

Caroline White
caroline.white@cec.eu.int

4 March 2005

Reference:

Dear Caroline

GM QUESTIONNAIRE - IMPLEMENTATION OF REGULATION EC 1829/2003

Please find attached a response from the UK Competent Authority in relation to the above questionnaire. Responses are provided for both GM food and feed.

The UK found the questionnaire difficult to complete given the short time frame between the regulation coming into effect and the questionnaire being issued. Implementing regulations have only been in place in England since 4 October 2004 which has provided little opportunity for surveillance work and local authorities who have responsibility for enforcing the regulations have only limited experience with the new regulations. In relation to our experience with authorisations under this regulation, it is really too soon to be able to comment as no applications have yet completed the process under this regime. We would be willing to provide comments at a later date on this.

We are interested to know how the Commission will use the responses to the questionnaire from member states. The Regulation states that the Commission will produce a report in November 2005 and we would hope that the Commission will seek wider views from member states on how the regulations are working in practice before drafting this report. Although we have consulted with UK stakeholders in completing the questionnaire this has been limited in the time available. We would welcome an opportunity to provide more extensive comments from our stakeholders on the regulations, if the Commission would welcome this input before drafting its report. We would also envisage a period of consultation with member states after the report is published and wondered what provisions will be in place to allow this.

Yours sincerely

[Sent by email]
Clair Baynton
Head of Novel Foods, Additives and Supplements Division

Keith Millar
Head of Animal Feed Unit, Primary Production Division

QUESTIONNAIRE FOR MEMBER STATES ON THE IMPLEMENTATION OF REGULATION (EC) N°
1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON GENETICALLY MODIFIED
FOOD AND FEED

Your contact details:

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Competent Authority: Food Standards Agency
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Are you competing this questionnaire for:

GM food	YES	✓	NO	?
GM feed	YES	?	NO	✓

The questionnaire to Member States has the following objectives in view of the preparation of the report provided by Article 48(1) of Regulation (EC) N° 1829/2003 on GM food and feed:

- to describe the experiences Member States had in implementing the Regulation,
- to identify any difficulties that have come up in implementing the Regulation,
- to make recommendations on how to strengthen the consistency and efficiency of the Regulation.

Please return the questionnaire to Caroline White by 4 March 2005: caroline.white@cec.eu.int or fax: +32-2-2960951

If you have questions regarding the questionnaire, please contact Päivi Mannerkorpi, Tel: +32-2-2993724, paivi.mannerkorpi@cec.eu.int

1. National legislation and practice

1. Regulations are directly applicable but was it necessary to some extent to adopt or adapt national legislation on Regulation (EC) N° 1829/2003? If so, please describe to what extent and please give the national legislative acts concerned.

It was necessary to provide for the enforcement of the measure by linking it to a range of offences and penalties for the potential failure by individuals or bodies corporate to comply with the requirements of the measure. This was achieved, for food, by the Genetically Modified Food (England) Regulations 2004 No. 2335. This provides the domestic enforcement powers for the EC GM Food and Feed Regulation (No. 1829/2003), and penalties for non-compliance. Separate but parallel legislation applies in Scotland, Wales and Northern Ireland. The relevant provisions of 1829/2003 are listed in the Schedule to these Regulations; regulation 5 sets out the offences and penalties for breach of them; and regulation 7 sets out the powers of inspectors with respect to GM food and action in respect of non-compliant consignments.

2. In your country, do any additional labelling practices on GM food and GM feed exist other than EU Regulations (N°s 1829/2003, 1830/2003)? If so, please provide details.

There are no other statutory labelling schemes. However, in response to customer pressure, we are aware that some supermarket chains request that their suppliers source certain products for human consumption (milk, meat and eggs) from animals which have not had GM material in their diets; the products are labelled accordingly.

3. Have there been any problems with interpretation of the Community legislation (Regulation (EC) N° 1829/2003, Regulation (EC) N° 641/2004)? If so, please give details.

There is difficulty in the interpretation of 'produced from' and 'produced with' a GMO, a clearer definition is required for clarity in interpretation. In addition there have been problems encountered with regards to fermentation products. Whilst the decision taken at Standing Committee has eased some of the concerns there is still a level of uncertainty with regards to these products in terms of the wording used in the minutes of the meeting e.g. totally or partially, whether viable or not.

4. Have any issues on Article 29 (public access) and 30 (confidentiality) arisen for you? If so, please provide the details.

We have received one request for access to information, which was passed to EFSA.

It is essential to maintain a high degree of openness and we urge EFSA to ensure that information is placed in the public domain as soon as practical, and that any claims for confidentiality are carefully scrutinised.

