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**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**

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## **List of abbreviations**

CA or CAs: Competent authority or Competent authorities

CRL: Community Reference Laboratory

DG SANCO: Directorate-General Health and Consumer Protection

DNA: Deoxyribonucleic acid

EFSA: European Food Safety Authority

ENGL: European Network of GMO Laboratories

FVO: Food and Veterinary Office of the Directorate-General Health and Consumer Protection

GM: Genetically modified

GMM: Genetically modified micro-organism

GMOs: Genetically modified organisms

ISO: International Organisation for Standardisation

RASFF: Rapid Alert System for Food and Feed

SCFCAH: Standing Committee on Food Chain and Animal Health

## 1. INTRODUCTION

Regulation (EC) No 1829/2003<sup>1</sup> on GM food and feed (“the Regulation”) has applied since 18 April 2004. It covers genetically modified organisms (GMOs) for food and feed use, food/feed containing or consisting of GMOs and food/feed produced from GMOs. This scope of application is large since all GMOs that may be used as food or feed or as a source material for the production of food or feed are considered as GMOs for food and feed use. It establishes a centralised procedure of authorisation by the European Commission based on an independent risk assessment carried out by the European Food Safety Authority (EFSA), rules for labelling and thresholds for presence of GM material that is adventitious or technically unavoidable. The risk assessment as provided for in the Regulation includes in particular a safety assessment of the GM food and/or GM feed as well as, as the case may be, an environmental risk assessment. In the case of GMOs for cultivation falling in the scope of the Regulation, EFSA shall ask a national competent authority (CA) under Directive 2001/18/EC to carry out the environmental risk assessment. In all cases where an environmental safety assessment is required, EFSA has to consult the national CA under Directive 2001/18/EC of each Member State.

The Commission was to adopt the necessary implementing rules and guidelines as well as to establish the Community register of GM food and feed (publicly available on the website of the Commission<sup>2</sup>).

The Commission is also required to monitor the application of the Regulation and its impact on human and animal health, consumer protection, consumer information and the functioning of the internal market.

According to Article 48 of the Regulation the Commission is to forward to the European Parliament and to the Council a report on the implementation of this Regulation and in particular of Article 47<sup>3</sup>. Article 48 states that the report should be accompanied, where appropriate, by any suitable proposal.

In order to gain more insight on the implementation of the Regulation, the Commission compiled a questionnaire comprising questions on its different provisions. The questionnaire was submitted to all CAs under the Regulation, as well as to relevant stakeholders from all involved sectors. The responses, as well as other information received and retrieved by the Commission from the date of application of the Regulation to the current time, have been carefully analysed.

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<sup>1</sup> OJ L 268, 18.10.2003, p. 1.

<sup>2</sup> [http://europa.eu.int/comm/food/dyna/gm\\_register/index\\_en.cfm](http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm)

<sup>3</sup> Article 47 of Regulation (EC) No 1829/2003 foresees, under certain conditions, transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.

The current report is based on the results of this consultation as well as on the discussions which took place in the Standing Committee on the Food Chain and Animal Health (SCFCAH) and in the Council. It focuses on the main aspects raised by Member States and stakeholders and therefore does not reflect individual positions as such. The report contains a first part concerning the experience acquired with the practical implementation of the Regulation and a second part which details additional implementing measures and specific clarifications which have been developed by the Commission to complement and explicit specific points of the Regulation.

Regulation (EC) No 1830/2003<sup>4</sup> on the traceability and labelling of genetically modified organisms and the traceability and labelling of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC was developed alongside Regulation (EC) No 1829/2003 and was also adopted on 22 September 2003. The two regulations are intended to operate in tandem and rely on each other for certain requirements.

Also Regulation (EC) No 1830/2003 contains a requirement (Article 12) for the Commission to produce a report concerning experiences gained with this regulation. This report was adopted on 10 May 2006<sup>5</sup>. The Commission has taken account of the above interplay between the two regulations and has attempted to avoid duplication in the two reports.

The legislative framework on GM products is generally recognised as complex by stakeholders. In order to facilitate its implementation, DG SANCO provides support to the operators and the general public on the website of the Commission and under the form of “questions and answers”<sup>6</sup>. Similarly, a number of Member States or associations of stakeholders also provided documents aiming to further explain the provisions of the legislation.

## **Part 1: Implementation of Regulation (EC) No 1829/2003**

### **2. THE PLACING ON THE MARKET OF GENETICALLY MODIFIED FOOD AND FEED SINCE THE DATE OF APPLICATION OF THE REGULATION**

#### **2.1. Authorisation procedure under the Regulation**

##### *2.1.1. Presentation of the authorisation procedure*

The authorisation procedure is composed of three major steps.

The first step is the submission of an application to obtain an authorisation for the placing on the market of a GM food or feed.

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<sup>4</sup> OJ L 268, 18.10.2003, p. 24.

<sup>5</sup> COM(2006) 197 final ([http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006\\_0197en01.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/com/2006/com2006_0197en01.pdf))

<sup>6</sup> [http://ec.europa.eu/food/food/biotechnology/gmfood/index\\_en.htm](http://ec.europa.eu/food/food/biotechnology/gmfood/index_en.htm) and; [http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda\\_en.pdf](http://europa.eu.int/comm/food/food/biotechnology/gmfood/qanda_en.pdf). It should be understood that only the Community courts can give an authoritative interpretation of EC legislation.

It has to be sent to the national CA under the Regulation of one Member State who has to acknowledge the receipt of the application, inform without delay EFSA and make the submitted information available to EFSA.

The second step is the preparation and the delivery of an opinion by EFSA. EFSA publishes summaries of the applications on the EFSA website and following a completeness check, valid applications are made available to the Commission and the Member States who are consulted on the application during a 3 month period. In case of a GMO to be used as seeds or other plant-propagating material EFSA asks a CA under Directive 2001/18/EC to carry out the environmental risk assessment, as required by the Regulation.

In accordance with the Regulation, EFSA endeavours to comply with a time limit of six months to provide its opinion. The procedure is stopped whenever EFSA (or the CRL via EFSA) seeks supplementary information from the applicant.

An overview of the applications received by EFSA is made available to the public on its website<sup>7</sup>. Until 1 July 2006, thirty four applications have been submitted.

In order to facilitate the numerous exchanges of information between EFSA, the Member States and the Commission, EFSA has put in place an electronic system (called “GMO EFSAnet) providing a secure data communication platform. This system is recognised by all the involved parties as contributing to the smooth operation of the authorisation procedure. EFSA is continuously working to improve this system, especially with regard to putting in place a system allowing the involved parties to access data in a more efficient way.

The scientific opinions adopted by the GMO Panel of EFSA are published on the EFSA website<sup>8</sup>. In the case of favourable EFSA opinions, the scientific opinion of the GMO panel shall be complemented by other information (including, among others, a proposal for labelling, any appropriate conditions or restrictions which should be imposed for the placing on the market, a method for detection validated by the CRL, an indication of where the reference material can be accessed, and, when the scope of the applications cover the placing on the market of a GMO, an environmental monitoring plan and information related to the Cartagena protocol) in order to constitute the overall EFSA opinion as required by the Regulation. It is therefore important to make a clear distinction between the scientific opinions of the GMO Panel and the overall EFSA opinions that are required by the Regulation.

