific evaluation of the highest possible standard before placing GMOs for food and feed use (as defined in the Regulation), GM food and feed on the market.

- To ensure the effective functioning of the internal market in relation to GM food and feed by making possible the free movement of safe and wholesome GM food and feed.

- To streamline and make more transparent the authorisation procedure of GM food in comparison to the one foreseen under the Novel Food Regulation.

- To establish a single, dedicated, efficient and transparent Community authorisation procedure for all GM feed.

- To establish a common procedure for risk assessment and authorisation of GMOs for food and feed use, GM food and feed which are efficient, time-limited and transparent.

- To ensure clear labelling of GM food and feed, irrespectively of the detectability of modified DNA or protein, in order to meet the demands expressed by consumers; to facilitate informed choice and to preclude potential misleading of consumers, as regards the production methods of the GM food or feed.

- To lay down labelling requirements for GM feed to provide final users, in particular livestock farmers, with accurate information on the composition and properties of feed, thereby enabling them to make an informed choice.

- To ensure the immediate enforceability and feasibility of the Regulation by establishing a transitional threshold for the adventitious and technically unavoidable presence on minute traces of non-authorised but already evaluated GM material in food and feed.

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7 COM(2006) 626 final (http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0626en01.pdf

2. SCOPE OF THE EVALUATION

2.1. Legal instruments to be analysed

- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

- Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

- Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

- Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms.

2.2. Other legal instruments to be considered as a necessary part of the evaluation

- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

- Regulation (EC) No. 258/97 of the European Parliament and the Council of 27 January 1997 concerning novel foods and novel food ingredients.

- Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission as amended.

2.3. Other sources of relevant information to be considered by the evaluators in preparing their proposal (see Annex I)

This list has to be considered as purely indicative and has to be extended by the contractor in line with the indication of the methodological part:

2.4. Main areas of focus of the evaluation

Keeping as a basis the objectives of the evaluation (as specified under chapter 3 of these terms of reference), and particularly the purpose of reviewing and assessing the totality of the EU intervention (legislative framework and related measures and procedures) in the field of GM food and feed in order to identify possible existing challenges in its implementation and to ensure its relevance for the current needs, the evaluator has to focus its attention on three key areas:

a) The risk assessment and regulatory approval process

After a period of halt, between 1998 and 2004, the new regulatory framework has re-launched the authorisation process for GM food and feed. Since the entry into force of Regulation 1829/2003, a total of 60 applications have been submitted; 15 opinions have been issued by EFSA, 7 authorisations have been granted and another 8 are pending at different stages of the regulatory approval procedure (situation as of 19 September 2008).

For none of the authorisations granted, however, a qualified majority amongst Member States could be attained, neither in the Regulatory Committee nor in the Council. The Commission thus adopted all the authorisation Decisions according to Article 5.6 last paragraph of the Comitology Decision[8].

Responding to this lack of support by Member States for the authorisation process of GMOs in the Community, the Commission proposed on 12 April 2006 a series of practical improvements to the way the European legislative framework for GMOs was implemented[9]. These measures aim at improving the scientific consistency and transparency for decisions on GMOs in order to reassure stakeholders and the general public that Community decisions are based on high quality scientific assessments which deliver a high level of protection of human health and the environment and as a result increase Member States' support in Community decisions. As a follow up of the Commission debate, the Commission staff developed an action plan setting out how to implement the proposed measures. As part of this action plan the Commission is working on the adoption of a legal text containing detailed guidelines for the risk assessment of GM food and feed which will absorb and replace the current guidelines used by EFSA.

Together with the persistent lack of support by Member States for the authorisation procedure, another crucial element that the evaluator will have to assess is the timeline for the granting of the authorisation.

- **The scientific evaluation of the risk assessment**

For each application, the EFSA GMO Panel has had to make frequent use of the possibility foreseen by the Regulation to suspend the risk assessment in order to seek supplementary or outstanding information from the applicant necessary for the

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[8] Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission

[9] See Commission press release IP/06/498 from 12 April 2005

completion of the risk assessment, leading to an extension of the time limit of 6 months (see Article 6 and 18 paragraphs 1 and 2 respectively).