We also support the publication of EFSA opinions available for a defined period of public comment before any decision on authorisation is made. This is the approach which we have followed for many years in the UK in our evaluation of dossiers for novel and GM foods. However, it is not yet clear how any comments sent to the Commission, as described in Articles 6(7) and 18(7) of regulation 1829/2003, will be handled. Will the applicant and/or EFSA be invited to respond? Will the comments be made public?

2. Controls

5. Please name the competent authority for controls according to Regulation (EC) N° 1829/2003 for the following subject areas at each level:

i) for GM food/feed:

- central – The Food Standards Agency

- local – At a local level, the enforcement of this legislation is delegated to individual local food authorities in the UK; more specifically, to Environmental Health Officers (EHO) and Trading Standards Officers (TSO). At entry points, Port Health Authorities (PHA) may be integral to the Local Authority or be a stand-alone organisation. Port Health Authorities are usually the local food authority for the purpose of imported food controls. However, in places where a PHA cannot be constituted e.g. airports the Local Food Authority will carry out the role.

- regional – The Local Authorities Co-ordinators of Regulatory Services (LACORS) co-ordinates the enforcement activities of Environmental Health and Trading Standards departments. It is a local government central body created by the UK Local Government Associations. LACORS operates a number of Regional Food Groups to examine and discuss enforcement issues of local and national importance to facilitate problem resolution and consistency in enforcement activity at regional and national level. These Regional Groups also serve as a sounding board for policy ideas and initiatives and contribute to the consultation process, both formally and informally. Each local food authority is represented on the Food Group for its region. The Association of Port Health Authorities (APHA) organisation co-ordinates and promotes an efficient port health service, represent the interests of Member Port Health Authorities in discussions with Government on all matters relating to health control of shipping and aircraft and imported food.

6. Does any coordination of controls on GM food, GM feed and GMO's in the scope of Directive 2001/18/EC take place? If so, please provide details about responsibilities and activities.

There is no information available on the level of activity at this stage.

7. Do you have a specific control plan for GM food and feed? Please describe briefly at what stage (e.g. import, processing, placing on the market etc) controls on Regulation (EC) N° 1829/2003 take place and describe the nature of the controls (e.g. documentary and/or physical checks, sampling, analysis etc).

Local Authority checks take place at all stages including import, processing and placing on the market. The majority of checks are documentary checks with very limited sampling and analysis due to the costs involved. For products where no DNA or protein is present there are practical issues to how these can be checked where analytical methods can't be used to verify GM presence. In such cases only documentary evidence can be used.

8. What have been the control priorities in 2004? What priorities are foreseen for 2005?

We have been informed by the Local Authorities Co-ordinators of Regulatory Services (LACORS) that priorities in 2004 were to advise and educate businesses as to their legal compliance obligations. Information on priorities in 2005 is not available.

9. If possible, please give the control results on labelling (0.9 % threshold) for 2004.

Food/feed – No information available at this stage.

Products inspected (number)	Samples taken and analysed (number)	Non-compliance (number)
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10. In the recent year, have any other issues with the rules on labelling arisen for you? If so, please give details.

Yes. There is a lot of confusion regarding the labelling of fermentation products. Another area where clarification is urgently sought is whether this regulation applies to catering establishments. There still remains differing views between the Commission, Council and Member States on the scope of the regulation with respect to the labelling of food sold in catering establishments . There is no scope in the regulation for national measures to be adopted. A consistent approach needs to be provided. There is also confusion over manufacturing techniques and end products and whether certain products fall within the scope of the regulation.

11. How have been the provisions on Article 47 of Regulation (EC) N° 1829/2003 and Regulation (EC) N° 641/2004 on the threshold of 0.5 % adventitious presence of GMO material been controlled? If possible, please give the control results for 2004.

No information is available at this stage.

Food/Feed

Products inspected (number)	Samples taken and analysed (number)	Non-compliance (number)
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12. Has unauthorised GM food and feed been imported or found on the market? If so, please give the number of occurrences, as well as the nature and origin of the GMOs and products concerned.

Information not available.

13. Have there been any problems in carrying out the controls with respect to aspects such as sampling, analytical methods or documentary control?

No information is available at this stage.

3. Other issues

14. In your opinion, how is the new authorisation procedure according to Regulation (EC) N° 1829/2003 functioning? Please provide details.

It is too early to say how the authorisation procedures are working as none of the applications is sufficient advanced in the process. We note that the first EFSA opinion is due to be discussed at a Working Group meeting in March and we would be pleased to provide comments at a later date.

15. In view of forthcoming legislation, what is your opinion on the fermentation products (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using genetically modified micro-organism (GMM) which is kept under contained conditions and is not present in the final product:

- should a risk assessment be required? yes ? no ?
- should labelling be required? yes ? no ?

A number of stakeholders have indicated differing views on both the risk assessment and labelling sections of this question.

If yes, please provide details on the kind of risk assessment required and a labelling proposal.