The third step of the procedure is the preparation and the adoption of a decision related to the application.

Within 30 days after the publication of the overall EFSA opinion, the public may make comments to the Commission. Section 2.1.3 of the current report is specifically dedicated to the organisation of this commenting period and to the handling of the received contributions.

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<sup>7</sup> [http://www.efsa.eu.int/science/gmo/gm\\_ff\\_applications/catindex\\_en.html](http://www.efsa.eu.int/science/gmo/gm_ff_applications/catindex_en.html)

<sup>8</sup> [http://www.efsa.eu.int/science/gmo/gmo\\_opinions/catindex\\_en.html](http://www.efsa.eu.int/science/gmo/gmo_opinions/catindex_en.html)

The Commission shall submit a draft Decision to the SCFCAH within 3 months after receiving the overall EFSA opinion. The adoption is subject to the comitology rules<sup>9</sup>.

### 2.1.2. *CRL, ENGL and validation of detection methods*

The Commission's Joint Research Centre was designated as the Community Reference Laboratory, whose task is the technical evaluation and validation of quantitative detection and identification methods for GM food and feed as part of the centralised authorisation procedure. The agreement on the European Network of GMO laboratories (ENGL) was made in 2002 and the network comprises over seventy National Control Laboratories.

On 18 April 2004, the CRL published "explanatory notes to applicants" in order to provide the applicants with practical instructions concerning the method validation task of the CRL as described in Regulation (EC) 1829/2003 and in the Regulation (EC) 641/2004<sup>10</sup> (see point 7 of the current report). These notes were complemented by additional documents notably related to the description of the CRL Validation Process and the definition of Minimum Performance Requirements for Analytical Methods of GMO Testing. These documents are available on the website of the CRL<sup>11</sup>.

On 1 July 2006, the CRL had carried out the validation of 16 methods. The reports of these validations are published on the website of the CRL<sup>12</sup> and are part of the overall opinions of EFSA.

### 2.1.3. *Comments of the public*

Articles 6(7) and 18(7) of the Regulation provide that the public may - within 30 days from its publication – make comments on the overall EFSA opinion. Comments should be addressed to the Commission. In order to facilitate the addressing of these comments, the Commission has created a dedicated webpage on the section of the website dedicated to the Regulation<sup>13</sup>. This page clearly indicates when a given application is within this commenting period and offers to the public a form in order to structure the comments. It also presents a link to the concerned overall EFSA opinion.

The opportunity to address comments for a given GMO is advertised throughout the commenting period on the first page of the website "Food Safety – From the Farm to the Fork"<sup>14</sup>. In addition, the start of the commenting period is announced via the "sanco news" e-mail service and a link on DG SANCO webpage is added to the EFSA webpage where the overall opinions are published.

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<sup>9</sup> See Article 35 of Regulation No (EC) 1829/2003 and Decision 1999/468/EC for more details.

<sup>10</sup> OJ L 102, 7.4.2004, p. 14.

<sup>11</sup> <http://gmo-crl.jrc.it/guidancedocs.htm>

<sup>12</sup> <http://gmo-crl.jrc.it/statusofdoss.htm>

<sup>13</sup> [http://ec.europa.eu/food/food/biotechnology/authorisation/public\\_comments\\_en.htm](http://ec.europa.eu/food/food/biotechnology/authorisation/public_comments_en.htm)

<sup>14</sup> [http://ec.europa.eu/food/index\\_en.htm](http://ec.europa.eu/food/index_en.htm)

After the commenting period, the comments received are communicated without delay to the CA of the Member States. As a consequence, both the Commission and the CA of the Member States can take these comments into consideration for the last phase of the authorisation process.

The comments received are also made available to the public on the same webpage. This is subject to the agreement of those making the comments.

Since the application of the Regulation, six overall EFSA opinions have been finalised in accordance with the provisions laid down in the Regulation. Therefore the experience related to this opportunity provided to the public and its further handling by the authorities within the framework of the Regulation is limited to these cases.

#### *2.1.4. Public access*

According to Article 29(2) of Regulation (EC) 1829/2003, EFSA shall apply the principles of Regulation (EC) No 1049/2001<sup>15</sup> of the European Parliament and of the Council regarding public access to European Parliament, Council and Commission documents when handling applications for access to documents held by EFSA. Consequently, EFSA has implemented the necessary tools and procedures to handle requests for access to documents according to the provisions of the Regulation. Up until May 2006, EFSA has received 26 individual requests from the public to access a total of 73 separate documents or applications submitted to EFSA under Regulation (EC) 1829/2003. Of the 26 individual requests 18 have come from 5 different Non Governmental Organisations (NGOs), mainly environmental NGOs, where 2 NGOs account for a majority of the requests. Furthermore members of National and European Parliaments have submitted 3 requests, National Authorities 2 and 3 have come from other stakeholders.

In addition, the Commission has received 3 requests for access to documents or applications submitted under the Regulation, two coming from NGOs, and the third from a Member of the European Parliament.

#### *2.1.5. Practical experience of the authorisation procedure*

So far, one authorisation<sup>16</sup> (for the placing on the market of food containing consisting or produced from 1507 maize) has been given following this procedure. Other products were authorised according to the transitional measures of the Regulation (see section 2.2. of the current report). Once authorised, the products are entered in the Community register of GM food and feed<sup>17</sup> that was established by the Commission.

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<sup>15</sup> OJ L 145, 31.5.2001, p. 43.

<sup>16</sup> OJ L 70, 9.3.2006, p. 82.

<sup>17</sup> [http://europa.eu.int/comm/food/dyna/gm\\_register/index\\_en.cfm](http://europa.eu.int/comm/food/dyna/gm_register/index_en.cfm)

Some remarks from the applicants have been made about the time used by EFSA prior to recognise an application as valid. This may be due to the lack of information in the data submitted. EFSA therefore requests and waits for this additional information before considering an application as valid. It is the opinion of the Commission that the period of time before declaring an application as valid should be as short as possible on the condition that all the requested data are provided. The Commission would like to stress the need for applicants to submit applications that fulfil the requirements of the Regulation and of the guidelines of EFSA. The request of additional information enabling EFSA to consider an application as valid should normally not be necessary.

According to the provisions of the Regulation EFSA should endeavour to finalise its overall opinions within six months. However, when additional data are requested during the scientific assessment or the validation of the detection method, the time period of 6 months may be extended. For most of the applications, additional information/clarification has to be requested from the applicant before specific issues raised by the GMO Panel or the Member States can be addressed and the GMO Panel can conclude its risk assessment. In case the scientific opinion of the GMO Panel or the validation method are finalised while the other particulars of the overall opinion are not yet available, EFSA, as a matter of transparency, publishes the scientific opinion or the validation method on its website. The validation methods are also published on the JRC website as soon as finalised. The overall opinion is then published later on with all particulars included. This has created some confusion regarding the stage of the authorisation process. Appropriate measures have been taken in order to clarify in the presentation of the GMO Panel scientific opinion that it needs to be complemented by other particulars prior to finalisation of the overall opinion of EFSA.