For all the applications so far assessed by EFSA, the 6 months period stipulated by the Regulation for the risk assessment has been extended by stopping the clock until applicants have answered questions or provided supplementary information as requested by the EFSA scientific panel for GMOs. The actual timeline has ranged between 9 months and more than 2 years from the submission of the application to the issuing of the final opinion. This time frame includes both the time needed for the administrative check for completeness of the application by EFSA staff and the time for the evaluation of the risk assessment by the GMO panel.

EFSA has taken measures in order to streamline the process of risk assessment: a) the authority took the commitment that the completeness check would not take more than 6 weeks and b) as provided for in the Regulation, EFSA requests the applicant to declare in which time limit he will be able to submit the requested supplementary information; c) the scientific staff at EFSA supporting the GMO panel has been increased substantially.

In this context implementation measures have been/will be adopted in order to (a) establish a common basis regarding the requirements for data submission and principles of risk assessment of applications for authorisation of GMOs (b) provide to EFSA and Member States a commonly accepted set of requirements for the assessment of GM products.

The implementation of these guidelines will have to be considered by the evaluators.

- **Risk management and the regulatory approval process**

Regarding the following risk assessment phase the Regulation indicates a time limit of 3 months for submitting a proposal to the Regulatory Committee. In this short timeframe, the services of the Commission have to take due account of the comments of the public (1 month after the EFSA opinion) and submit a proposal agreed at inter-service level. Although for certain applications the submission to the regulatory committee was done before the expiry of the 3 months period, the timeframe foreseen by the Regulation has sometimes been exceeded. In some cases this was due to procedural reasons, in other cases to the need to clarify outstanding scientific issues, by requesting a supplement of analysis to EFSA and in one case to the European Medicines Agency. This resulted in a delay in submitting proposals to the Standing Committee. The time for discussion at the Standing Committee deemed necessary in order for the Committee to reach and opinion was relatively short and for the majority of applications, the opinion was taken the same day the proposal was submitted. As already indicated, for all the draft decisions for authorisation, the Commission had to follow the entire comitology procedure, since the Member States could not come to a conclusive result in the Regulatory Committee nor in the Council.

Particularly important in the consideration of the regulatory approval process is the way stacked events are currently regulated in the EU. Each stack event undergoes a specific evaluation and authorisation procedure, even in the case – quite common – when the composing single events have already been assessed / authorised. Other regulatory systems in the world apply a different approach to staked events.

Another potential issue concerns the safeguard measures ("emergency measures" in the wording of the legislation) that Member States could adopt under the Regulation[10]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[11]. The Member State may maintain its national interim measure until the Community measure has been adopted. No consultation with EFSA is foreseen. Two national safeguard measures are currently pending under this procedure and both concerns the GM maize MON810.

- **Asynchronous authorisations**

The theme of the average length of the authorisation procedure for GMOs in the EU is linked to the issue of asynchronous authorisations between the EU and its major trading partners. This situation occurs when a certain GM crop has been evaluated for its safety and authorised in the exporting country (X) whereas the importing country (Y) might or might have not evaluated this GM crop for its safety and has not authorised it (yet). Traces of this non-authorised GMO might occur in conventional or other GM food and feed exported from X to Y as a result of adventitious or technically unavoidable presence during seed production, cultivation, harvest, transport or processing in country X.

This problem, as such, is not new. It was already acknowledged by Regulation 1829/2003 for certain GMOs authorised by the EU's major trading partners but pending for authorisation in the Community since a considerable time despite a positive safety assessment. The Regulation foresaw a three-year transitional measure for the adventitious and technically unavoidable presence of GM material of those non-authorised GMOs under the condition that a safety assessment had been carried out at Community level and that detection methods were publicly available. Under these conditions, material from these GMOs was tolerated up to 0,5% in food and feed. A series of GMOs benefited from this transitional measure[12]. This has however expired in April 2007, bringing the level of tolerance to zero for all GM material not authorised in the EU.

