

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

53rd Meeting of ACAF on 2 March 2011

Discussion Paper

German Feed Dioxins Incident 2010 – 2011

Action required

The Committee is asked to:

- **be aware of the events surrounding the recent dioxin incident in Germany; and**
- **discuss whether additional safeguards should be considered to prevent the occurrence of a similar incident in the United Kingdom. In particular, Members might wish to consider whether any of the issues included in the ten-point plan devised by the German Federal authorities (see Annex I) would be of assistance in this regard.**

Secretariat

February 2011

German Feed Dioxins Incident 2010 - 2011

Purpose

1. This paper is to:

- inform the Committee of the events surrounding the recent dioxin incident in Germany; and
- ask the Committee to discuss whether additional safeguards should be considered to prevent the occurrence of a similar incident in the United Kingdom. In particular, Members might wish to consider whether any of the issues included in the ten-point plan devised by the German Federal authorities (see Annex I) would be of assistance in this regard.

Introduction

2. On 27 December 2010, the Federal German authorities reported a feed contamination incident to the European Commission via the Rapid Alert System for Feed and Food (RASFF). The incident concerned the use of 'mixed fatty acids' intended for technical (i.e. non-feed or non-food) purposes containing dioxins in the manufacture of feed fat products. The German authorities had initially been alerted to the incident due to the finding of dioxins in a sample of compound feed. The source of the contamination was traced back to the feed fat used in its manufacture. The contamination entered the feed and food production systems in Germany and restrictions were placed on farms and feed producers by the authorities. Member States and the European Commission are considering whether new controls are required to help prevent similar incidents.

Technical mixed fatty acids

3. Eight consignments of mixed fatty acids (a total of 206 tonnes) that were derived from biofuel manufacture were delivered by an operator in the Netherlands to a company in Schleswig-Holstein, Germany from 11 November to 16 December 2010. The product in question was originally intended for technical uses (e.g. paper manufacture) and was labelled as such. The consignments were somehow diverted to feed use – investigations by the Dutch and German authorities continue. Subsequent analysis of retained samples for the eight consignments found dioxins to be present at up to 123 ng PCDD/F WHO TEQ /kg. (The current maximum permitted level for feed materials of plant origin, including vegetable oils and their by-products is 0.75 ng PCDD/F WHO TEQ /kg.)

Feed fat

4. The eight consignments of technical mixed fatty acids were used in the manufacture of approximately 2,250 tonnes of vegetable feed fat. This was sent to 25 compound feed manufacturers in Germany. The German Federal authorities maintain that no deliveries of the contaminated feed fat were made to other Member States, or to third countries. Analysis of the feed fat made with the mixed fatty acids found levels of dioxins at up to 62 ng PCDD/F WHO TEQ /kg.

Compound feed

5. The feed fat in question was found to have been used in the manufacture of compound feeds with an incorporation range of 2-10%. The feed fat was used to manufacture compound feed for poultry, pigs, cattle (fattening and dairy) and rabbits. This potentially contaminated

feed was distributed to farms in eight German Länder. Investigations by the German authorities lead to restrictions being placed on more than 4,700 farms that were believed to have received contaminated feed. Suspect feed and food was blocked – the blocks on consignments were lifted only after they could be shown to be compliant with the maximum permitted levels set under European Parliament and Council Directive 2002/32 on undesirable substances in animal feed. The remaining contaminated feed will be incinerated. The only known exports of feed that was suspected to contain contaminated feed fat were those of consignments of complete feed for breeder hens sent to Denmark and to France. Of these, one part of the feed exported to Denmark was expected to have only low level contamination; the remainder was believed to be within the statutory maximum limit.

Food

6. On 6 January 2011, the Food Standards Agency (FSA) was notified that eggs from German farms that had received suspect feed were used in a liquid egg formulation prepared in the Netherlands. This had been supplied to two bakery product manufacturers in the UK. As a precaution, the affected bakery products were traced and a number of retailers took the commercial decision to withdraw or recall them. This was not done on the advice of the Food Standards Agency and was not necessary for reasons of safety. Subsequent testing of samples of liquid egg retained by the Dutch manufacturer showed that dioxin levels were well within compliance.