In the framework of the environmental safety assessment, EFSA has to consult the CA under Directive 2001/18/EC of each Member State upon receipt of an application with environmental safety requirements. EFSA took the initiative to expand this consultation to all members of the GMO EFSA net, independently of the scope of the application (CA under Directive 2001/18/EC, CA under the Regulation as well as scientific bodies nominated by their Member States). This consultation process allows for EFSA to take into consideration all the scientific comments from the Member States prior to finalising the scientific opinion of the GMO Panel.

According to Articles 6(3)(c) and 18(3)(c) of the Regulation, EFSA shall ask a CA under Directive 2001/18/EC to carry out the environmental risk assessment when an application concerns GM seeds or other GM plant-propagating material for food and/or feed use. To this end EFSA launches a call for expression of interest among the Member States to select a CA under Directive 2001/18/EC to carry out the environmental risk assessment based on the particular crop and trait, the availability of the CA and experience in GMO risk assessment. EFSA experiences difficulties to find CA willing to carry out the initial risk assessment for such applications.

#### *2.1.6. Practical improvements of the authorisation procedure*

In light of recent practical experience acquired with the placing on the market of GMOs and of Member State's demands for more streamlined decision making

procedures, the Commission has concluded in April 2006 that practical improvements could be made to the system regarding the scientific consistency and transparency for Decisions on GMOs taken under Directive 2001/18/EC and the Regulation and to develop consensus between all interested parties. These improvements will be made within the existing legal framework taking due account of the need to preserve an efficient decision making procedure, in compliance with EC law. In particular any undue delays in the adoption of the final decision shall be avoided.

With the objective of building greater consensus and transparency and recognising the importance of maintaining the scientific credibility, excellence and independence of EFSA, the Commission proposed that the following practices be implemented.

In the scientific evaluation phase:

- to invite EFSA to liaise more fully with national scientific bodies, with a view to resolving possible diverging scientific opinions with Member States;
- to invite EFSA to provide more detailed justification, in its opinions on individual applications, for not accepting scientific objections raised by the national competent authorities;
- the Commission will fully exercise its regulatory competences foreseen in the basic legislation to specify the legal framework in which EFSA assessment is to be carried out;
- to invite EFSA to clarify which specific protocols should be used by applicants to carry out scientific studies (for example regarding toxicology) demonstrating safety;
- applicants and EFSA will also be asked to address more explicitly potential long-term effects and bio-diversity issues in their risk assessments for the placing on the market of GMOs;

In the decision-making phase:

- the Commission will also address specific risks identified in the risk assessment or substantiated by Member States by introducing on a case by case basis additional proportionate risk management measures in draft decisions to place GMO products on the market, as appropriate;
- where in the opinion of the Commission a Member State's observation raises important new scientific questions not properly or completely addressed by the EFSA opinion, the Commission may suspend the procedure and refer back the question for further consideration.

In June 2006, EFSA outlined its ongoing strategy in relation to the assessment of GMOs and its initiatives to build closer collaboration with Member States<sup>18</sup>.

## **2.2. Authorisation of food and feed according to the transitional measures provided for by Article 46 of the Regulation**

Prior to the entry into force of the Regulation, authorisation processes for GM food and feed were carried out under Regulation (EC) No 258/97 and Directive 2001/18/EC. In order to ensure a smooth transition to the new authorisation regime, Article 46 of the Regulation provides for transitional measures allowing applications that were in an advanced stage of the authorisation procedure to continue to be considered and authorised under the relevant legislation.

Before 1 July 2006, 4 decisions authorising the placing on the market of GM food were adopted under Regulation (EC) No 258/97 and 4 decisions authorising the placing on the market of feed containing or consisting of a GMO were adopted under Directive 2001/18/EC.

These authorisation decisions - while adopted under the previous legislative framework for GM food and feed - take into account the provisions of the Regulation in terms of coordination of authorisation for food and feed related to the same GMO, availability of a validated method of detection and of the reference material.

An overview of the products that have been authorised in the framework of these transitional measures is provided in the annex.

## **2.3. Notification of products legally placed on the market before the date of application of the Regulation**

Certain GM food and feed products have been legally sold in the EU since as early as 1997 as they were approved under other legislation or did not require specific approval procedures. In order to cover these GM products, articles 8 and 20 of the Regulation stipulate that operators who wished to continue marketing an “existing product” had to notify the Commission and submit detailed information on the GM products before 18 October, 2004.

Regulation (EC) No 641/2004 has laid down detailed implementing rules for the notification of existing products.

The Commission has then examined the validity of these notifications and agreed to enter 26 GMOs into a specific section of the Community register of GM food and feed. Once one of these “existing products” is on this register, it can remain on the market for a set period of between 3-9 years, after which the operator has to resubmit an application for the renewal of the authorisation. Specific aspects related to this procedure for GMOs that were authorised under previously existing legislation are provided in point 8 of the current report.

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<sup>18</sup> For more details, see: [http://www.efsa.europa.eu/science/gmo/109/gmo\\_actionplan1.pdf](http://www.efsa.europa.eu/science/gmo/109/gmo_actionplan1.pdf)

In this respect the Commission wishes to take this occasion to further clarify that the notification exercise was intended to cover also GM seeds for food or feed use which were previously authorised. Indeed articles 8 and 20 apply by derogation to articles 4(2) and 16(2) of the Regulation that cover GM seeds or other GM plant propagating material for the production of food or feed. GM seeds are therefore covered by the scope of articles 8 and 20. Although the notification form prepared by the Commission services has created some confusion among notifiers by not explicitly mentioning the seeds in the list of products which could be notified and referring only to food and feed products, on the basis of the indication provided by the companies and of the analysis of the actual content of the notification, the Commission concluded that seeds were correctly notified. This has been reflected in the Community Register via a specific footnote added on 11 July 2005.

More generally the notification of existing products represented an important step in the implementation of the legislative framework introduced by the Regulation, by allowing clarification of the situation of food and feed products produced from GMOs on the Community market.

### **3. LABELLING OF GM FOOD AND FEED**

Under Article 13 of the Regulation, food must carry a label referring to the presence of GM in defined circumstances. However, Article 12 provides that these labelling requirements shall not apply to food containing material, which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 % of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable. Similar rules are laid down for feed in Articles 24 and 25

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 the Regulation. Even though the majority of replies does not question this range, it is for some stakeholders still considered to be either too extended (i.e. products that do not contain DNA or proteins should not be labelled as GM) or too restricted (i.e. products of animal origin fed with GM feed such as meat, milk or eggs should be labelled as genetically modified).

#### **3.1. Occurrence on the market of food labelled as genetically modified**

According to different reports, few food products labelled as genetically modified are at the present time on the Community market. The situation is however not uniform throughout the EU since in some Member States the number of GM products is negligible while in others their number is more significant.

The Regulation as such did not have an impact on the sale of food labelled as genetically modified. The sale of this type of products is mainly governed by factors that are not related to the legislative framework, such as consumer demand and the policies of food producers and retailers.