The issue of asynchronous authorisations has also been debated in the Codex Task Force for Foods derived from Modern Biotechnology. The Task Force has developed a guideline on how to carry out a food safety assessment in the situation of a low-level presence of recombinant-DNA plant material in food. At the same time, the guideline requires data and information sharing mechanisms as a precondition to facilitate its use (a database containing information on r-DNA plants that are authorised in a Codex member State in accordance with the Codex plant

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

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

[12] See list of the genetically modified material which has benefited from a favourable risk evaluation within the meaning of Article 47 of Regulation (EC) No 1829/2003

guideline and the place where detection methods and reference materials may be obtained).

A report by DG AGRI[13] analysed the possible impact of asynchronous authorisations in maize and soybean products on feed imports and the EU livestock industry. The study concluded that the presence of non-approved GMOs will become an increasingly important factor that will limit the possibilities for animal feed imports and that could lead in the future to a real shortage of feed products.

In such a context the Commission could propose to harmonise the way control measures are used by the Member States within the framework provided by the existing legislation on GMOs. The proposed solution would provide greater certainty for operators by defining the criteria for laboratories performing official control analysis for GMOs. The implementation of this new measure will have to be considered by the evaluators.

b) The compulsory labelling of GM food and feed

The definition of the range of products that should be subject to compulsory GM labelling was the result of an extensive exchange of views during the legislative process that led to the adoption of Regulation 1829/2003.

It was decided to define a compulsory labelling scheme of food and feed containing, consisting or produced from a GMO irrespective of the detectability of modified DNA or protein with the objective of meeting the demands expressed by consumers and provide them with the possibility to make an informed choice on the market.

The Regulation provides, however, that these labelling requirements shall not apply to products containing material, which contains, consists of or is produced from GMOs in a proportion no higher than 0.9%, provided that this presence is adventitious or technically unavoidable.

According to various reports and although the situation is not uniform throughout the EU, few food products labelled as "genetically modified" are at the present time on the Community market, although many products have now been approved in the EU.

By contrast with food, compound feed labelled as genetically modified is reported to become predominant at EU level. This can be largely explained by the predominance of GM soy in the production of soy at world-scale level, the difference of costs between non-GM soy and GM soy and the fact that animal products obtained from animals fed with GM feed have not to be labelled.

On the basis of this situation in the last two years a debate began on the existing labelling rules and various 'GM free' labelling schemes have appeared. In this context a certain number of Member States has developed or started to develop

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

specific rules to frame the use of these 'GM free' labelling schemes and to ensure their credibility.

In February 2007, a petition signed by 1 million EU citizens has also been handed over to the Commission. The petition called on the European Commission to propose legislation foreseeing that food products such as eggs, meat and milk produced from animals that have been fed with GM feed should be labelled as such. After asking EFSA to clarify whether there are scientific arguments that would speak in favour of the request, the Commission concluded - on the basis of the negative reply provided by the Authority - that the elements which had been taken into account when Regulation 1829/2003 have been approved remain valid.

2.5. Period to be examined in the evaluation

The evaluation shall encompass the timeframe since the entry into force of Regulation 1829/2003. Whenever appropriate the evaluator will have to take comparatively into account the pre-existing situation and the legal framework.

2.6. Geographical scope of the evaluation

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.

3. OBJECTIVES OF THE EVALUATION

The evaluation shall analyse the EU legislative framework on GM food and feed with a special regard to points a) to c) as described in chapter 2.4.

The contractor shall complement the background provided in chapter 2.4 by collecting data and factual evidence. On this basis the contractor is requested:

- To assess to what extent the legislative framework on GM food and feed has addressed effectively its objective of protecting human and animal health, the environment and consumers' interest, whilst ensuring the effective functioning of the internal market

- To assess to what extent the new legislation has introduced harmonised procedures for the risk assessment and authorisation of GM food and feed that are efficient, time-limited and transparent in comparison to the previous procedures.

- To provide an analysis of the time taken by each step of the authorisation procedure, the completeness and quality of the application dossiers, and base its evaluation on these data.

- To evaluate the way the risk assessment, and risk management of stacked events is treated in the EU, the efficiency of the system and the comparison with the way the same issue is dealt with by other regulatory systems.

