

**Provision of updated guidance to enforcement authorities for  
sampling food and feed to determine the presence of GMOs:  
draft guidance for consultation/feedback**

**Summary of consultation responses  
from stakeholders**

- 1 The consultation; "Provision of updated guidance to enforcement authorities for sampling food and feed to determine the presence of GMOs", was issued 25 July 2007 and closed on 17 October 2007. The consultation was issued to seek the views of stakeholders on a guidance note to enforcement officers for the sampling of food and feed to determine the presence of GMOs. This consultation was carried out in England, with parallel consultations in Scotland, Wales and Northern Ireland. Notification of the consultation was sent to a wide variety of stakeholders by post or email. Stakeholders were directed to the documents on the FSA website, or were asked to contact us if hard copy of the document was required. Two hard copies were requested and 6 responses were received. The full text of all responses received has been placed in the FSA library.
- 2 The FSA is grateful to those stakeholders who took the time to respond. The comments covered a wide range of issues relating to control of imports of GM crops and these will be addressed in a separate response to the organisations concerned. The comments included below relate directly to the GM sampling guidance note.
- 3 A Table of stakeholders who responded.

<b>Organisation</b>	<b>Acronym used in table</b>
Food and Drink Federation	FDF
GM Freeze	GMF
Hemel Hempstead GM Action Group	HHGMAG
Local Authorities Coordinators of Regulatory Services	LACORS
Trading Standards Service, Southampton City Council	TSSSCC
Which?	W

- 4 The Food Standards Agency's considered responses to stakeholders' comments are given in the right hand column of the table.

**SUMMARY OF SUBSTANTIVE COMMENTS TO THE FSA CONSULTATION – Provision of updated guidance to enforcement authorities for sampling food and feed to determine the presence of GMOs: draft guidance for consultation/feedback**

1. Introductory comments from stakeholders

Respondent	Comment	Response
FDF	The FDF welcomes this supplementary guidance note which, though aimed at enforcement authorities, also offers helpful guidance to food and drink manufacturers.	Comment noted.
GMF	<p>Recent research published by Defra from the KeLDA project documents the presence of spatial patterns in all the investigated lots, proving that the most widely used sampling protocols based on the assumption of normality, will lead to non-representative samples, and, as a consequence, to wrong and unreliable analytical results.</p> <p>It is therefore a serious omission that the draft guidance note does not mention the Defra sponsored research on sampling of cargoes to assess the presence of GMOs despite the clear evidence that the assumptions behind some sampling methodologies are seriously flawed.</p>	<p>The research referred to in the response was designed to assess the distribution of GM material in soybean lots and the variability in distribution patterns among lots. The project can be found on the Defra website at the following link:  <a href="http://www2.defra.gov.uk/research/project_data/More.asp?!=CB02016">http://www2.defra.gov.uk/research/project_data/More.asp?!=CB02016</a></p> <p>Recommendation 2004/787/EC 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, gives technical guidance on the sampling of bulk commodities and is applicable in the situations described in the KeLDA project article.</p> <p>This is reinforced by the following statement in the introduction to the KeLDA study: “Among all currently used sampling guidelines for GMO testing only two (Recommendation (EC) 787 and prCEN/TS 21568) which were specifically developed for GMO surveys, are free from distribution assumptions, and are therefore applicable also in cases of heterogeneity”. The second document mentioned (prCEN/TS 21568) is also referred to in the guidelines.</p> <p>This research demonstrates the need for the use of the recommended sampling protocols.</p>

