

European Commission  
Directorate General for Health and Consumers

## Evaluation of the EU legislative framework in the field of GM food and feed

Framework Contract for evaluation  
and evaluation related services - Lot 3: Food Chain  
(awarded through tender n° 2004/S 243-208899)

### **August Progress Report**

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***Food Chain Evaluation Consortium (FCEC)***

*Civic Consulting - Agra CEAS Consulting -*

*Van Dijk Management Consultants - Arcadia International*

***Project Leader: Agra CEAS Consulting***

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27.08.2009

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## **1. Introduction**

DG SANCO launched this evaluation of the EU legislative framework in the field of genetically modified (GM) food and feed in early June 2009. This refers in particular to Regulation (EC) No 1829/2003 on GM food and feed<sup>1</sup>, as complemented by Regulation (EC) No 1830/2003<sup>2</sup> on GMO traceability and labelling and other relevant accompanying legislation<sup>3</sup>, which together replace previous legislation<sup>4</sup>.

This study is led by Agra CEAS Consulting of the Food Chain Evaluation Consortium (FCEC), with inputs from Arcadia International and Civic Consulting, in the context of the ongoing Evaluation Framework Contract for Lot 3 (Food Chain).

This short report sets out progress made since the submission and acceptance of the Inception Report.

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

<sup>2</sup> 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.

<sup>3</sup> In particular: Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 as regards the application for the authorisation of new MG food and feed, the notification of existing products and adventitious or technically unavoidable presence of GM material which has benefited from a favourable risk evaluation; and 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.

<sup>4</sup> Previously GM foods were regulated under the Novel Food Regulation 258/97, whilst GM feeds were partially regulated under Directive 2001/18 on the deliberate release of GMOs into the environment.

## **2. Progress since submission of Inception Report**

### **2.1. Inception Report meeting with the Steering Group**

A meeting between the consultants and the Commission Steering Group was held in Brussels on 16 July, 2009. The consultants presented the draft Inception Report and its contents were discussed. The majority of the discussion concentrated on the elaboration of the Evaluation Questions in terms of issues which need to be addressed and the indicators for doing this.

A proposal for the five case study topics was put forward by the consultants and this was agreed by the Steering Group.

The consultants subsequently submitted the final Inception Report which the Commission accepted and published on the project website on 24 August, 2009.

### **2.2. Meeting with the DG Environment contractors**

A meeting was held on 16 July, 2009 between the consultants and the contractors responsible for carrying out the DG Environment evaluation covering the cultivation of GMOs. The teams exchanged information on their respective projects and ensured that questionnaires were aligned and survey timings would not overlap.

### **2.3. Meeting with the working group of the Advisory Forum for the Food Chain**

A meeting was held on 17 July, 2009 between the consultants, the Commission and the working group of the Advisory Forum for the Food Chain. The consultants presented the evaluation to the stakeholders and explained the process and the timetable for the evaluation. Stakeholders offered their feedback which was welcomed by the consultants.

Stakeholders were asked to provide the consultants with relevant data sources and documents and full contact details of stakeholders throughout the EU covering technology providers, users, trade, processors, retail, consumer organisations and NGOs for inclusion in the stakeholder survey, the more in-depth follow up interviews and the case studies.

The meeting was followed by an email from the consultants on 20 July, 2009 setting out this request for assistance in greater detail. To date (27 August, 2009) a small number of stakeholders have provided relevant data sources and documentation and some of these have also supplied contact details (see Section 2.5.2).

### **2.4. Standing Committee on the Food Chain and Animal Health**

The consultants presented the evaluation and timetable to the Standing Committee on the Food Chain and Animal Health on 22 July, 2009. Member State feedback was welcomed by the consultants.

Member State Competent Authorities were asked to provide the consultants with relevant data sources and documents and full contact details of stakeholders throughout the EU (with the same coverage as above) for inclusion in the stakeholder survey, the more in-depth follow up interviews and the case studies.