- To provide an analysis of the way the "emergency measures" on authorised GMOs and the relevant procedure foreseen by the Regulation have been applied and to assess whether this procedure represents an appropriate tool to deal with the "emergency measures" taken by Member States.

- To analyse the dimension of the socio-economic consequences for stakeholders (in particular food and feed availability/pricesand public perception) of the functioning of the current authorisation system.

- To base this assessment on the existing data, compiling and analysing them and taking into account the likely trends regarding the use of GM crops in the EU and in third countries.

- To assess the overall impact of the current labelling system against the objective of meeting consumers demand for a clear labelling of GM food and feed, able to facilitate informed choice and to preclude potential misleading of the consumer as regards the production methods of the GM food or feed. The assessment will have to be based on market and/or other data collected/created at the EU level.

- To provide an overview of the existing approaches taken by Member States on the issue of "GM free" labelling, providing an analysis of those.

The evaluator is required to present different options, including the "status quo" option (i.e. keeping the current intervention on GM food and feed as it is) and analyse their relevance and impact.

For each of them, the evaluator should analyse the economical, environmental and social impacts, the stakeholders´ level of support, their feasibility, their strengths and weaknesses (advantages and disadvantages), and an analysis of the reductions of administrative burden and associated costs anticipated by the proposed measures. For the different options proposed, a calculation of the variations compared to the baseline as regards costs (administrative costs in particular) should be sought.

All the data collected/created shall be presented in a form that could later on feed a possible impact assessment on the legislation.

In putting forward these policy options, a balance should be sought between:

– The need for a risk assessment and regulatory approval process that provides the highest protection possible to human and animal health, the environment and the consumers' interest, whilst ensuring the effective functioning of the internal market as stipulated in the legislation.

– The stakeholders' need for an effective and time-predictable authorisation procedure for GMOs for food and feed use, GM food and feed in the EU[14].

– The need to prevent major trade disruptions that could hamper the competitiveness of EU operators.

– The need to ensure comprehensive scientific approach allowing risk management based on uncontroversial scientific elements.

– The need to address consumer concerns, facilitate informed choice and to preclude potential misleading of the consumer as regards the production methods of the GM food or feed.

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 ENV, AGRI, TRADE, ENTR, RTD, BUDG, JRC, SG) shall be represented in order to ensure a wide viewpoint across the Commission as well as the European Food Safety Authority for the issues directly related to its competence as risk assessor.

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

4. STRUCTURE OF THE EVALUATION AND EVALUATION QUESTIONS

4.1. Structure of the evaluation

The evaluation is to be structured in two parts.

A **first descriptive part** will be devoted by the evaluator to the description of the development of the area of GM food and feed since the entry into force of Regulation 1829/2003, with particular attention to the implementation of the regulatory framework in the areas identified under chapter 2.4.

In preparing this part the evaluator is expected to

– take into account the characteristics of the current regulatory framework as compared with the previous system governing GM food and feed at EU level

– examine the implementation of the authorisation procedure

[14] The US Biotech Industry Organisation (BIO) has recently adopted a "product launch stewardship policy" in which the regulatory approval systems of USA, Canada, Japan (and Mexico in the future) are taken into account to avoid the consequences of asynchronous associations. The EU is excluded from their stewardship policy because of the alleged unpredictability of the timetable of its authorisation mechanisms.

– provide a description of the evolution of the sector worldwide (number of GM crops, extension of the GM production, impact on the food/feed sector)

– evaluate and characterise the current level of risk aversion of EU citizens in this domain

The **second part will represent the evaluation itself.**

This part must provide answers to the questions identified under chapter 4.2. Beyond collecting, creating and analysing data, the evaluation must provided founded judgements based on analysis and put forward reasoned conclusions and recommendations. The contractor has to foresee capacities and tools for data gathering in order to provide evidence for answering the evaluation questions and fulfil the objectives of the evaluation as outlined in chapter 3.

4.2. Evaluation questions

The evaluation questions are intended to steer and facilitate the work of the evaluators. Replying to these questions on the basis of factual evidence and founded analysis is considered the core activity of the evaluator and the basis for the recommendations required by chapter 3. In replying to the questions the evaluator will have to consider four basic criteria according to which the questions are classified:

- The **effectiveness** of the measure: the extent to which the intended impacts or the objectives of the measure are met.

