Response by GM Freeze to the FSA consultation on the Guidance Note for Sampling Food and Feed to Determine the presence of Genetically Modified (GM) Material

September 2007

GM Freeze

GM Freeze is an alliance of 55 organisations *calling for a moratorium on GM foods, the growing of GM crops for any purpose and on patents on genetic resources in agriculture, food production and forestry until the need for and safety of GM technology has been established and alternative approaches have been fully evaluated.*

Our members include consumer groups, farming organisations, environmental groups, development agencies, religious groups, animal welfare groups and food companies.

Northern Ireland's consultation on the Guidance Note for Sampling Food and Feed to determine the presence of Genetically Modified (GM) Material.

Introduction

GM Freeze welcomes the consultation on determining the presence of GM materials in food and feed. Despite the lack of commercial cultivation of GM crops in the UK and the very low number of test sites over the past four years, the spread of GM crops around the world means that food and feed imports are at risk of contamination with GM traits which are unapproved in the European Union or at the experimental stage of development.

Over 170 different crops have been genetically modified somewhere in the world and then tested in the field or commercially grown. If the UK imports food and feed crops from countries where the same species has been genetically modified and either commercially grown or grown in field trials then there is a risk of imports being subject to contamination. In many cases, GM contamination would render the import illegal for placing on the market because the GM trait had not been granted an EU Marketing consent either under directive 2001/18 or Regulation 1829/2003.

GM contamination incidents are on the increase[1] and often incidents are only detected once the food chain and environment have been widely contaminated because of the lack of monitoring and enforcement around the world. In the recent incidents in the UK involving Bt10 maize and LL601 rice, the cat was a long time out of the bag before either incident was detected. Neither was picked up by the regulators in the USA. Bt10 came to light as a result of routine scanning in Germany and LL601 because of monitoring by a private corporation in the rice supply chain.

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The range and type of genetic modification are growing and now include traits designed to produced pharmaceuticals or industrial chemicals in the plant. Crops which have been genetically modified in this way include ones also used for food and feed production, for instance maize and oilseed rape. There is therefore an increasing risk that future food or feed imports may be contaminated with genes and chemicals which were not intended for mass consumption but are biologically active.

GM Freeze has carried out two pieces of research on GM contamination of imports. The first (in 2005) looked at the level of activity of local authorities in enforcing the GMO Traceability and Labelling Regulations (see http://www.gmfreeze.org/admin/uploads/report_doc.pdf) and the second (in 2007) was an analysis of which food and feed import were at greatest risk of GM contamination (see http://www.gmfreeze.org/uploads/GM_contamination_final.pdf).

The conclusions and recommendations in the second report which are pertinent to this consultation are outlined below:

- Each EU Member States to establish a single competent authority for monitoring incoming food, feed and biofuel cargoes and enforcement of GMO traceability and labelling. In the UK responsibility varies depending on which country of the UK the law is being enforced. Logically the FSA should be the competent authority with oversight of the whole process of regulation which would be carried out a local level by staff of the Port Health Authorities and Local Authorities funded from the central budget.
- Levels of enforcement vary between Member States and within the UK. Therefore the movement of imported or home grown crops also needs to be monitored for GM content to avoid contamination incidents. Any Member State found not to be reaching the required standard of enforcement of the GMO traceability and labelling regulations should be required to certify the GM content of any exports to other Member States to avoid the risk of spreading contamination.
- Biotechnology companies should be legally obliged to provide analytical methods and reference materials for all the GM traits they have released anywhere in the world commercially or experimentally as a pre-condition for receiving marketing or experimental consent for a GMO in the EU. This would enable GM monitoring to be more comprehensive and regulators more responsive when incidents are detected.
- The EC should establish a unit to monitor development in new GM traits and new GM crops around the world to ensure there is an up-to-date "at risk" list of imports on-line plus reference materials for each trait should be made available to all competent authorities and EU approved laboratories at all times.
- The production of a publicly accessible and searchable website to allow food and feed companies access to this information. This would help target their own monitoring and enforcement and assist in reducing costs across the board from conducting duplicated research.
- All incoming cargoes comprising of crops which have been genetically modified in the country of origin should be held at the port of entry until proven to be an approved GMO or non-GM in content.