According to the results of the sample analysis reported by Member States, the frequency of non compliance to the food labelling requirements of the Regulation across the EU may be estimated below 2% (113 out of 7129 analysed samples). It must be further stressed that this figure is related to controls that often are targeted to products that are likely to contain GMOs or their derivatives and that the number of reported tests as well as the percentage of non compliance varied significantly from one Member State to another.

### **3.2. Occurrence on the market of feed labelled as genetically modified**

By contrast with food, compound feed labelled as genetically modified is much more present on the Community market and is even reported to be predominant at EU level. This can be largely explained by the predominance of GM soy in the production of soy at world-scale level and the difference of costs between non-GM soy and GM soy.

Practices consisting in systematic labelling with a statement of the type “may contain GMO” have been reported. These practices are not compatible with Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003 which prescribe explicit wording to be used for food and feed containing GM. The required wording does not allow ambiguous statements like "may contain GMOs”. In addition, practices consisting in systematic labelling of feed products as genetically modified irrespective of the information provided regarding the origin of the products have been reported in several Member States. On the basis of Regulation (EC) No 1830/2003, operators have to be systematically informed of the GM nature of the feed materials that they buy. Regulation (EC) No 1830/2003 also provides that operators must take appropriate steps to avoid the presence of GM feed if they want to avoid their products to be labelled as GM in case of adventitious or technical presence of GMO products. However, the Commission does not consider that this provision implies that operators are entitled to label products as GM without appropriate justification.

According to the results of the sample analysis reported by Member States, the frequency of non compliance to the feed labelling requirements of Regulation (EC) No 1829/2003 across the EU may be estimated to be around 6% (153 out of 2478 analysed samples). It must be further stressed that this figure is related to controls that often are targeted to products that are likely to contain GMOs or their derivatives and that the number of reported tests as well as the percentage of non compliance varied significantly from one Member State to another.

## **4. UNAUTHORISED PRODUCTS**

Three cases of unauthorised GM products that entered the EU deserve a specific analysis.

### **4.1. Unauthorised GM papaya**

The presence of **unauthorised GM papaya from the US (Hawaii)** was detected by the authorities of one Member State on seven occasions, three of which after the date of application of the Regulation.

Such cases were notified to the other Member States via the Rapid Alert System for Food and Feed (RASFF) and a specific detection method has been made available via the Joint Research Centre.

The measures taken by customs administrations to ensure that papaya imports from Hawaii were tested for genetic modification at border controls posts in view to communicate positive results to other Member States and reject the concerned import proved to be effective. Since July 2005 no further discovery of unauthorised GM papaya has been notified to the RASFF.

#### **4.2. Contamination of GM maize imported from the United States by unauthorised GM maize Bt 10**

The Commission was informed on 22 March 2005 by the US mission to the EU of the accidental release in the US of the **unauthorised GM maize Bt10**, erroneously commercialised as the approved line Bt11<sup>19</sup>. This was three months after the company responsible for the commercialization of the product had notified the accident to the US governmental authorities. According to the US authorities, maize products contaminated with Bt10 were likely to have been exported to the EU since 2001 and it was likely that such exports were still continuing.

After the communication of the accidental release the Commission took a series of actions to prevent the unauthorised product from entering the Community market.

In particular, the Commission, with the support of Member States, adopted on 18 April 2005 Decision 2005/317/EC<sup>20</sup>. This Decision lays down that each consignment of products likely to be contaminated by Bt10, i.e. GM corn gluten feed and brewers grains originating from the US, has to be accompanied by a report of analysis demonstrating the absence of the unauthorised GM maize, before being placed on the Community market. It further provides that Member States shall take the appropriate control measures for products that are already on the Community market.

Between April and September 2005 1600 analytical tests have been reportedly carried out in the US on corn gluten feed intended to be exported to the EU. At the same time more than 1400 controls were carried out by Member States at the import stage or on food and feed products already on the market. No positive results were recorded.

There is no evidence that the emergency measures did negatively impact the US exports of maize products to the EU. More generally the approach taken by the Commission received broad support by Member States and the public at large as effective and proportionate. No difficulty has been reported by Member States in the implementation of the Decision.

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<sup>19</sup> Bt10 is a GM maize line, resistant to the European corn borer developed in the 90ies by the company Syngenta together with Bt 11 maize. Further development of Bt10 has then been discontinued before reaching the stage of regulatory approval. The accidental release has occurred because some batches of Bt 10 were erroneously labelled as Bt11

<sup>20</sup> OJ L 101, 21.4.2005, p. 14.

The appropriateness of the measures provided in the Decision is regularly reviewed.

#### **4.3. Contamination of rice imported from the United States by unauthorised GM rice LL601**

The Commission was informed on 18 August 2006 by the US authorities of the accidental release in the US of the **unauthorised GM rice LL601**<sup>21</sup>. This was three weeks after the company responsible for the GMO had officially notified the contamination to the US governmental authorities. According to the US authorities, at that time, it was not known to what extent the supply chain had been contaminated and information on possible contamination of exports to the Community could not be provided.

After the communication of the accidental release the Commission took a series of actions to prevent the unauthorised product from entering the Community market.

In particular, the Commission adopted on 23 August Decision 2006/578/EC on emergency measures regarding the non-authorized genetically modified organism LL RICE 601 in rice products<sup>22</sup> to prevent the placing on the market of these contaminated products. This Decision lays down that each consignment of products likely to be contaminated by LL601 rice, i.e. US long grain rice originating from the US, has to be accompanied by a report of analysis demonstrating the absence of the unauthorised GM rice, before being placed on the Community market. It further provides that Member States shall take the appropriate control measures for products that are already on the Community market. These measures were further confirmed by Decision 2006/601/EC<sup>23</sup>. On the top of that, the Commission requested the European Food Safety Authority to provide scientific support on the issue. The Authority adopted a statement on 14 September. Whilst the Authority concluded that the available information was not sufficient to complete a comprehensive risk assessment, on the basis of the information available, it has been in a position to conclude that the consumption of imported long grain rice containing trace levels of LLRICE601 is not likely to pose an imminent safety concern to humans or animals.

The findings of products contaminated with LLRice601 were notified to the other Member States via the Rapid Alert System for Food and Feed (RASFF) allowing, in particular, the withdrawal from the market of products that had been dispatched to several Member States.

In accordance with the decision, the effectiveness of the measures is being monitored by the Member States. The measures shall be reviewed by 28 February 2007 at the latest.

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<sup>21</sup> LLRICE601 is a GM rice that has been developed for tolerance to the Liberty® herbicide. It is similar to the GM rice LLRICE62 for which an application is currently pending under Regulation (EC) No 1829/2003. Further development of LL601 has been discontinued in 2001 before reaching the stage of regulatory approval.

<sup>22</sup> OJ L 230, 24.8.2006, p. 8.

<sup>23</sup> OJ L 244, 7.9.2006, p. 27.

#### **4.4. Conclusions**

From the experience of the GM papaya, Bt10 maize, and LL601 rice some conclusions can be drawn.