7. In Germany, tests on 209 samples of eggs from affected laying farms showed a non-compliance rate of about 16% for dioxins (regulatory limit 3.0 pg PCDD/F WHO TEQ /g fat), with most levels in the 3.0 - 6.0 range and the highest around 12.0 pg PCDD/F WHO TEQ /g fat. Although non-compliant, such levels would not be regarded as a significant health concern. Six out of 269 pigmeat samples from affected farms have also been reported to be non-compliant (levels up to 1.6 and compared with a regulatory limit of 1.0 pg PCDD/F WHO TEQ /g fat), plus a further four samples that exceeded the Action Level set under Directive 2002/32 of 0.6 pg PCDD/F WHO TEQ /g fat which would normally prompt an investigation. A risk assessment performed by FSA colleagues has indicated that such levels are not a significant health concern. These levels are at least two orders of magnitude lower than the contamination reported in pork during the 2008 'Irish dioxin incident'. It is also worth noting that the levels found in pork in the current incident would be compliant if found in poultry, beef or lamb.

Current status

8. The German authorities now claim that the incident has now reached a stage that no further official measures are required to control the current incident. The existing blocks on agricultural holdings continue to be removed by the competent authorities, but only where conclusive investigations indicate that food produced will be compliant. By 2 February 2011 the number of farms that were still subject to restrictions had been reduced from 4,700 to 280. The authorities have claimed that the measures taken have resulted in effective consumer protection, and have allowed food producers to resume production where it is safe to do so.

Further measures

9. At the 20 January meeting of the Animal Nutrition Section of the Standing Committee on the Food Chain and Animal Health (SCoFCAH) the German authorities presented ten measures that it intends to undertake in order to help prevent future contamination incidents occurring. The German ten point plan is reproduced at Annex I. The German authorities have stated that they would like to see some of these items (e.g. mandatory insurance and an exclusive positive list of feed materials) to be adopted as EU-wide measures. At the SCoFCAH meeting UK officials were of the view that it would be better for any new measures to be made on an EU basis, but did not think that there was a need to rush into new controls.

Discussion of possible new controls

10. The Committee is asked to consider the German ten point plan and to consider whether any of these (or any other measures) might help prevent significant contamination of feed in the United Kingdom. In particular, members are asked to consider to what extent possible new controls would be effective and proportionate to the risks and to consider alternatives to formal controls such as assurance schemes. Any new statutory measures would probably have to be made on an EU-wide basis. To aid the Committee's discussions some comments are included for each of the points in the German plan. The precise details for the ten points have not yet been released. However, UK officials will request more information from their German counterparts.

11. *Duty of feed producers to obtain authorisation* (1). Under the EU Feed Hygiene Regulation (183/2005/EC) most feed businesses need to be either approved or registered.

- Approval of a feed business establishment requires a prior on-site inspection by the enforcement authority before an approval is granted. This is mainly confined to establishments that manufacture and market certain additives and premixtures.
- Registration entails an establishment being placed on an enforcement authority's records with follow-up inspection visits by the authority. This applies to the majority of businesses that manufacture, market or distribute feed. Exceptions include the feeding of non food producing animals, and feeding of food producing animals for private consumption.

Approval is considered to be the more onerous and extensive procedure for both feed business operators and enforcement offices. If the prior inspection for approval identifies any shortcomings at an establishment, the enforcement authority may give the feed business operator a certain period of time to rectify these or refuse to approve it, depending on the seriousness of the deficiency. Approval is subject to a fee payable to the enforcement authority. Many of the requirements of EU Regulation 183/2005 (e.g. standards applicable to facilities and equipment, and record-keeping) apply equally to approved and registered feed business establishments. However, it may be possible to amend the Regulation to include additional requirements applicable to certain sectors of the feed industry (e.g. suppliers of feed fats). It appears to be the intention of the German authorities that feed fat producers should be subject to a requirement for mandatory approval under Regulation 183/2005/EC.

12. *Separation of production flows* (2). It is not clear whether the German authorities are suggesting entirely separate production sites for feed and food fats and oils and for technical products. An acceptable alternative might be where the two product types can be on the same site, but contained, moved stored within dedicated plant. Some information concerning a scheme operating in the UK is provided at paragraphs 21 – 24.

13. *Expansion of legal requirements in respect of feed controls* (3). The intention here seems to be to require companies to perform stipulated analyses for contaminants on feed products and to provide the data to the control authorities. A similar system was introduced into Belgium following the 1999 dioxins/PCB incident. Current control systems in operation in the United Kingdom for both the feed industry and enforcement offices are based on an assessment of hazards and risks.

14. *Duty of private laboratories to report* (4). The German authorities would place a legal obligation on all laboratories to inform the authorities of non-compliances. This might be expected to help provide information on feed contamination incidents more quickly. However, there might be possible legal problems with client/contractual confidentiality issues.