The meeting was followed by an email from the consultants on 31 July, 2009 setting out this request for assistance in greater detail and asking Member States to nominate one contact point. To date (27

August, 2009), sixteen Member States have nominated a contact point and some of these have also provided relevant data sources and documentation and stakeholder contact details (see Section 2.5.2).

## **2.5. Competent Authority and stakeholder surveys**

### **2.5.1. Questionnaires**

A questionnaire for use in the Competent Authority survey was drafted and submitted to the Commission. Comments were provided and the questionnaire was subsequently approved. The questionnaire was then tested with one Competent Authority to ensure that the questions are easily understood and that the answer options are appropriate. The questionnaire was then translated into French and German and it is currently being prepared for distribution.

A questionnaire for use in the stakeholder survey has been submitted to the Commission for comments and approval. This is based on the Competent Authority questionnaire with some additional questions and the removal of a series of questions only relevant to Competent Authorities.

Once approval has been received this questionnaire will also be translated into French and German and will be prepared for use.

### **2.5.2. Contact information**

As noted above, contact information for the stakeholder surveys has been requested from stakeholder members of the working group of the Advisory Forum for the Food Chain and from Member State Competent Authorities. Perhaps partly as a result of the unavoidable timing of our requests over the summer we have not received very many contacts to date (27 August, 2009). However, the consultants are in the process of compiling contact lists from the websites of relevant organisations. Contacts compiled in this way are not always as useful as those supplied by stakeholders because it is often difficult to identify the correct individual within each organisation. That said, it is anticipated that requests to complete the stakeholder survey will be passed to the relevant contact within each organisation. It should also be noted that stakeholders are continuing to respond and it is likely that more will do so as the summer draws to a close.

The list of Member State Competent Authorities attending the Standing Committee meeting was used as the basis for contacts within the Member States and, as noted above, from more than half of these contacts a single individual has been identified as the point of contact for the Competent Authority survey. A reminder has been sent out to those Member States yet to respond and where no response is forthcoming by the survey launch, the survey will be sent to all contacts with a further request for a co-ordinated response.

## **2.6. Literature review**

A literature review comprising some 191 documents, sources and/or websites has been established to date (27 August, 2009). A spreadsheet has been constructed setting out these sources with hyperlinks to the documents themselves. Each source is classified in terms of the group of Evaluation Questions to which it has relevance to facilitate searching. Each source has also been screened for content with a short description set out to assist researchers to identify relevant documents efficiently.

Our literature review is dynamic, i.e. will continue throughout the evaluation. Although we have located a large number of relevant documents we expect that others will be located as we continue through the project.

Finally, a news clipping file has been established under which all relevant press information concerning relevant topics are collated for the use of the evaluation team.

## 2.7. Case studies

The five thematic case studies and the coverage of Member States across these themes has been agreed with the Commission as follows:

- **Risk assessment and regulatory approvals process:** Austria, France and Belgium.
- **Consequences of EU lagging behind third countries in authorisations:** Netherlands, UK, Italy, Spain, and Poland.
- **The current labelling regime:** UK, France, Germany and Spain.
- **Extensions to the labelling regime to include livestock products and GM-free labelling:** France, Germany Spain, and Finland.
- **Public acceptance:** Czech Republic, Italy, UK, Poland and Greece.

### 3. Project work plan

The evaluation is proceeding in line with the timetable set out in the Inception Report. The key milestones are set out as follows:

- **Launch of Competent Authority survey:** early September, 2009 with at least a six week response window.
- **Launch of stakeholder survey:** early September, 2009 with at least a six week response window.
- **Semi-structured interviews with stakeholders:** from early October, 2009.
- **Case studies:** from late-October, 2009.
- **Submission of Interim Report:** 27 November, 2009.
- **Stakeholder conference:** January/February, 2010.
- **Draft Final Report:** March, 2010.
- **Final Report:** May 2010.

Further brief progress reports will be submitted in September and October.