- The **efficiency** of the measure: the extent to which the best relationship between resources employed and results are achieved in pursuing the objective of the intervention.

- The **coherence** of the measure: the extent to which the intervention does not contradict with other interventions.

- The **relevance** of the measure: the way in which the objectives of the measure are pertinent to the evolving needs, problems and issues addressed.

The evaluator is also required to examine whether unintended effects occurred.

The answer to each evaluation question shall include the following elements:

– interpretation and comprehension of the key terms of the question,

– indication of the judgement criteria allowing to answer the question,

– indication of the quantitative and qualitative information needed/collected/used,

– description of the evaluation methods used (including their possible limitations),

– detailed description of the reasoning followed in the analysis,

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

The evaluation questions are grouped under the following evaluation areas.

A. The overall objectives of the legislation in the light of the expected developments of the sector

(1) On the basis of the evidence collected, to what extent are the established objectives of the Regulation accepted by consumers, stakeholders and Member States as being fully in line with the needs of the EU society? (***Effectiveness***) To what extent have these objectives been correctly made operational, in particular with respect to the scope of the regulation, the foreseen approval process and the labelling requirements? (***Relevance***)

(2) What factual developments are to be expected as the consequence of the evolution of the sector (global adoption rates of GM crops, second and third generation GMOs) and how could these developments affect or benefit the EU food industry and livestock sector and the European consumers? To what extent are the tools defined by the existing legislation apt to ensure that the EU could make use of these developments in economic, social and environmental terms? How could these potential benefits be measured and integrated in the context of the regulatory approval? (***Efficiency***)

These first two questions are intended to define a sort of 'reality check' of the legislation against the evolution of the sector in the last five years and that foreseeable for the next future. The answer should be based on hard facts and data.

B. The risk assessment and regulatory approval process

(3) To what extent the EU authorisation procedure and its implementation has ensured a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market? (***Effectiveness***) To what extent is the current EU approach on stacked events consistent with the objectives of the legislation and what has been its overall impact on the implementation of the regulatory approval process, including the number of pending authorisations and the workload for both EFSA and the Commission? (***Effectiveness and Efficiency***)

(4) To what extent are the different steps of the harmonised procedures established by the Regulation for the risk assessment and authorisation of GM food and feed efficient, time-limited and transparent and correspond to demonstrated risks in a proportionate manner? What has been their impact on the evolution of the sector and the EU society at large? (***Efficiency***)

(5) To what extent the procedure foreseen by the Regulation (Article 34 of the Regulation in conjunction with Articles 53 and 54 of Regulation (EC) No 178/2002) ensures an appropriate way to deal with "emergency measures" taken by Member States.

These questions should be considered in the global context of harmonised procedures for the management of food and feed products (Regulation 178/2002, Commission proposal on the food improvement agents package[15]) and on the experience gained under previous or present applicable EU legislation related to the management of GMOs (Regulation (EC) No 258/97, Directive 90/220/EC and Directive 2001/18/EC). In this context the evaluator will have to assess the way the existing procedures have actually been implemented, including the procedure of "stopping the clock" during the risk assessment for questions and clarification on application dossiers and the applicable timelines, the co-operation of stakeholders in the risk assessment, the comments of MS and their inclusion in the EFSA opinions.

(6) To what extent is the common and centralised authorisation procedure foreseen by Regulation 1829/2003 (one door, one key principle) efficient compared to the situation that was prevailing before the adoption of the Regulation? (***Efficiency)*** To what extent is this procedure coherent with other procedures applying to similar sectors of the food safety *acquis*? (***Coherence)***

This question is aimed at evaluating only the procedural aspects of the "one door, one key" principle. The specific considerations concerning the authorisation of GMOs for cultivation are excluded by the scope of this evaluation and covered by a parallel evaluation launched by Dg ENV. The coherence of the above-referred procedure should be considered in the light of the harmonised authorisation systems that are in place for active substances in pesticides and seed plant varieties.