The UK's position on the labelling of GM products is that it must be practical, proportionate and enforceable to ensure that consumers are not misled. We are waiting for the advice of EFSA's GM panel on the risk assessment of GM micro-organisms before taking a view on this.

Please provide details on products on the market.

16. Please provide statistics on GM plants cultivated (ha/year) and gm food and feed imported (tn/year) to your country.

There is currently no commercial cultivation of GM crops in the UK.

Information on the quantity of GM food imported in the UK is not available.

17. Would you like to comment on any other aspect of the Regulation (EC) N° 1829/2003 or on other related legislation that would improve the EU legislative framework for genetically modified food and feed?

There is a need for clarity on the inter-relationship between the Regulation and Directive 2001/18 in relation to applications for authorisation and applications for import and cultivation.

There is a need for a protocol to deal with the question of false positive results when sampling and analysis is undertaken.

There is no provision under the current legislation for the adventitious presence of GM events approved or assessed in third countries such as the USA but not in the EU, although the majority of events in third countries fall into this category. If detected in imported commodities, such shipments would require to be rejected and returned, at additional work and cost for all stakeholders.



QUESTIONNAIRE FOR MEMBER STATES ON THE IMPLEMENTATION OF REGULATION (EC) 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON GENETICALLY MODIFIED FOOD AND FEED

Your contact details:

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Competent Authority: Food Standards Agency
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Are you competing this questionnaire for:

GM food	YES	?	NO	✓
GM feed	YES	✓	NO	?

The questionnaire to Member States has the following objectives in view of the preparation of the report provided by Article 48(1) of Regulation (EC) N° 1829/2003 on GM food and feed:

- to describe the experiences Member States had in implementing the Regulation;
- to identify any difficulties that have come up in implementing the Regulation; and

- to make recommendations on how to strengthen the consistency and efficiency of the Regulation.

Please return the questionnaire to Caroline White by 4 March 2005: caroline.white@cec.eu.int or fax: +32-2-2960951

If you have questions regarding the questionnaire, please contact Päivi Mannerkorpi, Tel: +32-2-2993724, paivi.mannerkorpi@cec.eu.int

1. National legislation and practice

1. Regulations are directly applicable but was it necessary to some extent to adopt or adapt national legislation on Regulation (EC) N° 1829/2003? If so, please describe to what extent and please give the national legislative acts concerned.

It was necessary to provide for the enforcement of the measure by linking it to a range of offences and penalties for the potential failure by individuals or bodies corporate to comply with the requirements of the measure. This was achieved, for animal feedingstuffs in England, by the Genetically Modified Animal Feed (England) Regulations 2004. Separate but parallel legislation applies in Scotland, Wales and Northern Ireland. The relevant provisions of 1829/2003 are listed in the Schedule to these Regulations; regulation 5 sets out the offences and penalties for breach of them; and regulations 8 and 9 set out the powers of inspectors with respect to GM feed and action in respect of non-compliant consignments.

2. In your country, do any additional labelling practices on GM food and GM feed exist other than EU Regulations (1829/2003, 1830/2003)? If so, please provide details.

There are no other statutory labelling schemes. However, in response to customer pressure, we are aware that some supermarket chains request that their suppliers source certain products for human consumption (milk, meat and eggs) from animals which have not had GM material in their diets; the products are labelled accordingly.

3. Have there been any problems with interpretation of the Community legislation (Regulation (EC) 1829/2003, Regulation (EC) 641/2004)? If so, please give details.

It remains unclear whether the requirement to label for the 0.9% threshold for technical/unavoidable contamination applies to the feed material content of finished compound feeds or the finished compound feed itself.

There are continuing problems over the applicability of the legislation to GM micro-organisms and fermentation products. The interim clarification issued by the Standing Committee in September 2004 has not fully resolved the contradiction in the wording of recital 16 of 1829/2003 vis-à-vis the definition at Article 2.10.

4. *Have any issues on Article 29 (public access) and 30 (confidentiality) arisen for you? If so, please provide the details.*

We have received one request for access to information, which was passed to EFSA.

It is essential to maintain a high degree of openness and we urge EFSA to ensure that information is placed in the public domain as soon as practical, and that any claims for confidentiality are carefully scrutinised.

We also support the publication of EFSA opinions available for a defined period of public comment before any decision on authorisation is made. This is the approach which we have followed for many years in the UK in our evaluation of dossiers for novel and GM foods. However, it is not yet clear how any comments sent to the Commission, as described in Articles 6(7) and 18(7) of regulation 1829/2003, will be handled. Will the applicant and/or EFSA be invited to respond? Will the comments be made public?