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1. Introduction

Respondent	Comment	Response
W	The guidance should be clearer about what would be considered to be adequate evidence that contamination is adventitious or accidental and therefore that the 0.9 per cent threshold comes into effect.	This is outside the remit of the sampling guidance. However, in the summary of the scope of the regulations EC/1829/2003 and EC/1830/2003 (annex B of the consultation pack), it states: “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”.
HHGMAG	<p>The FSA is suggesting providing informal guidance. This in our view is worthless in the face of potentially serious contamination of the food and feed chain by GMOs.</p> <p>If the FSA was serious about protecting the public it would insist that 'best practice' would become a statutory code of practice rather than 'informed guidance'.</p>	The guidance is for local authority enforcement officers, who have responsibility for enforcement of the GM food and feed regulations.
HHGMAG	The FSA repeats the misleading figure of 0.9% put forward by Defra, as the upper limit of the presence of GMOs before labelling is required. The scientific term to be used would be <u>up to 1.2%</u> . Defra's scientists maintain an unavoidable variation of + or - 0.3%.	The 0.9% figure is correct as it is set out in the legislation (Regulation EC/1829/2003). However, for each sample analysed for GMO content the public analyst (PA) routinely reports the expanded measurement uncertainty of the reported result, which can vary depending on a number of factors. The expanded measurement uncertainty allows the PA to report a limit for the %GM content at which the 0.9% threshold would be exceeded. This could well be 1.2% for a particular sample, but could also be higher or lower, depending on the specific sample type and test.
HHGMAG	Since 'this guidance note is supplementary to the Agency's general GM guidance', this consultation seems to be quite unrealistic. Both need to be looked at together.	A consultation was undertaken on the general guidance when it was issued in 2004 and it is not under review here.

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2.1 Sampling of food and feed for presence of GMOs Introduction

<b>Respondent</b>	<b>Comment</b>	<b>Response</b>
HHGMAG	The fact that 'some protein detection methods are available, but are not validated for enforcement purposes' should be rectified urgently. The credibility of the enforcement procedures depends in part on reliable validation.	This was mentioned merely to highlight the fact that the reason DNA methods are used for detection is because there are few suitable methods available to quantify proteins at the required level of sensitivity. DNA methods are validated for enforcement.

2.2 Where to sample

<b>Respondent</b>	<b>Comment</b>	<b>Response</b>
GMF	GM Freeze agrees with the Draft guidance that raw materials should be sampled for the presence of GMOs rather than after they have been processed in any way. The most strategic place to sample is as cargoes arrive into UK ports from third countries. This would allow any cargoes contaminated with an unauthorised GMO to be held at port and either returned to the country of origin or to be destroyed.	Comment noted.
HHGMAG	The Hemel Hempstead GM Action Group fully agrees with the statement 'to sample imports at the point of import or at the manufacturing premises before they are processed'.	Comment noted.

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2.3 What to sample

Respondent	Comment	Response
FDF	Sub-section (i), <i>Crop species to consider</i> , helpfully links to the Commission’s register of approved GM crop lines, and to EFSA’s website for those undergoing authorisation. Table 1 lists those crop species for which GM lines have been authorised.	Comment noted.
FDF	FDF takes issue with the statement that GMOs may be authorised for feed use only and the use of the word “contamination” of foods with GM material.	The guidance has been amended to address these two points.
FDF	FDF highlights the problem of obtaining reference materials when sourcing commodities from third countries outside the EU. In such cases, only general broad screening is an option, with limited accuracy.	Negotiations are ongoing at international level to allow a database to be put in place to facilitate the exchange of information on unauthorised GM varieties. It is however too early to include reference to this in the guidance.
GMF	GM Freeze agrees with the draft guidance that sampling should be targeted upon those cargoes which are likely to be contaminated with GMOs either approved or unapproved by the EU. However, we feel that analysis in the draft guidance falls well short of what is required to allow regulators to prevent future contamination entering the food/feed chain. The document mentions four crops which have been approved by the EU for import: Maize, Soya, Oilseed rape and Cotton. However it neglects to emphasise that only a few approvals for each crop are current and that some have already been revoked making their presence over 0.5% illegal in EU food and feed.	The crops which have been approved by the EU for import are mentioned in no particular order in the guidance, recognising that this list will change. For this reason links to the EC website listing authorisations, pending authorisations and varieties that have been withdrawn are included in the guidance as these lists will be updated regularly. The list is now in alphabetical order.