15. *A binding positive list of feedstuffs* (5). Germany already has such an exclusive positive list of feed materials; the most recent version (8th Edition) was published in January 2010. It is seeking to have a mandatory list imposed on all EU Member States.

http://www.dlg.org/fileadmin/downloads/fachinfos/futtermittel/positivliste/positivlist_en_8.pdf

This is not a new issue; it was discussed during the negotiation of the EU Parliament and Council Regulation on marketing and use of feed (EU Regulation 767/2009). The Commission and most Member States were unsupportive of the concept of an exclusive positive list. However, EU Regulation 767/2009 requires the establishment of an EU Catalogue and a Register of Feed Materials – these are now both in place.

16. *Coverage of the risk of liability* (6). German officials argued for a legal requirement for feed operators to have insurance (or equivalent arrangements) to protect against any liability resulting from their products leading to third parties incurring significant costs. This has been explored previously at EU level. Agency officials have met with representatives from the insurance industry on several occasions, with the conclusion that such cover would be prohibitively expensive and unworkable.

17. *Revision of the system of penalties* (7). This would be probably an issue specific for each Member States' legislation. It might be assumed that the German authorities would want to increase potential penalties for causing significant feed incidents. Apparently, European feed industry associations are drawing up proposals for increased dioxin monitoring.

18. *Expansion of dioxin monitoring – establishment of an early-warning system* (8). Monitoring is to be performed by both the feed industry and enforcement/control offices. Data are to be sent to a central location and results relayed rapidly to affected farms and businesses where these suggest a problem.

19. *Improvement of the quality of food and feed controls and inspection* (9). This is an issue for Germany and possibly also for other Member States. The German Lander have already said that they are willing to step up monitoring if the Federal Government is willing to pay for it.

20. *Transparency for consumers* (10). The German Government is seeking to provide more information to consumers on future feed and food incidents. This might involve names of companies and products concerned.

Protective measures for feed fats and oils in the United Kingdom

21. In addition to the statutory controls in place to help prevent the use of contaminated feed (e.g. maximum limits for undesirable substances), there are additional voluntary controls in place in the United Kingdom. An example of this is the Feed Materials Assurance Scheme (FEMAS) is run under the auspices of the Agricultural Industries Confederation (AIC):

<http://www.agindustries.org.uk/content.output/95/95/Trade%20Assurance/Trade%20Assurance%20Schemes/FEMAS.msp>

22. FEMAS is based on the approach that good risk assessment and control of sources are essential. The FEMAS Core Standard contains this requirement for all feed ingredients and is essential for the effectiveness of the scheme.

FEMAS takes a risk-based approach to the management of hazards within the feed industry. The emphasis is away from prescriptive testing requirements, but towards a requirement to demonstrate at audits that:

- the hazards associated with the products/ materials handled are understood;
- these are contained within the HACCP plan; and
- HACCP has adequate controls and monitoring.

The FEMAS documents are in two parts:

- the [International Core Standard](#) that contains the requirements that all businesses must comply with; and
- specific [Sector Notes](#) for the vegetable oil participants which provide more detailed information on compliance with the core standard requirements.

The key element in ensuring that businesses are producing safe product is the robustness of the auditing of the FEMAS participants. This is mostly achieved through a team of specialist

feed auditors. A participating business is expected to demonstrate to the assessor that it has identified all the hazards that it has these under control.

It is a contractual obligation for many companies supplying feed to food producers that they sign up to FEMAS and adhere closely to the scheme.

23. With regard to feed fats/oil operations the following specific rules apply under FEMAS:

- each operator will have his/her own HACCP; this will reflect the sources that are used. These are 'live' documents, so only examples will be held by the FEMAS certifier as evidence collected at annual audits;
- wholly segregated systems are required by FEMAS. However, feed- and non-feed fats/oils are permitted on the same site. Where this does occur, physical separation of the two is required, ideally by the use of separate tanks and pipes. However, blanking plates and/or locked off valves may be employed instead. Such systems will be subject to scrutiny by the auditors;
- members of the Scheme must undertake an assessment of the risks associated with each source of fat/oil, and to ensure that the statutory controls concerning undesirable substances are complied with;
- Polychlorinated biphenyl (PCB) (on a risk basis) data (but not dioxins) are available for oils prior to blending or sale. PCB tests are sometimes performed on samples from each separate ship's tank and from road tankers. About 250 sets of data are generated annually;
- Palm Fatty Acid Distillate (PFMA) is a product with a higher risk of dioxin contamination. Dioxin analysis is required for all 'parcels' of this substance where used as feed;
- PCB (but not dioxin) data must be obtained for the following prior to incorporation in feed unless the source is certified to FEMAS or the Vegoil By Product Scheme in its own right