2. Controls

5. *Please name the competent authority for controls according to Regulation (EC) N° 1829/2003 for the following subject areas at each level:*

i) for GM food/feed:

- *central* Department for Environment, Food and Rural Affairs (Defra) and the Food Standards Agency
- *local* – At a local level, the enforcement of this legislation is delegated to individual local food authorities in the UK; more specifically, to Environmental Health Officers (EHO) and Trading Standards Officers (TSO). At entry points, Port Health Authorities (PHA) may be integral to the Local Authority or be a stand-alone organisation. Port Health Authorities are usually the local food authority for the purpose of imported food controls. However, in places where a PHA cannot be constituted e.g. airports the Local Food Authority will carry out the role.

- *regional* – The Local Authorities Co-ordinators of Regulatory Services (LACORS) co-ordinates the enforcement activities of Environmental Health and Trading Standards departments. It is a local government central body created by the UK Local Government Associations. LACORS operates a number of Regional Food Groups to examine and discuss enforcement issues of local and national importance to facilitate problem resolution and consistency in enforcement activity at regional and national level. These Regional Groups also serve as a sounding board for policy ideas and initiatives and contribute to the consultation process, both formally and informally. Each local food authority is represented on the Food Group for its region. The Association of Port Health Authorities (APHA) organisation co-ordinates and promotes an efficient port health service, represent the interests of Member Port Health Authorities in discussions with Government on all matters relating to health control of shipping and aircraft and imported food.

6. *Does any coordination of controls on GM food, GM feed and GMOs in the scope of Directive 2001/18/EC take place? If so, please provide details about responsibilities and activities.*

Information on this point is not available at this stage.

7. *Do you have a specific control plan for GM food and feed? Please describe briefly at what stage (e.g. import, processing, placing on the market etc) controls on Regulation (EC) 1829/2003 take place and describe the nature of the controls (e.g. documentary and/or physical checks, sampling, analysis etc).*

Enforcement authorities to make checks at all stages, including import, processing and placing on the market. These are primarily documentary checks. Sampling and analysis is limited due to financial constraints. For products where no DNA or protein is present there are practical issues to how these can be checked where analytical methods can't be used to verify GM presence. In such cases only documentary evidence can be used.

The feed industry makes random checks in order to meet the requirement of due diligence.

One feed industry stakeholder has stated that sampling and analysis is undertaken on imported soya for the purposes of both due diligence and to confirm its identity preservation status (i.e., below the labelling threshold of 0.9% GM content).

8. *What have been the control priorities in 2004? What priorities are foreseen for 2005?*

A local authority enforcement stakeholder has stated that the priorities in 2004 were to advise and educate businesses as to their responsibilities under the legislation.

Information on priorities for 2005 is not available at this stage.

9. *If possible, please give the control results on labelling (0.9 % threshold) for 2004.*

Food/feed

Products inspected <i>(number)</i>	Samples taken and analysed <i>(number)</i>	Non-compliance <i>(number)</i>
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Information on this point is not available at this stage.

10. *In the recent year, have any other issues with the rules on labelling arisen for you? If so, please give details.*

Information on this point is not available at this stage.

11. How have the provisions on Article 47 of Regulation (EC) 1829/2003 and Regulation (EC) 641/2004 on the threshold of 0.5 % adventitious presence of GMO material been controlled? If possible, please give the control results for 2004.

Food/Feed

	Products inspected	Samples taken and analysed	Non-compliance
(number)	(number)	(number)	(number)

Information on this point is not available at this stage.

12. Has unauthorised GM food and feed been imported or found on the market? If so, please give the number of occurrences, as well as the nature and origin of the GMOs and products concerned.

Information on this point is not available at this stage.

13. Have there been any problems in carrying out the controls with respect to aspects such as sampling, analytical methods or documentary control?

Due to deficiencies in the wording of the relevant Article, there is some uncertainty over whether the 0.9% threshold for technical/unavoidable contamination refers to the feed material(s) incorporated in finished compound feeds or the finished compound feeds themselves.

3. Other issues

14. In your opinion, how is the new authorisation procedure according to Regulation (EC) 1829/2003 functioning? Please provide details.

It is too early to say how the authorisation procedures are working as none of the applications is sufficient advanced in the process. We note that the first EFSA opinion is due to be discussed at a Working Group meeting in March and we would be pleased to provide comments at a later date.

There is a need for clarity on the inter-relationship between the Regulation and Directive 2001/18 in relation to applications for authorisation and applications for import and cultivation.

There is a need for a protocol to deal with the question of false positive results when sampling and analysis is undertaken.

There is no provision under the current legislation for the adventitious presence of GM events approved or assessed in third countries such as the USA but not in the EU, although the majority of events in third countries fall into this category. If detected in imported commodities, such shipments would require to be rejected and returned, at additional work and cost for all stakeholders.

