Guidance note for sampling food and feed to determine the presence of genetically modified (GM) material

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1. Introduction

This supplementary guidance note has been produced by the Novel Foods, Additives and Supplements Division of the Food Standards Agency with the aim of providing informal guidance to enforcement authorities for sampling food and feed to determine the presence of genetically modified (GM) material.

Food and feed containing GM material can only be marketed in the EU once a GMO variety has been authorised. Food and feed containing material from authorised genetically modified organisms (GMOs) must be labelled to allow consumers to make an informed choice. An exemption to the labelling requirement exists below a threshold of 0.9% for adventitious or technically unavoidable presence of a GMO, where operators can demonstrate that adequate measures have been taken to avoid GM material. Material from unauthorised GMOs is not permitted at any level.

The purpose of this document is to provide information regarding best practice for the sampling of food and feed to determine the presence of GM material in accordance with food law and the regulations governing GM food and feed.

This document is not a statutory code of practice nor is it a substitute for the Regulations and should be read in conjunction with them.

European and national legislation relating to food and feed containing GM material are listed in Annex A.

This guidance note is supplementary to the Agency's general GM guidance on Regulation (EC) 1829/2003, genetically modified food and feed, and Regulation (EC) 1830/2003, traceability and labelling of genetically modified organisms. This general guidance can be found on the Agency's website at:
http://www.food.gov.uk/foodindustry/guidancenotes/foodguid/gmguidance

A summary document describing the scope of the GM food and feed and GM traceability and labelling regulations is attached as Annex B.

If you require any further advice then please contact the Food Standards Agency, clearly stating the nature of your enquiry.

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2. Sampling of food and feed for the presence of GM material

2.1 Introduction

This supplementary Guidance Note provides clarification of where, what, when and how to sample for GM material in food and feed.

As set out in Annex B, the labelling exemption threshold for adventitious or technically unavoidable presence of GM material is 0.9% for varieties that have undergone a safety assessment and have been approved for use in the European Union. Material from unauthorised GMOs must not be present at any level.[1]

Any product containing GM material must be clearly labelled as containing GM. The 0.9% limit for adventitious presence applies to each food or feed ingredient rather than to the finished food or feed product.

Analysis of samples for the presence of GM material usually relies on the detection of DNA sequences specific to GMOs. Some protein detection methods are available but are not recommended for enforcement of the GM food and feed regulations.

2.2 Where to sample

Generally, where to sample depends on the likelihood of GM material being present. Because of a reduction in sensitivity of GM detection methods in processed ingredients (due to degradation of the target DNA or removal during processing), it is recommended that sampling of food and feed is done as early as possible in the manufacturing process. Therefore it is more effective to sample raw ingredients at the point of import or at manufacturing premises before they are processed into finished products. Where this is not possible the type of finished product should be considered before sampling, as outlined in section 2.3 below.

2.3 What to sample

When selecting what food or feed to sample for the presence of GM material the following should be considered:

The likelihood that the product may contain ingredients from GMOs (see section *i)* '*crop species to consider'*).

Whether the product will contain sufficient intact DNA to allow identification of GM material (see section *ii)* '*types of food/feed to sample'*).

[1] The temporary threshold of 0.5% for the presence of material not yet authorised but that has a favourable assessment from an EU scientific committee expired in April 2007.

***i) Crop species to consider**:* Reference should be made to the list of authorised GMOs to which the 0.9% threshold applies. Table 1 contains a list of crop species for which GMO lines have been authorised for food and feed in the EU. This list will continue to be extended. An up to date list of GM varieties authorised (1), and undergoing authorisation (2), for sale in the EU, can be found at the weblinks below:

(1) http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

(2) http://www.efsa.europa.eu/en/science/gmo/gm_ff_applications.html

Table 1: GMOs authorised as food and/or feed ingredients within the EU (as of 19 December 2007).

List of GM crops
Cotton[2]
Maize
Oilseed rape (Canola)
Soyabean
Sugar beet

Consideration should be given to the potential presence of GMOs which have not been authorised within the EU, or for which the authorisation under transitional arrangements has now expired. These could be varieties previously authorised for feed use only, or those which have been authorised by third countries, or for which experimental crops exist.