The three cases prove that the possibility of unauthorised GM products arriving at the doors of the EU can not be excluded.

The reaction of the Commission in these cases was and will be targeted to guarantee full respect of the EU legislation especially as regards the protection of human and animal health and the environment. A prompt evaluation on a case-by-case basis and close co-operation between the Commission and the Member States that are responsible for the implementation of official controls are necessary. In this respect the RASFF worked as an effective communication tool allowing a timely reaction.

It is also important to acknowledge the relevant role played in the Bt10 and LL601 cases, by both EFSA in its quality of scientific evaluator for safety aspects and the Joint Research Centre as Community Reference Laboratory (CRL) for GMOs for the validation of the required detection methods. It is nevertheless to be noted that it is unlikely that, in this type of situations where the GMOs in question are not intended to be commercialised, the available data will be sufficient to complete a full safety assessment in accordance with EU standards. In the same way, it is unlikely that a robust specific detection method will always be readily available. When such method is available, the capacity of the CRL to validate detection methods rapidly is of strategic importance to identify contaminated products. In all cases, the rapid sharing of relevant information, data and material in a transparent and efficient manner is crucial to allow an efficient and proportionate response to the issue.

Of equal importance is the readiness of GMO producers and exporting countries authorities, when it is the case, to quickly communicate possible problems and to co-operate with the EU authorities in order to find effective solutions.

Finally preventing the import of unauthorised GM products into the EU market implies a high degree of vigilance from operators and Member States in order to detect at an early stage any unauthorised product that might be placed on the EU market. It also requires prompt information from the companies responsible for the concerned GMO and, from the exporting country where the contamination is firstly reported. Overall, better international cooperation is urgently needed.

Based on the lessons from these three cases, the Commission will consider whether specific actions are needed.

#### **5. FOOD VETERINARY OFFICE: OUTCOME OF INSPECTIONS CARRIED OUT IN THIRTEEN MEMBER STATES**

With the entry into force of the Regulations (EC) No 1829/2003 and 1830/2003 the Food and Veterinary Office of DG SANCO (FVO) planned a series of inspections to Member States with the objective of evaluating on the spot the official control systems implementing the above Regulations. In pursuit of these objectives the inspection teams evaluated controls at central and regional levels, those steps relating

to import, processing and retailing of products consisting of or produced from GMOs, including food, feed and seed.

To date there have been 13 inspections to Member States, preliminary findings of which are detailed below:

- All have designated responsibility for GMO controls for both food and feed. Different authorities are normally responsible for food and feed.
- All Member States had adequate controls regarding Commission Decision 2005/317/EC on BT10.
- The majority of infringements found by Member States related to the mislabelling of food and feed products.
- As with other FVO inspections the findings indicated that those Member States having a high degree of regional autonomy, had weaker co-ordination between the regions and central level as evidenced by a lack of overall results for controls.
- The level of sampling reported by MSs varied considerably for food, feed and seed. Specifically, 6 MSs did not perform sampling controls at the point of entry for food, and feed. Based on data provided for 2004/2005, 3 MSs performed no sampling controls on seed consignments for the adventitious presence of GMO.
- Commission Recommendation 2004/787/EC on technical guidance for sampling and detection of GMOs and material produced from GMOs as or in products in the context of Regulation (EC) No. 1830/2003 was not being routinely complied with in the Member States visited. In a number of cases Member States used alternative sampling strategies such as international standards ISO 2859, or Community legislation (Directive 76/371/EEC for feed control, or Directive 98/53/EC on mycotoxin sampling). Competent authorities indicated a difficulty in applying the sampling provisions of the recommendation in particular to large consignments of food and feed.
- Official control laboratories dealing with GMOs analysis were usually accredited to ISO standards (either ISO 17025 or ISO 45000) although there were still some laboratories lacking the necessary accreditation. Most laboratories could analyse qualitatively and quantitatively those GMOs for which certified reference material was available, although the number of events which were analysed for varied between MSs.

- However, four MSs had limited or no capabilities regarding the quantification of GMOs in food or feed. This means that they were unable to determine if food or feed samples which were positive for the presence of GMO were above the threshold level of 0.9% and thus they were unable to enforce the labelling requirements set down in Art 12 of the Regulation.
- Six MSs did not take action in all cases with regard to positive results (trace amounts) for seed consignments.

## **Part 2: Development of implementing measures and specific clarifications**

### **6. ACTIVITIES OF THE STANDING COMMITTEE ON THE FOOD CHAIN AND ANIMAL HEALTH (SCFCAH)**

Since the entry into force of the Regulation on 7 November 2004, the section on GM Food and Feed and environmental risk of the SCFCAH held 8 meetings. The agendas and the minutes of its meetings are published on the “Food and Feed safety” section of the website of the Commission<sup>24</sup>.

In addition to Regulation (EC) No 641/2004 (see point 7 of the current report), the Committee provided a positive opinion on the draft Commission Decision on emergency measures regarding the non-authorised GMO Bt10 in maize products that was adopted as Decision 2005/317/EC<sup>25</sup> (see point 4.2 of the current report for further details). By contrast, it provided no opinion on a draft Decision related to the authorisation of food containing, consisting of, or produced from maize 1507.

During the meetings of this committee, different exchange of views took place regarding some aspects of the Regulation that should be clarified. The Commission is providing clarifications for some of these aspects in the following sections of the current report.

### **7. ADOPTION OF IMPLEMENTING RULES AND GUIDELINES**

On 6 April 2004 the Commission adopted Regulation (EC) No 641/2004<sup>26</sup> 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 GM 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.

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<sup>24</sup> [http://ec.europa.eu/food/committees/regulatory/scfcah/modif\\_genet/index\\_en.htm](http://ec.europa.eu/food/committees/regulatory/scfcah/modif_genet/index_en.htm)

<sup>25</sup> OJ L 101, 21.4.2005, p. 14.

<sup>26</sup> OJ L 102, 7.4.2004, p.14.

The detailed requirements concerning applications submitted in accordance with Articles 5 and 17 of the Regulation are provided for in Chapter I of Regulation (EC) No 641/2004. Those have been complemented by guidance documents issued by EFSA (see hereunder). Chapter II of Regulation (EC) No 641/2004 provides the requirements for the notification of existing products. In addition to indicating the compulsory pieces of information to be included in the notification dossiers, this Chapter also clarifies the interplay of the Regulation with previous Community legal acts under which GM products could already be authorised, and defines the rules for establishing the date on which a product was first placed on the market.

Chapter III of Regulation (EC) No 641/2004 contains the implementing rules related to Article 47 of the Regulation providing for transitional measures for adventitious or technically unavoidable presence of GM material which has benefited from a favourable risk evaluation. These measures remain applicable until 18 April 2007. In accordance with this Chapter, the Commission published a list that distinguishes between material fulfilling all the requirements of Article 47 and material for which a method of detection is not publicly available. The Commission will continue to update this list until 18 April 2007.

Annexes I and II of Regulation (EC) No 641/2004 define the technical requirements related to the validation of the detection method and to the reference material.