Summary of Responses to the 4 February 2005 Consultation on a Questionnaire Member States on the Implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on Genetically Modified Food and Feed

Article 48 of the regulation requires the Commission to forward to the European Parliament and the Council a report on the implementation of this measure by 7 November 2005. In order to prepare this report, the Commission has circulated member states with the questionnaire attached at the foot of this page. This has the following objectives:

- to describe the experiences member states have had in implementing the regulation
- to identify any difficulties which may have arisen in implementing the regulation
- to make recommendations on strengthening the consistency and efficiency of the regulation, if required

Responses requested on:

1. Questions posed by the Commission on the implementation of Regulations (EC) No 1829/2003

RESPONDENTS TO THE FSA CONSULTATION EXERCISE ON A QUESTIONNAIRE MEMBER STATES ON THE IMPLEMENTATION OF REGULATION (EC) NO 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON GENETICALLY MODIFIED FOOD AND FEED.

Agricultural Industries Confederation	AIC
Ajinomoto	AJIN
British Poultry Council	BPC
British Society of Plant Breeders	BSPB
Fermentation Products Alliance	FPA
Food and Drink Federation	FDF
GeneWatch	GW
LACORS	LACORS
Meat and Livestock Commission	MLC
Pet Food Manufacturers Association	PFMA
Scotch Whisky Association	SWA
Syngenta	SYN

RESPONDENTS TO THE FSA CONSULTATION EXERCISE ON A QUESTIONNAIRE MEMBER STATES ON THE IMPLEMENTATION OF REGULATION (EC) NO 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON GENETICALLY MODIFIED FOOD AND FEED.

Please note that this table is a summary and is not meant to be exhaustive.

Question 2 – In your country do any additional labelling practices on GM food and GM feed exist other the EU Regulations (1829/2003 & 1830/2003)?

Respondent	Comment
BPC	Yes, there are additional labelling practices in place. Although meat from animals fed on GM animal feed does not have to be labelled UK retailers are doing this and insisting that the feed is non-GM.

Question 3 – Have there been any problems with the interpretation of the Community legislation (Regulation (EC) 1829/2003 and Regulation (EC) 641/2004)?

Respondent	Comment
AIC	In view of the difficulties that the feed industry had in interpreting the legislation, AIC has developed working guidance in conjunction with LACORS in order to help member companies meet the requirements of the legislation. Areas of difficulties included fermentation products and whether the 0.9% threshold applies to feed materials in a finished compound feed or to the finished compound feed itself.
SYN	We are supportive of a one-door-one-key approach to regulation rather than duplicative procedures. As such there is need for clarity on the interrelationship between Regulation (EC) 1829/2003 and Directive 2001/18/EC in relation to GM food and feed applications and those relating to import and cultivation. An improvement in the co-ordination between the three different bodies (Commission, EFSA and JRC) would also help the process. In addition, problems were encountered with the interpretation of the scope of Regulation (EC) 1829/2003 with regard to fermentation products. The preamble (16) clearly says that food or feed produced with a GMO is exempt and the determining criterion is that the genetically modified source material is absent from the food or feed. However Article 2, Definition 10, defines "produced from" as "derived in whole or in part from GMO's..."

This has led to the confusion in scope that required clarification of the Standing Committee on 24 September 2004. To rectify this, we suggest the need to include a definition that defines "produced from" more clearly, (as in the Standing committee interpretation) or/and a statement that clearly defines produced "with GMO" for clarity of interpretation in the revision. While we welcomed the Standing Committee clarification which provided a useful, but non binding agreement from a majority of member states on the interpretation of the issue, as the clarification came very late it left some compliance challenges to operators in order to meet the deadline of 18th October 2004 for notification of existing products. In such cases operators may have been forced to submit a complete application under Regulation (EC) 1829/2003 for fermentation products, which was not necessary following the Standing Committee clarification.

Question 4 – Have any issues on Article 29 (public access) and 30 (confidentiality) arisen for you?

Respondent	Comment
GW	<p>Our main points are;</p> <ul style="list-style-type: none"> • Public access to the full dossiers has been appalling. The EFSA has not been ready to fulfil such requests and is thus, well exceeding the time limits set down in Regulation (EC) 1049/2001. • The EFSA has not been provided reasons for CBI claims over certain sections of the dossiers. • GeneWatch does not understand how many sections of the dossiers are covered by CBI claims. <p>The failure to provide the full dossiers and the lack of reasoning over CBI claims will only fuel distrust in the EFSA and in the GMOs the public are being asked to accept.</p> <p>The debate over GM crops and food has been characterised by a distrust in the risk assessment procedure carried out by applicants and how Competent Authorities view these assessments. GeneWatch believes that full access to these dossiers is crucial in maintaining informed debate from all sides of the argument. Without informed debate the public can only be sceptical at the secrecy surrounding the safety assessments of foods they are being asked to eat.</p> <p>On the issue of confidentiality, GeneWatch believes that very little if any of the dossier should be confidential. These GMOs are about to be commercialised. It is necessary for the applicants to provide full molecular details of the modification to enable identification of those specific transformation events. It is also usual for the transformation events and techniques used to be protected by patents.</p>