The Community Reference Laboratory (CRL) for GMOs validates methods to identify new GMOs as they are authorised. It has also validated methods for some unauthorised GMOs where accidental presence has been identified in imported food and feed. The CRL, in collaboration with the European Network of GMO Laboratories (ENGL), is responsible for distributing reference materials to enable enforcement laboratories to carry out the tests.

ii) Types of food/feed to sample: Less processed food or feed is more likely to contain sufficient intact DNA suitable for testing. Composite products containing a large number of ingredients (e.g. ready meals), with a small proportion of a potential GM ingredient are less likely to yield a result that accurately reflects the GM content of the product. This is due to the dilution effect and the limitations of the sensitivity of the test. For these types of foods it is recommended that the individual ingredient is sampled at the point of manufacture. Other examples of foods that are likely to be unsuitable for testing are listed in Table 2. If there are

[2] Used to produce cottonseed oil and animal feed.

doubts about the suitability of sampling a particular product then a public analyst (PA) with experience of testing for GMOs should be consulted.

Table 2: Examples of foods that are not usually suitable for testing for presence of GM ingredients

Food Type	Reason DNA unlikely to be present
Boiled sweets	DNA removed due to processing
Refined vegetable oils	" " "
Refined sugars (e.g. corn syrup)	" " "
Maltodextrins (e.g. sweetners)	" " "
Canned foods	No detectable DNA remaining due to degradation
Acidic foods (e.g. pickles)	" " " "
Salty foods (e.g. soy sauce)	" " " "

2.4 When to sample

It is the responsibility of enforcement authorities to decide the overall frequency of sampling depending on local priorities and the sampling budget. Any recent Commission Decisions or food alerts involving GM material should be taken into account when deciding what and when to sample.

2.5 How to sample

Guidelines on how to sample for GM material from food are already in place. It is recommended that the documents listed below are consulted. It is also recommended that a public analyst should be consulted regarding preferred sampling methods.

i) 2004/787/EC: Commission Recommendation on technical guidance for sampling and detection of GMOs and material produced from GMOs as or in products in the context of Regulation EC 1830: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_348/l_34820041124en00180026.pdf

ii) CEN/TS 15568/2006: Foodstuffs - Methods of analysis for the detection of genetically modified organisms and derived products – Sampling strategies (previously ISO prEN 21568/2004)

iii) In addition the FSA practical sampling guidance gives general sampling advice under the Official Food and Feed control legislation: http://www.food.gov.uk/enforcement/foodsampling/guidance/

iv) Feed or feed ingredient samples should be taken in accordance with Directive 76/371/EEC as implemented by The Feeding Stuffs (Sampling and Analysis) Regulations 1999 (as amended).

Consideration should also be given to the merits of formal versus informal sampling. Part 2 (Section 2.2) of the FSA practical sampling guidance (2.5iii above) refers to this process. If informal samples are taken, follow-up formal sampling should be considered for non-compliant results.

It should be noted that the capabilities of PA laboratories are continually developing, and many now have the capability for rapid DNA screening. Those without this facility will be able to refer analysis to a suitable laboratory.

3. Follow-up action

It is the responsibility of enforcement officers to follow-up results that indicate non-compliance. If appropriate, the enforcement authority at the point of entry should be contacted, so that testing can be carried out on further consignments of bulk commodities.

When a positive result using a qualitative screen is obtained, consideration should be given to a confirmatory test to identify the specific genetic modification present. This could be followed by a quantitative assay if it is confirmed as an authorised GMO. Formal sampling should be undertaken if enforcement action is considered.