In addition, Commission Regulation (EC) No 65/2004<sup>27</sup> establishing a system for the development and assignment of unique identifiers for genetically modified organisms and Commission Recommendation 2004/787/EC<sup>28</sup> on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003 were adopted on 14 January 2004 and 4 October 2004, respectively.

These texts further complement the Regulation with regard to the designation of the GMO by a defined unique identifier and to the testing of GMOs and GM products in the context of official controls. Their implementation is further developed in the report on the implementation of Regulation (EC) No 1830/2003.

In accordance with Articles 5(8) and 17(8) of the Regulation, the European Commission has requested EFSA to publish detailed guidance to assist the applicant in the preparation and the presentation of the application for authorisation of GM food and/or feed.

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<sup>27</sup> OJ L 10, 16.1.2004, p. 5.

<sup>28</sup> OJ L 348, 24.11.2004, p. 18.

On 8 November 2004, the Scientific Panel on genetically modified organisms (GMO Panel) finalised, after extensive consultation, the first guidance document for the risk assessment of GM plants and derived food and feed to assist the applicant in the preparation and presentation of applications<sup>29</sup>. The EFSA guidance document has been updated, on December 2005, with a section on general surveillance of unanticipated effects of GM plants as part of the post market environmental monitoring<sup>30</sup>.

A second guidance document for the risk assessment of genetically modified microorganisms and their derived products intended for food and feed use has been adopted by the GMO Panel on 17 May 2006<sup>31</sup>.

## 8. INTERPLAY BETWEEN DIRECTIVE 2001/18/EC AND REGULATION (EC) NO 1829/2003 RELATING TO EXISTING PRODUCTS AND FEED PRODUCED FROM GMO

The Regulation provides for several transitory measures related to the authorisation for the placing on the market of GM food and feed, e.g. for so-called “existing products”.

Existing products are products that were lawfully placed on the market prior to 18 April 2004, either on the basis of a Decision taken under Directive 90/220/EEC, Directive 2001/18/EC, Regulation (EC) No 258/97, Directive 70/524/EEC or Directive 82/471/EEC or on the basis that the products did not require any specific authorisation. Such products can continue to be used, on condition that they were notified under the Regulation as “existing products” within 6 months of the date of application of the Regulation (i.e. October 2004).

According to Articles 8(4) and 20(4) of the Regulation, the placing on the market of existing products is subject to the procedure for the renewal of authorisations, which applies *mutatis mutandis*.

- Applicants who wish to apply for a renewal of authorisations for existing products falling under Articles 8(1)(a) and 20(1)(a) of the Regulation (in particular, products that were already covered by an authorisation for placing on the market before the application of the Regulation, including GMOs that were authorised under Directive 90/220/EC or Directive 2001/18/EC) should not submit their applications before 18 April 2007, which is the earliest possible date, three years after the date of application of the Regulation.
  - For the products for which the period of 9 years of placing on the market elapses before this date, the applications have to be submitted on 18 April 2007.

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<sup>29</sup> [http://www.efsa.eu.int/science/gmo/gmo\\_guidance/660\\_en.html](http://www.efsa.eu.int/science/gmo/gmo_guidance/660_en.html)

<sup>30</sup> [http://www.efsa.eu.int/science/gmo/gmo\\_guidance/1275\\_en.html](http://www.efsa.eu.int/science/gmo/gmo_guidance/1275_en.html)

<sup>31</sup> To be published on the website of EFTA.

- For the other products, the time limit can be later on condition that it is within 9 years from their first placing on the market.
- Applicants who wish to apply for a renewal of authorisations for existing products falling under Articles 8(1)(b) and 20(1)(b) (products for which an authorisation was not required before the application of the Regulation) should submit their applications before 18 April 2007.

The Community register of GM Food and Feed clearly indicates whether a given product has been notified in accordance with, respectively, Articles 8(1)(a), 8(1)(b), 20(1)(a) or 20(1)(b).

If these rules are respected, the products in question may remain legally on the market until a decision on the basis of the Regulation has been taken (see Articles 11(4) and 23(4)), without regard to the expiry date laid down in the authorisation that was granted under a different legislation.

It also appears useful to clarify the situation for several GMOs (e.g. NK603, GT73, 1507 and MON 863) that have been recently authorised on the basis of a positive assessment in terms of safety to human health and the environment as part of the approval under Directive 2001/18/EC, including feed use according to the transitory measures of the Regulation. Since the need for an authorisation for the placing on the market of feed produced from GMOs is a new requirement in Community law that has been introduced by the Regulation (see Recital 7 of the Regulation which reflects this state of affairs), a further authorisation for feed produced from these GMOs will be required under the Regulation.

The feed produced from the aforementioned GMOs have all been notified as existing products indicating that notifiers are aware of the situation. The notifications cover food/feed additives and feed materials produced from the GMOs. These products are therefore allowed to remain on the market as existing products and they will have to go through a renewal procedure within the timeframe indicated in Article 20(4) of the Regulation.

## **9. MEASURES FOR ADVENTITIOUS OR TECHNICALLY UNAVOIDABLE PRESENCE OF GENETICALLY MODIFIED MATERIAL NOT AUTHORISED UNDER COMMUNITY LEGISLATION**

Article 47 of the Regulation states that the presence in food or feed of material which contains, consists of or is produced from GMOs in a proportion no higher than 0.5 % shall not be considered to be in breach of Article 4(2) or Article 16 (2) which require an authorisation prior to the placing on the market of GM food or feed. This threshold is only valid for the adventitious or technically unavoidable presence of products that have benefited from the favourable opinion of a Community Scientific Committee or of EFSA before 18 April 2004, and provided that the application for its authorisation has not been rejected in accordance with the relevant Community legislation and that a detection method is publicly available. The thresholds may be lowered in accordance with the Committee procedure referred to in Article 35(2), in particular for GMOs sold directly to the final consumer. This later possibility has not been used so far.

The Commission has adopted Regulation (EC) No 641/2004 that includes detailed rules for the implementation of Article 47. On that basis the Commission has published on 18 April 2004 a list including 4 GM foods and 9 GM feed products that fulfilled all the above-mentioned requirements as well as 3 GM feed products for which no detection method was publicly available. An updated list is currently available on the website of the Commission<sup>32</sup>.

Since the publication of this list, 4 Decisions authorising the placing on the market of GM foods have been adopted (cfr. Annex). As a consequence, Article 47 now only covers one food product: food containing or consisting of GM maize GA21. The list of GM feed was also amended following the authorisation for the placing on the market of 2 GM feed products.

Article 47 will remain applicable until three years after the entry into force of the Regulation, i.e. 18 April 2007.

The possibility to apply a similar approach to other products that have been similarly risk assessed should also be considered. Authorisations for the placing on the market of GM products are granted for a time period of 10 years and may not be requested to be renewed. At the end of the authorisation period, these legally marketed products may be present at different levels of the food and feed chain. It should, therefore, be ensured that the phasing out of the products concerned does not lead to production or use, which might unavoidably include these products or traces of these products, being rendered illegal.