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GMF	<p>Also lacking from the draft Guidance is any attempt to analyse how many varieties of each crop are currently been field tested in various countries and have not or may never enter the EU approval process. Bt10 maize and LL601 rice had not been developed to the point of commercialization by their respective companies for reasons unknown and had only been grown in test sites. Yet they still cause widespread low level contamination around the world.</p>	<p>This is outside the remit of the guidance. However the guidance does suggest that analysts should consider the presence of unauthorised crops. The database referred to above for sharing such information should facilitate this.</p>
GMF	<p>Types of Food/Feed to sample Monitoring for the presence of GMO presence has two main objectives</p> <ul style="list-style-type: none"> <li>• To ensure that only approved GM traits are entering the UK food/feed chain.</li> <li>• To ensure that the labelling of GMOs in food and feed meets the requirement of Regulation 1830/2003.</li> <li>• GM Freeze agrees with the draft guidance that this is best achieved by sampling raw foods at the point of entry into the UK or at the point of manufacture prior to processing. This is essential if ingredients which are legally required to be labelled such as refined vegetable oils, starch, refined sugars and highly processed ingredients are to be accurately labelled as required by Regulation 1830/2003. GM Freeze feels that although the draft guidance has dealt with these issues in section 2.3(ii) there is scope for a more explicit explanation of how traceability systems should work further up the food/feed chain after the GMO content of the raw materials has been satisfactorily ascertained by analysis.</li> </ul>	<p>This is outside the scope of the guidance. The responsibilities of food operators with respect to traceability and labelling of GM products is set out in the regulations and is referred to in the general guidance on the GM food and feed regulations.</p>
HHGMAG	<p>Table 1 section 2.3: The FSA's statement that 'contamination of foods with GM material only authorised for feed use should be considered' is out of order. The FSA need to insist in this draft that GM feed <u>must not contaminate food under any circumstances</u>. This would be law breaking.</p>	<p>This statement has been modified (see above), however the purpose of the guidance is to help assist enforcement officers to detect illegal presence of GM material.</p>

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HHGMAG	Equally the term 'Consideration should also be given to species of GMO which have not been authorised within the EU, but which have been authorised by third countries, or for which experimental crops exist' is totally unacceptable. The EU is the arbiter. The authorisation by third countries and 'experimental crops' are potentially dangerous. Change the sentence to <u>under no circumstance should consideration be given . . . .</u>	This sentence is to assist enforcement officers to decide which samples to take. Testing should not always be limited to the authorised crop species mentioned in the guidance. There are a large number of crops for which GM varieties exist outside the EU which might be sampled.
HHGMAG	Re section ii) Types of food/feed to sample: The Hemel Hempstead GM Action Group supports the Draft's view, that 'the individual ingredient is sampled at the point of manufacture'.	Comment noted.
HHGMAG	Re table 2: There must be tonnes of canned foods, which are highly susceptible to GM contamination such as sweet corn. Ways must be found to spot-check these, then follow the paper trail and the source of import. Heavy fines should be available for potential large-scale contamination.	Traceability and labelling requirements for such products that contain GM ingredients are set out in the regulations (EC/1830/2003).
W	Which? would like to see the guidance be more specific about consideration that should be given to unauthorised genetically modified organisms (GMOs).	This is more appropriately addressed via the database of such GMOs mentioned above. This will provide a mechanism for the exchange of new information as it becomes available.

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2.4 When to sample

<b>Respondent</b>	<b>Comment</b>	<b>Response</b>
GMF	The occurrence of GM contamination is very unpredictable, as the Bt10 maize and LL601 rice incidents have shown. However, without due vigilance at UK ports of entry it could soon become routine. Therefore GM Freeze believes that sampling of every at-risk cargo should take place. Thus companies trading in at risk crops should become more aware of the consequences of their cargo being rejected because of GM contamination. These range from loss of the cargo or being forced to label a non-GM cargo as GM depending on the nature of the contamination.	Comment noted.
HHGMAG	The enforcement authorities need directives as to when to sample in case that there appear to be hot spots, which become evident nationally. Regular sampling in areas with food and feed imports and substantial food processing must have a legal duty to sample and be additionally funded.	Comment noted.

2.5 How to sample

<b>Respondent</b>	<b>Comment</b>	<b>Response</b>
GMF	GM Freeze believes that far more detailed and legally binding sampling protocols should be produced as soon as possible. These should provide clear guidance on how to sample different types and size of cargo to ensure that the GM content of all parts of the batch are correctly characterized.	Reference to the guidance available on how to sample for GMO content is made in the document (section 2.5, 'How to sample').