In case of dispute the Government Chemist fulfils the statutory function of Referee Analyst under the Food Safety Act 1990. Further information on the role of the Government Chemist is given on the website below:
www.governmentchemist.org.uk

The procedure for submitting samples for referee analysis is given in the following link:
http://www.governmentchemist.org.uk/Function.aspx?elementId=563

The Agency is currently rolling out the UK Food Surveillance System (UKFSS), which enables the electronic transfer of sampling data between local authorities and public analyst laboratories and ultimately allows the data to be stored in a central database. The system has been fully implemented in Scotland and Northern Ireland, and a number of English laboratories are also actively using the system. The remaining Local Authorities in England and Wales will be trained and have access to the UKFSS by the end of 2008.

The system provides an ideal mechanism for enforcement officers to report GMO sampling and testing results. More information on the system can be found at: http://www.food.gov.uk/enforcement/foodsampling/fss/.

Annex A

European and national legislation relating to food and feed containing GMOs.

European Union	England	Scotland	Wales	Northern Ireland
EC Regulation 1829/2003 on genetically modified food and feed	**SI 2004/2335** – the Genetically Modified Food (England) Regulations 2004 and **SI 2004/2334** – the Genetically Modified Feed (England) Regulations 2004	**SSI 2004/432** – the Genetically Modified Food (Scotland) Regulations 2004 and **SSI 2004/433** – the Genetically Modified Feed (Scotland) Regulations 2004	**SI 2004/3220 (W.276)** – the Genetically Modified Food (Wales) Regulations 2004 and **SI 2004/3221 (W.277)** – the Genetically Modified Feed (Wales) Regulations 2004	**SR 2004/385** – the Genetically Modified Food Regulations (Northern Ireland) 2004 and **SR 2004/386** – the Genetically Modified Animal Feed Regulations (Northern Ireland) 2004
EC Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC	**SI 2004/2412** – the Genetically Modified Organisms (Traceability and Labelling) (England) Regulations 2004	**SSI 2004/438** – the Genetically Modified Organisms (Traceability and Labelling) (Scotland) Regulations 2004	**SI 2005/1914 (W.157)** – the Genetically Modified Organisms (Traceability and Labelling) (Wales) Regulations 2005	**SR 2005/271** – the Genetically Modified Organisms (Traceability and Labelling) Regulations (Northern Ireland) 2005
Recommendation 2004/787/EC technical guidance for sampling and detection of GMOs and material produced from GMOs as, or in, products in the context of Regulation EC 1830/2003	n/a			

EC Regulation 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.	**SI 2006/15** - The Official Feed and Food Controls (England) Regulations 2006	**SI 2005/616** - The Official Feed and Food Controls (Scotland) Regulations 2005, as amended by the Food Hygiene (Scotland) Regulations 2006 (SSI 2006/3)	**SI 2006/590 (W.66)** - The Official Feed and Food Controls (Wales) Regulations 2006	**SR 2006/2** - The Official Feed and Food Controls Regulations (Northern Ireland) 2006
EC Regulation 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.	**SI 2004/3279** - The General Food Regulations 2004	**SI 2004/3279** - The General Food Regulations 2004	**SI 2004/3279** - The General Food Regulations 2004	**SR 2004/505** - The General Food Regulations (NI) 2004
EEC Regulation 76/371 establishing Community methods of sampling for the official control of feeding stuffs	**SI 1999/1663** - The Feeding Stuffs (Sampling and Analysis) Regulations 1999 (as amended)	**SI 1999/1663** - The Feeding Stuffs (Sampling and Analysis) Regulations 1999 (as amended)	**SI 1999/1663** - The Feeding Stuffs (Sampling and Analysis) Regulations 1999 (as amended)	**SR 1999/296** - Feeding Stuffs (Sampling and Analysis) Regulations (Northern Ireland) 1999 (as amended)

Annex B

SCOPE OF EC GM REGULATIONS 1829/2003 GM Food and Feed and 1830/2003 Traceability and Labelling of GMOs

(Statutory Instruments 2004 No. 2334, No.2335 and No. 2412 enforce the regulations in England)

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GM food and feed in the EU must be authorised for use and labelled [No.1829/2003]. To facilitate labelling there is a requirement for information relating to the use of GMOs to be transmitted through the supply chains and retained for 5 years [No. 1830/2003].