(7) What is the foreseeable trend of the GM authorisations in the EU when compared with the authorisations granted in third countries and taking into account the expected worldwide evolution of the GM sector? What would be the consequences of possible differences between the pace of authorisations between the EU and its trading partners? (***Effectiveness and Efficiency***)

C. The compulsory labelling of GM food and feed

[15] The 4 COM references for the Food Improvement Agents packages as follows:
Proposal for Regulation on Common authorisation procedure COM(2006) 423 final
Proposal for Regulation on food additives COM(2006) 428 final
Proposal for Regulation on food enzymes COM(2006) 425 final
Proposal for Regulation on flavourings COM(2006) 427 final
For info the above docs (in English) as well as the amended proposals are available on
http://ec.europa.eu/food/food/chemicalsafety/additives/prop_leg_en.htm
The Codecision procedure is nearly finished and the above docs have been changed to some extent and all four proposals are now subject to an agreement in second reading between EP/Council and COM and should be finally adopted by Council and published in the OJ by the end of the year.

(8) To what extent the current labelling rules for GM food/feed are facilitating an informed choice and precluding misleading of consumers? ***(Relevance)*** What is the consumers' acceptance of the existing labelling rules? (***Relevance and Effectiveness***)

(9) What impact have the rules on labelling of GM food/feed had on the different actors of the food/feed market? (***Effectiveness***)

(10) To what extent is food on the market labelled as GM? To which extent is feed on the market labelled as GM? What are the reasons for this situation? (***Effectiveness***)

These questions should be considered in the context of the parallel approach for food and feed chosen by the legislation. The justification for this correspondence should also be analysed.

(11) What consequence would an extension of the scope of the labelling rules including the labelling of animal products have? (***Effectiveness and Efficiency***)

(12) What are the approaches currently used by Member States in the field of 'GM free' labelling? Do these approaches contribute to improve consumers' informed choice? What could be the added value (both in terms of information to consumers and market share) of a harmonized "GM free" (or similar) labelling scheme? (***Relevance and Effectiveness***)

On the questions related to point D considerations should be given to the possible different perceptions and expectations in the EU Member States.

D. Acceptance

(13) The approval process is still subject to controversy amongst stakeholders and the general public. What are the aspects of the authorisation procedure that nourish this controversy? (***Relevance***) What is the impact/cost of this risk aversion? (***Efficiency***) Are there variations in the sensitivity of EU-wide opinion, as between seed, cultivation, feed and food use? How can the risk acceptance of EU citizens be measured against the concept of ALARA (as low as reasonably achievable) risk? (***Relevance***) Can the quality of the EU-wide trust in science based risk assessment be improved in the GM context ***(Effectiveness)***?

E. Conclusions and recommendations

(14) What conclusions and recommendations can be drawn on the basis of the evaluation? What are the different options (in terms of legislation, procedures, implementation capacities…) for the future to address the identified issues and the new challenges? What is the relevance and the social, environmental and economical impact of each proposed option? ***(Relevance – Effectiveness - Efficiency)***

5. EVALUATION METHODOLOGY AND REQUIRED TASKS

5.1. Evaluation tasks and methodology

In carrying out this evaluation, the contractor is required to follow four methodological steps:

- Structuring,
- Observing,
- Analysing
- Judging

As a principle, these four methodological steps will have to be applied to the evaluation as a whole as well as the answers to individual questions. The interim and the final deliverables will reflect these four tasks, and be built progressively, incorporating the results of each task.

As an additional task the contract will have to assist the Commission in disseminating the results of the evaluation.

5.1.1. 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.

5.1.2. 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.

5.1.3. 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.

5.1.4. 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 only 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)

5.1.5. 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.

6. BUDGET

Object of the negotiation with the evaluator

7. CRITERIA FOR QUALITY ASSESSMENT

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 1) will be used.

8. ANNEXES

Annex I - Other sources of relevant information to be considered by the evaluators in preparing their proposal

Annex II - Quality Control Checklist

Annex III – Timeline foreseen for the evaluation

Annex I

Other sources of relevant information to be considered by the evaluators in preparing their proposal

This list has to be considered as purely indicative and has to be extended by the contractor in line with the indication of the methodological part

- Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed[16]

- Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC[17]

- Communication from the Commission to the Council, to the European Parliament, to the European Economic and Social Committee and to the Committee of the Regions on the mid-term review of the Strategy on Life Sciences and Biotechnology.[18]

- Community Register of genetically modified food and feed.[19]

- DG AGRI report on the economic impact of unapproved GMOs on EU feed imports and livestock production.[20].