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GMF	Running parallel to this process has to be a commitment to fund the sampling, analysis and enforcement process. Monitoring and enforcement activity should be at a level which encourages all companies along the supply chain to adopt the best possible practice for certifying the GM content of their ingredients and to have systems in place to prevent cross contamination (eg by having dedicated production lines and stores for GM and non-GM). An essential part of preventing GM contamination and ensuring that GMO labelling is accurate is also a commitment to prosecute if breaches of the regulations occur.	It is for local authorities, who are responsible for enforcement, to decide their sampling priorities and whether this will include GMOs. They also have the necessary powers to enforce the GM food and feed regulations when necessary.
HHGMAG	The Hemel Hempstead GM Action Group are encouraged that some PA laboratories are capable of 'rapid DNA screening'.	Comment noted.

**3. Follow up action**

Respondent	Comment	Response
FDF	<i>Follow-up action</i> refers to action if a positive result is obtained using a qualitative screen, and that consideration should be given to a confirmatory test to identify the specific GMO. The FDF suggests a note on the limitations of such action might be included, and also the absence (as far as we are aware) of any internationally agreed reference base for experimental GM crop varieties.	If a sample is found to be positive and the product is not labelled, then it would be logical to quantify and identify the specific GMO present. The JRC publishes validated methods for all authorised GMOs on its website. If the GMO cannot be identified using one of these methods then it may indicate the presence of an unauthorised GMO.
HHGMAG	Much is said in this draft about Sampling and in this section about Action. The Hemel Hempstead Action Group has much doubt, whether effective action is, in fact, being taken. We need to see the evidence.	It is the responsibility of the enforcement authority to decide on the appropriate follow up action.
W	There is currently no clear guidance on what action should be taken in relation to potentially affected products up the supply chain if an ingredient is found to contain GM material.	Comment noted. This is outside the scope of this guidance note on sampling.

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Annex A

Respondent	Comment	Response
HHGMAG	The Hemel Hempstead Action Group expresses serious doubt about the scientific verification of EC Regulation 178/2002 regarding food safety.	Comment noted.

**OTHER COMMENTS:**

Respondent	Comment	Response
HHGMAG	The FSA has missed the dimension of <u>Who should sample</u> . You implicitly refer to local enforcement authorities. You have overlooked the urgent need for a national team to operate systematically and under FSA or Defra control and check our points of import and the national distribution network. This cannot be done effectively at local level. Please take this point into your draft.	The guidance is aimed at local authority (LA) enforcement officers. However, when necessary, we will request that LAs carry out sampling on our behalf. For example, with both the Bt10 maize and LL601 rice incidents, surveys were carried out to gather information on the extent of the contamination.
HHGMAG	<u>Involving the public</u> . All food and feed is eventually for the benefit of the public. A mechanism should be available for the public to highlight potential examples of GM contamination and thus to assist in the enforcement of the law.	Any member of the public concerned that a company may not be complying with the law should inform their local trading standards office.
HHGMAG	<u>'GM animal feed'</u> should be shown on meat and dairy products, where animals have been fed GM feed. The product must urgently be labelled as such.	As set out in the regulations, such products do not need to be labelled.
LACORS	LACORS has no comments on the text other than to say that local authority sampling officers will find it useful to have guidance in relation to this area of enforcement work.	Comment noted.

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TSSSCC	<p>Trading Standards Service, Southampton City Council is supportive of the guidance with one concern regarding the practicality of sampling feed and feed ingredients at the point of import. Bulk shiploads can contain 15000 tonne food or feed, either loose, bagged or on pallets.</p>	<p>The Agency and the European Commission are aware of the practical problems associated with the sampling of bulk consignments of both feed and food. A working group of Member States has been established to consider the issue.</p> <p>You will be aware that the guidance note indicates that it is possible to take "informal" samples (see paragraph 2.5). Again the best method for taking such samples would be that outlined in Commission Recommendation 787/2004, although we understand that this may present practical difficulties with bulk shipments of the size quoted.</p>
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