Authorisation – Before a GM crop is authorised by the European Commission it must undergo a rigorous safety assessment by the European Food Safety Authority. A number of GM crops have been authorised for food and feed use in the EU e.g. soya, maize, oilseed rape, cotton seed. A list of authorised GM crops is available at http://europa.eu.int/comm/food/food/biotechnology/authorisation/index_en.htm. Authorisation is limited to a 10 year period and it is an offence for products from GM crops to be on the market if they are not authorised.

Labelling – There is a requirement for food and feed ingredients from GM crops to be labelled. Examples of ingredients for food that could potentially be produced from GM crops include soy foods (soy beverages, tofu, soy oil, soy flour, lecithin), rapeseed oil (products made with this oil may include fried foods, baked products and snack foods), maize foods (sweet maize, kernels, oil, maize flour, sugar and syrup), cottonseed oil (products made with this oil may include fried foods, baked products and snack foods). Please note that although these products may contain ingredients from GMOs they may not contain sufficient DNA to be suitable for testing (see FSA guidance note on sampling for GM). Examples for feed include maize, corn gluten feed, soybean meal and rapeseed meal**.** The following do not fall within the scope of these regulations and do not need to be labelled food produced with the help from a GM enzyme (such as cheeses produced by enzyme chymosin, products from animals fed GM animal feed (e.g. milk, meat and eggs) and food and feed produced by a fermentation process using a genetically modified micro-organism which is kept under contained conditions and is not present in the final product e.g. vitamins. Rules for providing labelling information are as follows:

Where a **food** contains more than one ingredient, the following indication must be given; 'genetically modified' or 'produced from genetically modified [name of organism]'.

Where a **food** is designated by the name of a category e.g. 'Emulsifiers', the following must appear in the list of ingredients; 'contains genetically modified (name of organism)', or contains (name of ingredient) produced from (name of organism)'.

If there is normally no list of ingredients given on a specific product the following must appear clearly on the labelling, 'produced from genetically modified (name of organism)'.

Where the **food** is offered for sale to the final consumer as non-pre-packaged food, or as pre-packaged food in small containers of which the largest surface has an area of less than 10cm^2, the information required must be permanently and visibly displayed either on the food display or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read.

For GMOs for **feed** use or **feed** containing or consisting of GMOs the words 'genetically modified (name of the organism)' shall follow in parentheses the name of the feed or alternatively can appear in a footnote.

For **feed** produced from GMOs the words 'produced from genetically modified (name of organism)' will need to appear in parentheses following the specific feed name or appear in a footnote to the list of feed.

Any characteristic which renders the **feed** different from its conventional counterpart will need to be specified. For example:

- Composition
- Nutritional properties
- Intended use
- Implications for health of certain species or categories of animals

In addition any characteristic or property of the feed which may give rise to ethical or religious concerns must be indicated.

An exception to the labelling rules – **Thresholds**

The Food and Feed Regulation provides for a threshold for the adventitious or accidental presence of GM material in non-GM food or feed sources (there is no threshold for supplies obtained from sources of unknown origin). This threshold is set at 0.9% and only applies to GMOs that have an EU authorisation. The temporary threshold of 0.5% for the presence of GM material not yet authorised but that had a favourable assessment from an EU scientific committee expired in April 2007.
The threshold is **not** a provision for lack of due diligence or intentional mixing of GM and non-GM. It will be for the operator to produce evidence to show that presence of GM is adventitious or technically unavoidable e.g. through the use of suitable identity preservation systems.
The threshold is applied at the level of each individual ingredient and **not** the final food.

How can the labelling rules be enforced?

Traceability – The above labelling rules apply across the food and feed chain for GM crops. To facilitate accurate labelling there is a requirement for traceability systems to be established throughout the GM supply chain to enable the transmission of information.

