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

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October Progress Report

Submitted by:

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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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 feed¹, as complemented by Regulation (EC) No 1830/2003² on GMO traceability and labelling and other relevant accompanying legislation³, which together replace previous legislation⁴.

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 of the September Inception Report.

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 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.

⁴ 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 the September Progress Report

2.1. Surveys

The survey of Competent Authorities was launched on 18 September, 2009 with a deadline of 28 October, 2009. As at 26 October, 2009, 23 Competent Authorities had accessed the survey link with two having fully completed the questionnaire.

The survey of stakeholders was launched on 25 September, 2009 with survey links sent to other relevant stakeholders as and when further contacts were identified. The deadline for this survey is 30 October, 2009. As at 26 October, 2009, some 112 stakeholders had accessed the survey link with 26 having fully completed the survey.

The stakeholder survey was promoted via the daily DG SANCO news email and reminders for both surveys were sent out on 15 October, 2009.

In order to boost the response rate, and following a number of requests, we will extend the deadline for stakeholder survey submissions by a short period of time. We are also prepared to extend the deadline for the Competent Authority survey if this proves necessary.

2.2. Semi-structured stakeholder interviews

Interviews with stakeholders commenced in mid-October and will continue in early November. Most interviews have now been arranged and the vast majority will be completed by the end of November.

2.3. Conference: GMOs in European Agriculture and Food Production

Members of the evaluation team will attend a conference on GMOs in European Agriculture and Food Production in the Hague on 25/26 November, 2009. As well as being likely to provide useful information for the evaluation this also presents an opportunity to discuss issues with other attendees, many of whom will be interviewed during the case study phase (see below).

2.1. Third country analysis

The desk research associated with our analysis of the regulatory treatment of GMOs within key third countries is complete and all interviews have been carried out with the exception of Brazil and the US where interviews are still outstanding. In addition, some third country national authorities are preparing position papers for use within our analysis. It is anticipated currently that this element of our research will be completed by the end of November, 2009.

2.2. Case studies

The case study visits are planned as set out below in Table 2.1. It should be noted that some case studies are yet to be confirmed and dates may therefore change. Not all appointments within case studies have yet been agreed. In the event that it is not possible to speak to all relevant organisations within the case study visit we will carry out remaining interviews by telephone.

The mix of interviews to be carried out in each case study country reflects the topics to be covered.

Table 2.1: Case studies timetable

Member State	Topics	Dates
Austria:	<ul style="list-style-type: none"> • Risk assessment and regulatory approvals process 	30 November-4 December
Belgium:	<ul style="list-style-type: none"> • Risk assessment and regulatory approvals process 	On-going
Czech Republic:	<ul style="list-style-type: none"> • Public acceptance 	7-11 December
Finland:	<ul style="list-style-type: none"> • Extensions to the labelling regime to include livestock products and GM-free labelling 	7-11 December
France:	<ul style="list-style-type: none"> • Risk assessment and regulatory approvals process • The current labelling regime • Extensions to the labelling regime to include livestock products and GM-free labelling 	Early November
Germany:	<ul style="list-style-type: none"> • The current labelling regime • Extensions to the labelling regime to include livestock products and GM-free labelling 	23-27 November
Greece:	<ul style="list-style-type: none"> • Public acceptance 	23-27 November
Italy:	<ul style="list-style-type: none"> • Consequences of EU lagging behind third countries in authorisations • Public acceptance 	30 November-4 December
Netherlands:	<ul style="list-style-type: none"> • Consequences of EU lagging behind third countries in authorisations 	Early November
Poland:	<ul style="list-style-type: none"> • Consequences of EU lagging behind third countries in authorisations • Public acceptance 	9-13 November
Spain:	<ul style="list-style-type: none"> • Consequences of EU lagging behind third countries in authorisations • The current labelling regime • Extensions to the labelling regime to include livestock products and GM-free labelling 	16-20 November
UK:	<ul style="list-style-type: none"> • Consequences of EU lagging behind third countries in authorisations • The current labelling regime • Public acceptance 	On-going

2.3. Semi-structured interviews with EFSA and Commission services

Our intention is to hold interviews with EFSA and the majority of Commission services relatively late in our data collection phase. No dates have therefore been set for these meetings which are likely to take place in January, 2010 subject to availability. That said, some meetings with Commission services may take place in November.

2.4. Literature review

Our database of relevant literature has been added to with articles, publications, etc. which have been brought to our attention during the conduct of the project.

3. Project work plan

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

- **Close of Competent Authority survey:** 28 October, 2009 with the possibility of a short extension where necessary.
- **Close of stakeholder survey:** 30 October, 2009 with the possibility of a short extension where necessary.
- **Semi-structured interviews with stakeholders:** started early October, 2009, the majority will be completed by mid-November.
- **Case studies:** from late-October, 2009 with all completed by Christmas, 2009.
- **Submission of Interim Report:** Winter 2009/2010.
- **Stakeholder conference:** January/February, 2010.
- **Draft Final Report:** Spring 2010.
- **Final Report:** Early summer 2010.
- **Dissemination:** Summer 2010.

The next report will be the Interim Report.