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- The EC's Reference Laboratory to develop legally binding sampling protocols to ensure that of GM contents in cargoes can be assessed with the highest possible certainty.
- Cargoes containing unauthorised traits should be returned to the country of origin at the exporter's expense or destroyed.
- Competent Authorities in Member States should submit an annual monitoring plan for the enforcement of the GMO Traceability and Labelling Regulation to the EC to include random checks on retail, mass catering products and animal feed samples to ensure that labelling is accurate and companies are keeping the required traceability paper trail. Monitoring plans must be comprehensive and not targeted at any sector (eg those labelled organic or GM-free).
- Biotechnology companies whose GM traits cause contamination should be strictly liable for any damage arising from the contamination to health and the environment and for the economic harm.
- Member States to prepare an annual report on the enforcement activity they have taken within six months of the year end, to send it to the EC and to make it publicly available via the internet at the same time.

In the absence of collective action at EU level the UK should implement the above measures as soon as possible.

Serious Omission from the FSA Northern Ireland's' consultation

One of the recommendations in our 2007 report (*GM contamination imports of food and feed at risk) was* to ensure that all member states were working to a binding protocol for sample cargoes of potentially contaminated raw materials.

The reason behind this recommendation was the growing evidence that some sampling protocols are based on false assumptions, namely, that the GM presence in any lot is randomly distributed. Recent research published by Defra[2] from the KelDA project:

> *"Our findings document 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. Indeed, if sampling is not performed in a correct and hence representative way, there is no reason to carry out the sampling at all"*

Evidence to support this conclusion comes from imports of soya beans into Switzerland via barges on the Rhine. Data presented[3] to the "Non GM Soya Summit" in Brussels in June 2005 for a barge load of 1,200 tonnes of non- GM soya beans passing into Switzerland highlighted the need to use a robust sampling protocol to ensure that an accurate level of GM in each load is recorded. Single samples taken on loading and unloading gave GM content at 0.35% and 0.45% respectively (ie below the labelling threshold). However, when the barge load was broken down into individual loads for feed producers the GM content of each load varied from zero to over 1.2%.

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. GM Freeze wrote to the Chair of the FSA when we recognized the

importance of this omission but the response we received in reply was far from satisfactory

Recommendation 2004/787/EC, which gives technical guidance on the sampling of bulk commodities. This recommendation is applicable in the situations described in the Kelda project article.

However, the draft guidance fails to make reference to this most recent research published by Defra which provides as excellent case study to illustrate why a binding sampling protocol is necessary to ensure that problems further down the supply chain can be avoided by ensuring that the GM content of any cargo is discovered at the port of entry using an appropriate sampling technique. Many responding to this consultation would be unaware of the KeLDA projects and therefore specific mention its findings would have been beneficial and developed a far greater understanding of need to adhere to the binding protocol.

Where to Sample

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 experience of recent contamination incident in the EU, for example Bt11 maize and LL601 rice, suggest that 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.

Once the cargoes have been broken up, the complexities and costs of tracing and sampling grow enormously. Preventing contaminated cargoes entering the food and feed chains is by far the best option for protecting the interests of UK businesses and protecting public health. Sampling beyond the port of entry of the raw materials requires regulators to have an excellent knowledge of the structure of the food/feed chain the cargo has entered. In the case of the LL601 incident it was clear that the Food Standards Agency was not aware of the importance of the catering sectors as a destination for long grain rice imports and at the start of the incident in August 2006 was content to rely on dealing with the incident through supermarkets alone. This approach also ignored institutional rice users and small retailers.