	Therefore, GeneWatch believes there can be very little real CBI information in the dossiers. GeneWatch finds it particularly difficult to understand how the protocols and results of feeding trials can be confidential. Again the secrecy surrounding such results only leads to public distrust of the applicants and the regulatory process.
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SYN	The Commission argues that because of data protection, confidentiality claims should be limited. Syngenta considers that data protection provisions have limitations; therefore it is important to apply confidentiality provisions. It should be noted that individual companies may have different policies on confidentiality and each has the right to claim confidentiality for what it considers to be commercially sensitive information. In case of disagreements with the Commission on confidentiality, the information should be kept confidential until a decision on approval is taken. Clarity on the public access to applications before they are deemed valid by EFSA is required. Release of information prior to finalisation of the completeness check has the potential to lead to confusion.
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Question 7 – Do you have a specific control plan for GM food and Feed?

Respondent	Comment
AIC	The feed industry will be undertaking random checks in order to fulfil due diligence requirements.
BPC	There are both imports and processing controls of soya purchased with identity preserved certification less than 0.9% GM content. Due diligence sampling and testing of raw material by PCR and due diligence of feed to show it is below 0.9% GM threshold for labelling.
LACORS	LA checks can and do take place at all stages including import, processing and placing on the market. The majority of checks would be documentary checks with very limited sampling and analysis because of the costs involved.

Question 8 – What have been the control priorities in 2004? What priorities are foreseen for 2005?

Respondent	Comment
LACORS	Priorities in 2004 were to advise and educate businesses as to their legal compliance obligations. Information on priorities in 2005 is not available.

Question 9 – If possible please give the control results on labelling (0.9% threshold) for 2004?

Respondent	Comment
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SYN	<p>Currently the threshold of 0.9% for labelling relates only to events that have been approved for commercial use in the EU. However the commercial use of GM crop plants is approved in third countries with comparable standards of safety assessment. These products have been commercialised following scientific risk assessment in accordance with OECD Safety principles and are legally grown on more than 80 million hectares worldwide. We believe that the following events should be allowable at appropriate adventitious levels:</p> <ul style="list-style-type: none"> • those events approved for deliberate release in Europe by competent authorities • those events approved by authorities in third countries with assessment and approval procedures based on OECD biosafety and food safety principles • Those events assessed and declared as safe by the EU Scientific committees.
Question 10 – In the recent year, have any other labelling issues with the rules on labelling arisen for you?	
Respondent	Comment
BPC	There is total confusion whether products from contained fermentation using a GMM need to be labelled under this legislation, for example some enzymes, vitamins and synthetic amino acids.
Question 11 – How have the provisions of Article 47 of Regulation (EC) 1829/2003 and Regulation (EC) 641/2004 on the threshold of 0.5% adventitious presence of GMO material been controlled?	
Respondent	Comment
BPC	We are not aware of any testing.
Question 12 – Has unauthorised GM food and feed been imported or found on the market?	
Respondent	Comment
BPC	We are not aware of any situation.
Question 13 – Have there been any problems in carrying out the controls with respect to aspects such as sampling, analytical methods or documentary control?	
Respondent	Comment
AIC	There has been some confusion over precisely whether the threshold in a finished feed refers to the feed material(s) incorporated into the feed or to the finished feed itself.

FPA	Yes, although Regulation (EC) 641/2004 mentions that products produced from genetically modified micro-organisms fall under the scope, it is not clear from Regulation (EC) 1829/2003, nor Regulation (EC) 641/2004 whether this also includes products obtained using (with the help of) GMMs in Containment and that do not contain the microorganism. This is especially true because Regulation (EC) 1829/2003 clearly doesn't take products falling under the Contained Use Directive 90/219 into account, and because the meaning of Recital 16 (produced from versus produced with) is not clear. The minutes of the Standing Committee (section on genetically modified food and feed and environmental risk) of 24 September 2004 do not contribute to clarify the situation either, since they contain elements that are contradictory. Based on a legal advice (attached), we therefore come to the conclusion that products made with the help of GMMs kept under containment are not falling under the scope of the GMFFTL Regulations.
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Question 14 – In your opinion, how is the new authorisation procedure according to Regulation (EC) 1829/2003 functioning?