- JRC Reference report: Consequences, Opportunities and Challenges of Modern Biotechnology for Europe. Published in April 2007.[21]

- JRC report "Scientific and technical contribution to the development of an overall health strategy in the area of GMOs"[22]

- List of the genetically modified material which has benefited from a favourable risk evaluation within the meaning of Article 47 of Regulation (EC) N^{o} 1829/2003.

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16 COM(2006) 626 final, Brussels, 25.10.2006

17 COM (2008) 560 final

18 COM(2007) 175 final

19 http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

20 "Economic impact of unapproved GMOs on EU feed imports and livestock production" http://ec.europa.eu/agriculture/envir/gmo/economic_impactGMOs_en.pdf

21 http://ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_200704_biotech.pdf

22 http://ec.europa.eu/dgs/jrc/index.cfm?id=2820&obj_id=232&dt_code=HLN&lang=en

– EFSA guideline documents for applicants for the risk assessment of GMOs

– Proposed Codex draft annex[23]: Food safety assessment in situations of low-level presence of recombinant-DNA plant material in food (at step 5/8 of the procedure).

– The OECD BioTrack product database.[24]

– ISAAA (International service for the acquisition of agri-biotech applications) Brief 37: Global Status of Commercialized Biotech/GM Crops: 2007, Clive James, Chair, ISAAA Board of Directors.

Annex II

[23] To the Codex guideline on conduct of food safety assessment of foods derived from recombinant-DNA plants (CAC/GL 45-2003)

[24] http://www2.oecd.org/biotech/

Quality Control Checklist

DG SANCO Evaluation Report Quality Control Checklist

Evaluation Reference :……. Evaluation Title : …….. …….

Contractor Name :……..

Objective	Detailed Check	Comments	Review point
Ensure the draft report adequately covers the subject and scope of work as outlined in the Terms of Reference and the work programme	Confirm with the Terms of Reference and the work programme that the contractor : ➢ Has addressed the key evaluation questions ➢ Has undertaken the tasks described in the work programme ➢ Has delivered the required outputs ➢ Has covered the subject in the area and depth agreed		
Ensure that data within the report is consistent and accurate	Check details within the report : ➢ Is information in the report technically correct ➢ Is the report consistent i.e. with no contradictions ➢ Are calculations correct		
Ensure the report is complete	Check that the report contains : ➢ Title and Content Page ➢ Executive Summary describing main findings ➢ Main Report with : ♦ Introduction describing the context and objectives of the evaluation ♦ Evaluation methodology ♦ Findings ♦ Conclusions ♦ Recommendations ➢ Annexes containing : ♦ Terms of Reference ♦ Additional Tables		

Objective	Detailed Check	Comments	Review point
	♦ References and source of information ♦ Glossary of terms		
Ensure the quality of the content of the report	Check that : ➢ Methodology used for each area of examination is clearly explained ➢ Findings and conclusions are based on accurate assumptions ➢ Findings are detailed and any calculations are logical and have been explained ➢ Conclusions flow logically from the findings ➢ Recommendations are made when required, and flow logically from the conclusions ➢ All parts of the report can be clearly understood and that statements are not ambiguous ➢ The report is grammatically correct ➢ The report does not omit key contributions		

Reviewer's Overall Opinion (5 = very good, 4 = good, 3 = satisfactory, 2 = poor, 1 = very poor)	
Subject	**Judgement (1 – 5)**
Evaluation as contracted	
Consistent and Accurate Data	
Report Complete	
Quality of content	
Overall Judgement and Comments :	

Report Reviewed by ……..

Date ……

Annex III – Timeline foreseen for the evaluation

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 – such evidence e.g. in form of the collected responses to the survey questionnaires should be annexed to the report. 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.
15 months	**Dissemination** 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.