Another type of product that should be considered relates to products that have been authorised in third countries after a safety assessment equivalent to the one required for EU authorisation. The establishment of such a tolerance would certainly require a dedicated procedure as well as extensive exchange of information between the EU and third countries. Preliminary international discussions on this matter were held during the fifth session of the Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived from Biotechnology that took place in January 2005<sup>33</sup>.

These measures, as it is the case at the present time, would only apply under specific conditions ensuring that this adventitious presence is compatible with a high level of protection of human life and health, animal health and welfare, and environment and that management measures are in place to enforce such measures.

## **10. STATUS OF FOOD OR FEED PRODUCED BY FERMENTATION USING GENETICALLY MODIFIED MICRO-ORGANISMS NOT PRESENT IN THE FINAL PRODUCT**

### **10.1. Background**

Upon the adoption of the Common Position regarding the proposal for the Regulation on GM food and feed, the following declaration was made “*The Council and the Commission agree that the status of food produced by fermentation using*

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<sup>32</sup> [http://europa.eu.int/comm/food/food/biotechnology/gmfood/events\\_en.pdf](http://europa.eu.int/comm/food/food/biotechnology/gmfood/events_en.pdf)

<sup>33</sup> The report of this session is available at: <http://www.codexalimentarius.net/web/archives.jsp?lang=EN>

*genetically modified micro-organisms not present in the final product, needs to be clarified, at the latest in the context of the report to be presented by the Commission as foreseen in Article [48] of the Regulation.”*

From the answers received from the Member States and stakeholders, one may conclude that there is a general opinion that a safety assessment of this type of products should be mandatory prior to their placing on the market. It is also mentioned that a great part of these products (for example food and feed additives) have already undergone an authorisation procedure that includes a safety assessment. All stakeholders were opposed to the GM labelling of this type of products. Few Member States are in favour while others are directly opposed to such a labelling.

## **10.2. Clarification of the status of food or feed produced by fermentation using genetically modified micro-organisms not present in the final product**

The status of food or feed produced by fermentation using genetically modified micro-organisms has to be clarified in the light of the recital n° 16 of the Regulation. When the GM micro-organism is used as a processing aid, the food and the feed resulting from such production process are not to be considered as falling under the scope of the Regulation.

## **10.3. Application of the clarification to food products and processing aids**

Article 1 of Directive 89/107/EC<sup>34</sup> defines food processing aids as “any substance not consumed as a food by itself, intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the unintentional but technically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not present any health risk and do not have any technological effect in the finished product”.

This may be the case, for example, when the micro-organisms are removed after the fermentation and that the produced food is further purified in the production process or when the micro-organisms are attached/fixed to a support/matrix in such a way that it is used during the treatment or processing of the food but it is not transferred into the final product as such or under an altered form.

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<sup>34</sup> OJ L 40, 11.2.1989, p. 27.

When the GM micro-organisms are not removed during the production process, they are not used as processing aids. In these cases, the produced foods and food ingredients fall under the scope of the Regulation and have to be authorised and labelled accordingly.

It is to be underlined that an extended range of food produced using GM micro-organisms as processing aids are already subject to requirements consisting in a safety assessment and a pre-market approval, or will be subject to such requirements by the way of new proposed legislation in the near future. It is the case for food additives (subject to Directive 89/107/EC as amended), flavourings (subject to Directive 88/388/EC<sup>35</sup>), and food enzymes. For these 3 types of substances, the Commission is finalising proposals to the European Parliament and the Council. It may also be the case for the placing on the market of food and food ingredients produced with new GM micro-organisms if they fall within the scope of Regulation (EC) No 258/97<sup>36</sup>, and in particular art.1(2)(f) thereof: “foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances”.

#### **10.4. Application of the clarification to feed products and processing aids**

Article 2(2)(h) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition defines feed processing aids as “any substance not consumed as a feedingstuff by itself, intentionally used in the processing of feedingstuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed”.

Article 2(2)(a) of the same Regulation provides that feed additives mean “substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3) [of Regulation (EC) No 1831/2003]”.

When the GM micro-organisms are present in the feed or when they are not removed during the production process, they are not used as processing aids. In these cases, the produced feeds fall under the scope of the Regulation and have to be authorised and labelled accordingly. When the GM micro-organisms are present as such in the feed, whether as or in a product that fall within the definition of feed additives provided by Regulation (EC) No 1831/2003, that product must also be approved under that Regulation before it may be placed on the market and used.

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<sup>35</sup> OJ L 184, 15.7.1988, p. 61.

<sup>36</sup> OJ L 43, 14.2.1997, p. 1.

Certain categories of feed materials which are produced by fermentation with bacteria, algae, yeasts or lower fungi and used as source of protein require pre-market assessment and approval before being placed on the market and used. Council Directive 82/471/EEC<sup>37</sup> of 30 June 1982 concerning certain products used in animal nutrition lay down the conditions for authorisation of such products as amended.

Consequently, an extended range of feed produced using GM micro-organisms as processing aids are, due to the fact that the produced feeds are used as additives or source of protein and manufactured by certain technical processes, subject to specific legal requirements laid down in Regulation (EC) No 1831/2003 or Directive 82/471/EEC regarding their safety in order to be lawfully placed on the market.

#### **10.5. Guidelines on the Safety assessment of food or feed produced by fermentation using genetically modified micro-organisms**

The GMO Panel of EFSA has adopted on 17 May 2006 its guidance document for the risk assessment of genetically modified micro-organism and their derived products intended for food and feed use<sup>38</sup>. The guidance was subject to public consultation between 15 July and 30 September 2005. The current document addresses all the uses of the GM micro-organisms and their derived products intended for food and feed use, irrespective of the fact that they are used as processing aids or not. The outcome of this work will be relevant for the safety assessment of all the uses of GM micro-organisms and their derived food and feed, irrespective of the fact that they fall under the scope of the Regulation or one of the other legislative framework presented above.

#### **10.6. Conclusions**

Food or feed produced using genetically modified micro-organisms as processing aids are not falling under the scope of the Regulation. However, an extended range of these products are already subject to an equivalent authorisation procedure under Community law and thus to equivalent requirements in terms of food and feed safety.

The Commission therefore considers that there is no particular need to review the Regulation for this type of products at the present time. However, the situation will be reconsidered when an in-depth review of the Regulation will be carried out on the basis of additional experience. In this regard, particular attention will also have to be paid on the appropriateness to develop tailored labelling rules for this type of product.

### **11. CLARIFICATIONS RELATED TO SOME ASPECTS OF THE LABELLING PROVISION OF THE REGULATION**

#### Operation of the labelling threshold

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<sup>37</sup> OJ L 213, 21.7.1982, p. 8.

<sup>38</sup> To be published on the EFSA website.

Articles 12 and 24 of the Regulation set the conditions under which GM food and feed are required to be labelled. Articles 12(2) and 24(2) provide an exemption for the adventitious or technically unavoidable presence of GM food and feed in a proportion that is no higher than 0.9 %.