Respondent	Comment
SYN	We welcome the position of Member States that support a centralised safety assessment by EFSA rather than a system that would result in 25 safety assessments by the individual Member States. We would, however welcome more contact with the EFSA Panel to discuss scientific matters, especially where gaps in the EFSA guidance document are leading to delays in assessments. As part of the EFSA completeness check, it is appropriate that both administrative and scientific assessments are made. In addition, while the timing on the completeness check has improved considerably, we believe that a time limit for this would be more appropriate. Due to the large number of applications, there is concern about the ability of the JRC to validate the detection methods within the 6-month time limit. Furthermore the lack of clear guidance on stacked products is leading to confusion. This has lead to a requirement for multiple validations relating to the same product under the regulations. It should be noted that costs associated with the validation are high and in some cases the testing goes beyond that required by the ISO standards.

Question 15 – In view of forthcoming legislation, what is your opinion on the fermentation products (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using genetically modified micro-organism (GMM) which is kept under contained conditions and is not present in the final product

Respondent	Comment
AIC	Fermentation products – a risk assessment should be required but labelling should not be required provided no GMM is present in the final product. The risk assessment should be within a regulatory framework.

AJIN	<p>Regulation (EC) No 1829/2003 on GM food and feed (GMFF) was not drafted with fermentation products in mind.</p> <p>We believe as stated in the comments of FPA that certain sections of the 9/24 Minutes are self-contradictory and do not give clear guidance to industry whether all fermentation products, or only certain fermentation products should be out of scope of GMFF. As GMFF was not designed to regulate substances produced under “Contained use”, it would appear that substances produced by GMMs in “Contained use” should not be under GMFF. However, we have taken the precautionary measure of notifying a Biomass derived product under GMFF as we felt that, products derived from dead cells could be characterised as being “produced from” a GMM rather than “produced with” a GMM and therefore in the scope of GMFF. We hope that the FSA can clarify the situation by helping the Commission devise logical criteria for determining the scope of products covered by GMFF.</p>
BPC	<p>"should a risk assessment be required be required for fermentation products" - NO. However, labelling should be required. The more information that is put on a label the less GM becomes an issue as the consumer is overwhelmed with information. Details of products on market:</p> <ol style="list-style-type: none"> 1. several feed enzymes including all phytases authorised in the EU 2. several vitamins including B2 and B12 3. several amino acids such as lysine and threonine.
FDF	<p>If “risk assessment” has the same meaning as “authorisation”, this would already be the case for additives and flavourings and will soon also apply to enzymes under a proposed EU Regulation. We would not support GM labelling in such cases as GMMs would act as processing aids and would not be labelled under the terms of Directive 2000/13. FDF does not support the “origin” approach to GM labelling as it is open to fraud and difficult to enforce, specifically in respect of imports from third countries</p>
FPA	<p>It is our opinion that Regulation (EC) 1829/2003 has not been designed for the above-mentioned products. From the text it clearly follows that the Regulation has been designed for the few GM-plants (and derived products) that recently have been introduced on the EU market, not for the much larger number of products made with the help of GMMs kept under containment, the first of which were already introduced on the EU market almost 20 years ago. Based on a legal advice (see also answer to question 3), we therefore believe that products made with the help of GMMs kept under containment are not falling under the scope of the GMFFTL Regulations. If it should be decided that a risk assessment and/or labelling is needed for these types of products, this should thus be regulated outside the scope of the GMFFTL.</p> <p>Before determining whether or not a risk assessment is required for these types of products, it should first be carefully evaluated which types of products are currently on the market and how they are presently regulated. In this evaluation, the so-called Qualified Presumption of Safety (QPS) system EFSA is currently setting up for fermentation products should be taken into account.</p> <p>Before determining whether or not labelling is required, the differences in perception of the general public regarding ‘white biotechnology’ versus ‘green biotechnology’ should be taken into account as well as the fact that labelling would cover more than 50% of all food products on the market.</p>
LACORS	<p>No risk assessment and no labelling.</p>

MLC	<p>If European legislation is to be consistent and not mislead consumers, we believe that all derivatives of GMOs, including additives, flavourings and vitamins produced through use of recombinant organisms in fermentation should be labelled. If they are not to be labelled, then there is no logical reason for labelling of highly processed derivatives of GM crops. Where these products are 'nature identical' we do not see the need for complex and expensive risk assessments. We would wish to see any risk assessment consistent with the assessments needed for similar compounds derived from non-GM routes. The level of risk assessment should be commensurate with the general level of risk to consumers.</p>
PFMA	<p>In general, the Genetically Modified Food and Feed Regulation is felt to be highly complex and difficult to comprehend and interpret. There is the view that enforcement of labelling legislation will be impossible, as resources do not appear to exist to carry out full traceability audits. In addition it is felt that companies complying with the legislation and labelling products accordingly could be put at a commercial disadvantage if other less conscientious companies do not comply because there is little or no risk of them being exposed.</p> <p>The initial unclear situation regarding fermentation products was unhelpful and was further complicated by a lack of guidance from the FSA or the Commission on timing for compliance with regard to labelling requirements. In general, PFMA members felt that more practical and regularly updated guidance would have assisted the industry in complying with this new and more wide-ranging provision.</p> <p>Our members would also appreciate improvements regarding information on authorised and approved substances. There was concern that information such as an updated list of approved and unauthorised GM substances was difficult to obtain. Under these circumstances it was, therefore, considered difficult to establish which threshold level should be being adhered to i.e. 0.5% or 0.9%.</p>
SWA	<p>Fermentation products made from GMMs under 'contained' conditions and which do not contain GMM in the final product, should be out with the labelling rules.</p> <p>Clear guidance is required on the situation where GMM is under 'non-contained' conditions and consider the same labelling exemption should apply provided the final product does not contain GMM.</p> <p>Products resulting from a fermentation process using GM yeast or yeast grown on a GM substrate should be exempt from labelling provided there are no traces of GM yeast or GM substrate in the final product.</p>

