



Health & Consumer
Directorate General

Evaluation of the EU legislative framework on GM food and feed

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Why an evaluation?

- Fifth anniversary of Reg. 1829/2003
- Completing the picture of the 2006 Report by an impartial assessment
- GMOs still a controversial issue
- Identifying present/future challenges
- Ensuring relevance for the current needs

Aim of the evaluation

■ To provide:

- Comprehensive set of data from a non-biased source
- Impartial external analysis on functioning, consequences and impact

■ To represent a basis for possible future policy options

Terms of reference

⇒ Results of the work of an *ad-hoc* Inter-Service Steering Group (ISSG)

- Part 1 – Context of the assignment
- Part 2 – Scope of the evaluation
- Part 3 – Objectives of the evaluation
- Part 4 – Structure of the evaluation and evaluation questions
- Part 5 – Evaluation methodology

I – *Context of the assignment*

1. Background (Reg. 1829/2003)

- Major features of the regulatory framework
- Evolution since 2004 (pipeline for authorisation, lack of support by MS, 2006 College debate)
- Report on the implementation – COM(2006)626

2. Specific and operational objectives of the area to be evaluated

- Human and animal health
- Functioning of the internal market
- Protecting consumers' interest

II – *Scope of the evaluation*

■ Legal instruments to be analysed

- [Regulation No 1829/2003](#)
- Regulation No 1830/2003
- Commission Reg. 641/2004 (implementing rules)
- Commission Reg. No 65/2004 (unique identifiers)

■ Other legal instruments

- Directive 2001/18/EC
- Regulation No 178/2002
- Regulation (EC) No. 258/97 (novel foods)
- Council Decision 1999/468/EC (comitology)

■ Any other relevant document (annex)

II – *Scope of the evaluation*

■ Main areas of focus of the evaluation

- The risk assessment and regulatory approval process including the issue of asynchronous authorisations
- The labelling rules on GM food and feed

■ Period to be considered ⇒ since 2004

■ Geographical scope ⇒ 27 MS, possibility to make reference to specific MS, taking into account representative samples and local characteristics and differences

III – Objectives

■ The contractor shall assess:

- ✓ To what extent objectives have been achieved
- ✓ The new authorisation procedure (efficiency – transparency)
- ✓ Its socio-economic impact (food and feed prices / consumers perception)
- ✓ The approach to risk assessment/management of stacked events
- ✓ The national safeguard measures
- ✓ The overall impact of the current labelling system and the GM free labelling schemes

■ Production of a comprehensive source of data and evidence

■ **Possible policy options, including "status quo" and preliminary impact**

IV – *Structure & questions*

■ Two parts:

- A **first descriptive part** devoted to the development of the area since the entry into force of Regulation 1829/2003
- The **second analytical part** heart of the providing answers to the questions on the basis of data and putting forward conclusions and recommendations

Evaluation questions

■ 5 categories of questions

- Overall objectives of the legislation in the light of the recent and future developments
- The risk assessment and regulatory approval process
- The compulsory labelling of GM food and feed
- Consumers' acceptance
- Conclusions and recommendations

■ 4 Basic criteria of analysis

- **Relevance** ⇒ objectives pertinence to evolving needs
- **Efficiency** ⇒ relationship resources / results
- **Effectiveness** ⇒ impact/objectives met
- **Coherence** ⇒ with other intervention

Evaluation questions

■ Overall objectives of the legislation in the light of the developments

1. Objectives of the Regulation still in line with the needs of the EU society?
2. Factual developments to be expected and appropriate tools for the EU to make use of them?

Evaluation questions

■ **The regulatory approval process**

3. To what extent the EU authorisation procedure and its implementation has achieved the objectives? Approach on stacked events.
4. Is the evaluation/authorisation procedure time-limited, transparent and proportionate?
5. Appropriateness of the procedure foreseen by the Regulation for the "emergency measures".
6. Coherence of the centralised authorisation procedure for GM food, feed and cultivation with legislations applying to similar sectors.
7. Evolution and consequences of the asynchronous authorisations.

Evaluation questions

■ **Labelling of GM food and feed**

8. Evidence of facilitating an informed choice and precluding misleading of consumers?
9. Impact on the different actors of the F&F market?
10. Presence of GM labels in food/feed chain? What are the reasons for this situation?
11. Consequence of an extension of the labelling rules to animal products?
12. Added value (consumers info/market share) of a EU "GM free" labelling scheme? Approach taken by MS

Evaluation questions

■ **Acceptance**

13. Why is the authorisation procedure still controversial? Impact/cost of EU citizens' risk aversion? Variations in the EU-wide opinions between food, feed and seed? How can the risk acceptance of EU citizens be measured against the concept of ALARA (as low as reasonably achievable) risk?

■ **Conclusions and recommendations**

14. Conclusions, recommendations and possible policy options? What is the relevance and the social, environmental and economical impact of each proposed option?

V - *Methodology*

- Contractor identified through a framework contract – Food Chain Evaluation Consortium
- Assignment to be carried out in close co-operation with the ISSG (ENV, AGRI, TRADE, ENTR, RTD, BUDG, JRC, SG)
- EFSA part of the ISSG as risk assessor
- MS and Non-institutional stakeholders will be involved in the different phases of the evaluation – emphasis on questionnaires and interviews
- Contractor to guarantee a mix of expertise (biotech/ economics/ consumers' behaviour/ evaluation)
- 5 methodological steps clearly identified

Structuring / Observing / Analysing / Judging / Disseminating

Reporting and deliverables

- **Kick-off meeting (2 June)**
- **Inception report ⇒ (July)**
 - Describe the evaluators' understanding of the evaluation
 - Present methodology, HR, bckg and number of meetings with ISSG
 - Include the draft questionnaires which the evaluators will use
- **Interim report ⇒ 5.5 months after the signature of the contract**
 - Info about initial analyses of data collected.
 - Possible preliminary answers
 - ISSG to check schedule and focus
- **Draft final report ⇒ 9 months after the signature of the contract**
 - Conclusions of the evaluator on the evaluation questions
 - Exploratory recommendations
- **Final report ⇒ 12 months**
 - Incorporate the quality assessment and discussions with ISSG
 - Include final executive summary and Key Messages

Conclusions

- SCFCAH will be informed of all the relevant steps
- All relevant docs will be uploaded in SANCO website
- **DG SANCO contact point:**
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- DG ENV launching a parallel exercise on GM cultivation