When the food/feed is composed of one food/feed (e.g. a feed material or an ingredient), the threshold must be calculated on the basis of such a food/feed. When the adventitious or technically unavoidable presence of material consisting of, containing or produced from GMOs (hereinafter referred to as GM material) is detected in compound feedingstuffs or foods composed of more than one ingredient, it is necessary to examine each of the different ingredients/feed components in order to establish the origin of such a presence. If the threshold of 0.9% is exceeded in one of those components of the food/feed, then the food/compound feed should indicate on the label the presence of the GM material in relation to that specific food/feed component.

#### Labelling of alcoholic beverages

According to Article 6(3) of the general labelling Directive 2000/13/EC, the Council shall adopt specific rules on the labelling of ingredients of alcoholic beverages containing more than 1.2 % by volume of alcohol. Since these specific rules have not been adopted by Council, the current interpretation is that labelling of ingredients of alcoholic beverages is not compulsory.

However, the Council and the Parliament have acted by laying down specific labelling rules for GM food in the Regulation. GM ingredients of alcoholic beverages have thus to be labelled according to the labelling requirements of the Regulation.

#### Labelling of carriers

Carriers for food additives that are exempted from labelling should also be exempted from labelling when produced from a GMO: The reason is that according to Article 13(1) of the Regulation, the labelling requirements of the Regulation apply to ingredients as defined in article 6.4 of the General Labelling Directive 2000/13/EC. If the requirements of Article 6(4)(c)(iii) of this Directive are met, the carrier is not considered as an ingredient and therefore the labelling of the carriers is not compulsory, even if they are produced from a GMO.

Carriers used in premixtures of feed additives however are considered as feed materials and GM labelling is mandatory if they are produced from a GMO.

### Labelling requirements for mass caterers

The labelling requirements of the Regulation are not applicable to food supplied by mass caterers to their customers where such foods have been prepared or processed. They do, however, apply to food which are supplied to mass caterers and which are delivered as such to the final consumer. This interpretation is consistent with the interpretation which has traditionally been given to Article 1(1) of Directive 2000/13/EC, which is written in a similar manner<sup>39</sup>.

### GM free labelling scheme

With regard to some practices related to label food or feed products as “GM free”, the following elements need to be clarified.

The Regulation is providing for labelling rules indicating the presence of GMO. However, it does not forbid additional labelling practices that would aim to inform the consumer that, in addition to what is prescribed by the EU legislation, specific measures have been taken to strictly exclude the presence or the use of GMO in some food or feed products.

Two categories of products can be distinguished:

- (1) Food categories that have not been genetically modified hitherto: labelling these foods as GM free is suggesting that they possess a special characteristic when in fact all similar food possess the same characteristic, and this is misleading within the meaning of Article 2(1)(a)(iii) of Directive 2000/13/EC.
- (2) Food products that can be genetically modified or not: Such food can be placed on the market without a GM label provided that they contain less than 0,9 % of GM material and that the presence of GM material is unintentional and technically unavoidable. For these foods, a GM free labelling can not be excluded a priori.

Some Member States have developed national rules regarding this type of labelling and the Commission notes that in most of those Member States such national rules stipulate that the threshold for adventitious and technically unavoidable presence of GM material in GM free products should be below the level of detection of the current analytical methods.

## **12. CONCLUSIONS**

The Regulation has only been operational for a limited period of time and experience in terms of its implementation is extremely limited. Consequently, this report can realistically only be viewed as preliminary and further experience and reporting will be required to gain a true picture of the implementation of the Regulation. It is therefore premature to bring forward proposals to amend the current Regulation.

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<sup>39</sup> This clarification was provided in answer to the written question No 4049/03 of a member of the European Parliament.

The procedures established by the Regulation to handle the submitted applications have been designed to streamline the authorisation process. EFSA is taking a central role in this process since it has, after due consultation of the assessment bodies of the Member States, to provide the opinions on which the authorisations are based. While this has been the case for the first authorisation, the Commission agreed in April 2006 on practical improvements with the objective of building greater consensus and transparency regarding the authorisation for the placing on the market of GM products either under the Regulation or under Directive 2001/18/EC and EFSA engaged to reinforce collaboration with Member States on GMO risk assessment. The high number of applications (more than thirty) is a direct indicator of the continuous development of new GM products and of the willingness of their producers to undergo the prescribed thorough safety assessment that is a pre-requisite for their commercialisation on the European market.

In comparison to the previous existing legislation, the range of products to be labelled as genetically modified or produced from a GMO was extended to all food and feed produced from GMOs. This is recognised as a major improvement in responding to European consumers' requests for the possibility to make an effective and informed choice between GM and non GM products. The EU market shares of food and feed products appear to be contrasted. Labelled GM feed products are much more placed on the market than GM food. This situation is mainly governed by factors that are not related to the legislative framework as such but by other elements including consumer demand, relative availability and costs of different commodities on the world market, and the policies of food producers and retailers.

The Commission will continue, in collaboration with the CA of Member States and EFSA, to ensure the appropriate implementation of the Regulation. In this regard, the Food and Veterinary Office of DG SANCO (FVO) will pursue its missions in Member States with the objective of evaluating on the spot the official control systems implementing the legislation on GM food and feed. In the case of information indicating the placing on the market of non-authorised GM products, appropriate actions will continue to be decided on a case-by-case basis.

A second report on the Regulation should be prepared after a sufficient period of time allowing more insight on the different aspects of the implementation of the Regulation.

## ANNEX

### **AUTHORISATIONS UNDER DIRECTIVE 2001/18/EC OR REGULATION (EC) No 258/97 IN ACCORDANCE WITH THE TRANSITIONAL MEASURES PROVIDED FOR IN ARTICLE 46.**

COMMISSION DECISION 2004/657/EC of 19 May 2004 authorising the placing on the market of sweet corn from genetically modified maize line Bt11 as a novel food or novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council [OJ L 300, 25.9.2004, p. 48]

COMMISSION DECISION 2004/643/EC of 19 July 2004 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L. line NK603) genetically modified for glyphosate tolerance [OJ L 295, 18.9.2004, p. 35]

COMMISSION DECISION 2005/448/EC of 3 March 2005 authorising the placing on the market of foods and food ingredients derived from genetically modified maize line NK 603 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council [OJ L 158, 21.6.2005, p. 20]

COMMISSION DECISION 2005/608/EC of 8 August 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line MON 863) genetically modified for resistance to corn rootworm [OJ L 207, 10.8.2005, p. 17]

COMMISSION DECISION 2005/635/EC of 31 August 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of an oilseed rape product (*Brassica napus* L., GT73 line) genetically modified for tolerance to the herbicide glyphosate [OJ L 228, 3.9.2005, p. 11]

COMMISSION DECISION 2005/772/EC of 3 November 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium [OJ L 291, 5.11.2005, p. 42]

COMMISSION DECISION 2006/68/EC of 13 January 2006 authorising the placing on the market of foods and food ingredients derived from genetically modified maize line MON 863 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council [OJ, L 34, 7.2.2006, p. 26]

COMMISSION DECISION 2006/69/EC of 13 January 2006 authorising the placing on the market of foods and food ingredients produced from genetically modified Roundup Ready maize line GA21 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council [OJ L 34, 7.2.2006, p. 29]