What to Sample

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
- 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. According to the EC website, the number of GM varieties for each species approved for commercial marketing are as follows:

- Maize 9
- Soya 1
- Oilseed rape 3
- Cotton 5

Marketing consents for two varieties of maize and three varieties of oilseed rape have been withdrawn. In addition, 27 varieties of GM maize are in the EU process but not yet approved. For soya, the corresponding figure is 5 varieties, for cotton 7 and oilseed rape 1. Papaya is currently grown commercially in the USA and is not approved in the EU. Nevertheless it was found to be contaminating imports by the German authorities on seven occasions in 2004.

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.

The draft Guidance fails to deal with crops that have no EU authorisation or applications in the pipeline. GM Freeze's analysis suggest that there are at least 29 different food exporting countries to the UK where around 33 GM crops have been tested In addition the USA, Canada, France and Italy have field tested GM pharmaceutical crops in the open air including oilseed rape, clover, mustard, flax, barley, rice, wheat , alfalfa , sugar cane, maize, aubergine, melon and tomato.

The analysis of GM contamination risk was published by GM Freeze in the belief that it would help to make import monitoring programme more effective. However, we feel that task should be taken on by either the FSA or the European Commission. The pattern of GM cropping (both commercial and test sites) will change over time as does the pattern and volume of exports. Thus information about which crops were at risk of GM contamination would have to be updated very regularly. The FSA or the EC are best placed to perform this task because of their international connections to regulators around the world who should have knowledge of what GMOs are being grown and where. All these factors have to be considered when designing a robust sampling programme at the ports.

Consumer demand for accurate and reliable labelling of GM presence in food and feed is good enough reason to improve the current low level of monitoring. However, the real possibility of imports being contaminated with pharmaceutical or industrial traits means that the level of vigilance and quality of monitoring has to improve by a huge amount if a major public health scare is to be avoided.

When to Sample

The occurrence of GM contamination is very unpredictable, as the Bt10 and maize and LL601n rice incident 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.

Types of Food/Feed to sample

Monitoring for the presence of GMO presence has two main objectives

- To ensure that only approved GM traits are entering the UK food/feed chain.
- To ensure that the labelling of GMOs in food and feed meets the requirement of Regulation 1830/2003.

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. We feel 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. This is a vital part of enforcement work because many people wish to avoid all GM ingredients regardless of whether they contain detectable DNA or not. It is also important because the labelling exemption for adventitious or technically avoidable GM presence also applies to processed ingredients which contain no detectable DNA. Therefore, we feel the guidance should clearly set out what regulators should be looking for to ensure that labelling of the final food or feed can be as accurate as possible:

- Does the producer have a certified analytical report on each batch of the raw ingredients in their products which potentially could be GM?
- Do the processors along the supply handle GM and non-GM ingredients of the same type in the same factory which could result in cross contamination either before or after processing?
- Do the processors along the supply chain have dedicated production lines and storage systems for GM and non-GM ingredients of the same type? If not what systems do they have in place to prevent cross contamination?
- Do the processors along the supply chain have a certification system for each batch of raw/processed ingredients showing the original analysis for GM?
- Do the processors along the supply chain have a designated person responsible for ensuring a high standard of traceability and segregation (if required) are being followed?
- Are systems maintained at all time particularly during periods when key staff are not present for whatever reason? Does it processor have an adequate back up procedures?

How to Sample

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.

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.

Availability of GM Reference materials

One of the main problems faced during the recent contamination incidents involving Bt11 maize and LL601 rice was the lack of a verified analytical test for the traits when contamination was first reported. This was compounded by the delays in developing a reliable test by the companies who released the GMOs and then by further delays in distributing the reference materials to approved laboratories. The very limited number of laboratories who then received the reference materials from Syngenta and Bayer CropScience respectively meant that retailers also experienced delays in getting samples analysed.

GM Freeze recommend that the FSA tackles these problems by working with the European Commission to ensure that an international register of all commercial and experimental GM traits is established which is readily accessible to all regulators and authorised laboratories. An opportunity to progress this idea will be available at the Conference of Parties of the Biosafety Protocol in Bonn in May 2008. Before any GMO is released into the environment there company responsible should be legally required to have a verified test available and to make the reference materials needed for the test available on the international register and thus be accessible quickly in the event of an incident or merely as part of routine monitoring for contamination.