At the first stage of placing on the market operators must provide in writing to the operator receiving the product: that it contains or consists of GMOs; the unique identifier assigned to the GMO (list of unique identifiers available at http://www2.oecd.org/biotech/frameset.asp**.** This applies to unprocessed GMOs e.g. soya beans. At all subsequent stages of placing on the market the above information will be transmitted in writing.
For products produced from GMOs e.g. soya flour, the following need to be submitted in writing (a) an indication of each of the food ingredients which is produced from GMOs; (b) an indication of each of the feed materials or additives which is produced from GMOs; (c) in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs. This information must be retained for 5 years.

Exemptions to these rules apply to GMOs which are accidentally present in non-GM sources and where lot numbering is used.

Testing – for unprocessed or partially processed products from GM crops e.g. it is possible to use analytical methods to detect DNA or protein to verify the crop origin in addition to monitoring via a paper audit trail. For highly processed ingredients (e.g. highly refined soya oil) then only a paper audit chain will verify how the product should be labelled.

Enforcement of all provisions by Trading Standards Officers, Environmental Health Officers and Port Health Authorities

Prohibition for placing on the market;
- GMOs for food/feed use
- Food/feed containing or consisting of GMOs
- Food/feed produced from or containing ingredients produced from GMOs

unless it is covered by an **authorisation** and satisfies relevant conditions of the authorisation. Article 4.2 and 16.2 of EC Regulation 1829/2003

Penalty and Offence for non-compliance:

- On summary conviction a term of imprisonment not exceeding 6 months for food and 3 for feed months or to a fine not exceeding the statutory maximum or to both
- On conviction on indictment a term of imprisonment not exceeding 2 years or to a fine or to both

Products for which information required for the notification of products have not been received within 6 months or is found to be incorrect. Article 8.6 and 20.6 of EC Regulation 1829/2003

Authorisation-holders do not inform the Commission of any new scientific or technical information, which might influence the evaluation of the safety in use of the food or feed. Failure to inform the Commission of any prohibition or restriction imposed by the competent authority of any third country in which the food or feed is placed on the market. Article 9.3 and 21.3 of EC Regulation 1829/2003

Applications not submitted for **re-authorisation** after the period specified (9 years). These products and those derived from these products will be withdrawn from the market. Such a measure may provide for a limited period of time within which existing stocks of the product may be used up. Article 8.6 and 20.6 of EC Regulation 1829/2003

Labelling not provided for food or feed products, which contain or consist of GMOs; or are produced from or contain ingredients produced from GMOs. Article 13 and 25 of EC Regulation 1829/2003

Penalty and Offence for non-compliance:

- On summary conviction a term of imprisonment not exceeding 6 months for food and 3 months for feed or to a fine not exceeding level 5 or to both.

Conditions or restrictions laid down as part of an **authorisation** are not adhered to and products placed on the market which do not meet these provisions.
Where authorisation-holders do not carry out post-market monitoring as imposed on them or do not submit reports to the Commission in accordance with the terms of the authorisation. Article 9.1 and 21.1 of EC Regulation 1829/2003

Specified information is not transmitted in writing to the operator receiving the products at the first stage of placing on the market. Article 4 (1) of EC Regulation 1830/2003

Specified information in article 4(1) is not transmitted in writing to the operator receiving the product at subsequent stages of placing on the market. Article 4 (2) of EC Regulation 1830/2003

Penalty and Offence for non-compliance:

- On summary conviction a term of imprisonment not exceeding 3 months or to a fine not exceeding level 5 or to both.

When placing products produced from GMOs on the market the information specified in Article 5(1) is not transmitted in writing to the operator receiving the product. EC Regulation 1830/2003

Products consisting of or containing GMOs to be used only and directly as food or feed or for processing are not accompanied by a declaration of use along with a list of the unique identifier for all those GMOs used to constitute the mixture. EC Regulation 1830/2003

Records of the information referred to in paragraphs (1), (2), (3) and (4) of Article 4 are not kept for a period of 5 years. EC Regulation 1830/2003

Records of the information referred to in Article 5 (1) are not kept for a period of 5 years. EC Regulation 1830/2003

The information specified in Article 4 (6) does not appear on the labels of products consisting of or containing GMOs. EC Regulation 1830/2003