SYN	<ul style="list-style-type: none"> • should a risk assessment be required? No (see below) • should labelling be required? No (since the final product does not contain a GM, labelling will not serve to inform to the consumer). <p>We support the preamble (16) of the Regulation (EC) 1829/2003, which clearly says that food or feed produced with a GMO is exempt and the determining criterion is that the genetically modified source material is absent from the food or feed.</p> <p>It should be noted that Article 17 3(i) requires that feed produced from a GMO require a unique detection method for the transformation event in the feed. In the case of feed additives that are produced by fermentation in contained use, where either no recombinant material is present in the final product or only very small non-functional fragments are retained, the production of such a detection method is impossible. If the scope of the regulation is strengthened to exclude fermentation products as described in preamble 16 then this requirement is also redundant, The requirement for additional risk assessment under Regulation (EC) 1829/2003 when a risk assessment for human and environmental safety of animal feed, as well as efficacy is already conducted under Regulation (EC) 1831/2003 is a duplication of regulation and disadvantages new and novel animal feed products which may be produced using genetically modification over those that are produced by more conventional means.</p>
Question 17 – Would you like to comment on any other aspect of the Regulation (EC) N° 1829/2003 or on other related legislation that would improve the EU legislative framework for genetically modified food and feed?	
Respondent	Comment
AIC	There should be a joined up approach taken for all feed and feed related legislation.
BPC	With regard to feed labelling this legislation is totally confusing both to feed manufacturers and feed users i.e. the farmer. It adds another layer of bureaucracy and cost to the poultry business while doing nothing to improve the choice of the supermarket consumer. While the EC is adding costs to our agricultural base, meat imports are coming in with no questions asked on GM status of feed used.

BSPB	<p>We would like the UK Government to take this opportunity to raise this issue of false positives with the Commission with a view to incorporating a protocol for dealing with them into the Regulations - not necessarily into 1829/2003 but possibly into the Regulation that deals with the sampling and testing regime. This omission needs to be corrected to bring more legal certainty for companies. We need an agreed procedure to follow to determine the outcome of a disputed or uncertain test result.</p> <p>The other omission from the current Regulation is any tolerance of adventitious presence of GM events that are approved or assessed outside but not within the EU. The majority of events currently on the North American market fall into this category and it seems inevitable that they will be detected in imported commodities. The tolerance is zero under the current Regulation. I do not know to what extent this is happening but if the legislation is being enforced it seems highly likely that there will be rejection and return of incorrectly labelled shipments being detected at point of import. Where these are not detected at point of import they will enter the food and feed chain and in all likelihood be detected by companies testing elsewhere along that chain, leading to further expense and dispute when this happens.</p> <p>We urge you to encourage the Commission to include some kind of equivalence arrangement to allow a reasonable tolerance for adventitious presence of GM events that have been through a full approvals procedure in third countries - something like the equivalence system that exists in seed certification to allow imports of seed from third countries.</p>
FDF	<p>FDF suggests that the Commission should take the opportunity of this review to undertake a reassessment of the intentions and anticipated impact of Regulation 1829/2003. If it was the intention to inform consumers about the origin of products derived from GMOs, it has in practice resulted in a more widespread use by the food industry of identity preserved non-GM supply streams in order to avoid hostility from anti GM activists. Many companies are now under increased pressure to either label products of animals fed on GM feed as “GM” or to avoid the use of GM feed, which is not possible in the UK on a widespread basis. We do not believe this impact was intended by the Commission, and is out of line with the Commission’s Strategy on Biotechnology¹, itself linked to the Lisbon Strategy, which has recently been the subject of refocus. Either the Commission needs to reassess the scope of the Regulation or undertake a massive consumer education programme to reverse the impact of media scare stories and the undermining of confidence in the safety of GM derived food products engendered by anti GM activists. The current situation is not sustainable within a global food market and prejudices EU production against the import of finished product from third countries.</p>