Adventitious or Technically Unavoidable GMO Presence

In Regulation 1830/2003, the exemption to the labelling of the GMO in food and feed below the threshold of 0.9% only applies if the GM presence is “adventitious or technically unavoidable”. GM Freeze believes that the draft Guidance on monitoring for the presence of GMOs should also include a section on how the results of monitoring should be interpreted in relation to the rules relating to the labelling exemption.

The following would need to be included:

- Companies would have to demonstrate that they had taken all reasonable measures to avoid the presence of GMOs right along the supply chain from field to final product.

- Companies would need to demonstrate that their raw materials did not routinely contain GMOs at low level and that they had made efforts to source alternative supplies if this was occurring but to no avail.

- Guidance on the point at which the frequency of a low level GMO presence in raw materials can be classed as adventitious or technically unavoidable. GM Freeze proposes that this figure should be set low to encourage best practice. We suggest that one in ten samples with GM presence between not detectable

and 0.9% could be classed as adventitious (subject to evidence that all measure to avoid that presence had been taken along the supply chain). GM presence at greater frequency than 1 in 10 should be subjected far greater scrutiny to ensure that all efforts to avoid contamination have been made.

- Random checks of consumer products should be made periodically to ensure the overall system is working.

Conclusion

From the evidence that GM Freeze has gathered in the past two years, the current level of monitoring and enforcement activity is not adequate to ensure that only approved GMO are entering the UK from third countries and the labelling of GMO content in food and feed is reliable and accurate. We feel that the draft guidance does little more than maintain the current position which in our view fails to enforce Regulation 1830/2003 with sufficient rigor meaning that the people's right to avoid GM ingredients in food and feed is not being upheld. To ensure that risky and high cost contamination incidents are avoided in the future (eg contamination of food or feed with pharmaceutical genes), we recommend the following measure should be taken:

- The development of a mandatory sampling protocol to ensure that the GM content of all lots is accurately characterised at the port of entry or as a raw material in the supply chain.

- The development of guidance on what constitutes an adventitious or technical unavoidable GM presence.

- The development of guidance on which crops imports or raw materials are at risk of GM contamination to enable monitoring to be efficiently targeted.

The development of guidance on how to deal with contamination of experimental GMO traits is urgently required.

In addition we also recommend d that the FSA take immediate steps to work with the EC to achieve the following:

- A dynamic system for assessing the risk of GM contamination in imported crops and raw materials to produce a web based information source for regulators.

- An international register of GMO analysis methods and reference materials for all traits released into the environment for commercial or experimental purposes which would immediately be available to any authorized laboratory to access around the clock

Implementing Regulation 1930/2003 and preventing unapproved GM entering the food and feed chain will not come cheaply. However, the costs are likely to be small compared to the costs falling on the food/feed industry from for instance the contamination of maize intended for human consumption with a GM pharmaceutical gene after it had been processed and entered the food chain. The Starlink incident in 2000/2001 cost the food chain in the USA over $100 million and some estimates put the final cost at $1 billion. To avoid such costs in the UK the investment in monitoring and enforcement would seem well worth it.

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[1] www.gmcontaminationregister.org/

2 www2.defra.gov.uk/research/project_data/More.asp?I=CB02016&M=KWS&V=CB02016&SCOPE=0

Published as Paoletti G, 2006 Kernal Lot Distribution assessment (KeLDA); *A study on the distribution of GMO in large soybean shipments,* Eur Food Res Tech (2007) DOI 101007/s00217-006-0299-8

[3] Kemenz, P (2005). *Perspectives of a Swiss feed producer and experiences with importing and handling non- GM soy meal*. Presentation at the Non-GM Soya Summit, Brussels 28-29th June 2005, www.avantel.de/acm/1269/download/getfiles1.php