-acid oils

- mixed unused vegetable oils
- factory produced used vegetable oils
- de-packaged oils;
- traceability is very important. It is a requirement that the following are available for all raw materials (including additives) utilised to produce feed
 - the name and address of the supplier of the raw material;
 - information of the production or process from which the raw material is derived; and
 - a risk assessment for each raw material, identifying potential hazards and the means by which these hazards are controlled by the supplier, the participant or both parties.

Where risk assessments identify the need for specific controls or limits to ensure the appropriate management of potential risks, these must be included in the specifications agreed with suppliers of these raw materials.

24. The UK feed trade cannot categorically say that FEMAS would have identified an incident where there was diversion of non-feed material before contaminated feed entered the feed and food chains. Any company using such contaminated material would have operated outside the rules of FEMAS. The scheme seems to encourage testing for PCBs (probably for reasons of cost) in the hope that this would also indicate the presence of dioxins. In the current incident the main contamination seems to be in the form of dioxins; it is unclear whether PCB testing alone would have picked up the extent of the problem.

Response from the European Commission

25. The European Commission and all Member States have been kept up to date on the incident and on the response from the German authorities – more information is expected. However, it is not yet clear whether the Commission would want to amend existing controls in response to the incident.

Conclusion

26. The Committee is asked to consider whether additional safeguards should be put in place to prevent the occurrence of a similar incident in the United Kingdom. In particular, Members might wish to consider whether any of the issues included in the ten-point plan devised by the German Federal authorities (see Annex I) would be of assistance in this regard.

Secretariat

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German Ten Point Action Plan for Consumer Protection in the Feed Chain

1. Duty of feed producers to obtain authorisation

Manufacturers of fats for feed will have to apply for authorisation; this will be linked to stringent requirements. The companies will have to prove, by carrying out analyses, reporting to the authorities and preserving retained samples that their products comply with the maximum statutory limits value for critical substances. As fats for feed will only be permitted to be produced in facilities that are intended to be used solely for food or feed (see 2 below). The management of these companies will have to have the necessary technical competence. The competent supervisory authorities of the Federal States will have to conduct regular and extensive on-site inspections.

2. Separation of production flows

The German authorities will stipulate in new regulations that fats and fatty acids for feed use must not be manufactured in facilities that are also used to produce substances for the technical (i.e. non feed or food) purposes. Germany will strive to make this a requirement in all EU Member States.

3. Expansion of legal requirements in respect of feed controls

The duty of feed operators to control their products will be made more stringent. Germany intends to stipulate by law that holdings must test their feed components for substances that are potentially hazardous to health and must report all results from these tests to the authorities.

4. Duty of private laboratories to report

Private laboratories that test food or feed and determine levels of undesirable substances that give cause for concern will have to report these results to the competent authorities.

5. A binding positive list of feedstuffs

Germany advocates the imposition of a legally-binding positive list of feed materials. It is only possible to introduce such a list at EU level. The intention of the positive list would be to improve the safety and transparency of the feed market. It must therefore be transparent, exhaustive, and binding.

6. Coverage of the risk of liability

Germany will require its feed operators to take out employer and product liability insurance or equivalent. The German government will call for this requirement to be adopted at EU level.

7. Revision of the system of penalties

They will revise the scale of penalties in respect of infringements of the Food and Feed Code. The authorities will work together with the Federal Ministry of Justice to revise both the classification of offences as either criminal or administrative, and the scale of the respective penalties.

8. Expansion of dioxin monitoring – establishment of an early-warning system

All data on dioxins in food, in feed and in the environment will be brought together and evaluated as a joint data pool. Data from the industry's internal controls will also be included. The German authorities will use this as a basis for establishing an early-warning system in order to be able to recognise problems earlier and instigate measures to counter any problems more quickly.

9. Improvement of the quality of food and feed controls and inspection

The quality of food and feed controls and inspections performed by the Federal State authorities is to be significantly improved. The aim of the German government is to make the organisation and implementation of the official controls transparent, and to subject the process to an independent evaluation.

10. Transparency for consumers

Consumers have a right to be informed about which foods are contaminated. The competent authorities will be required to publish without delay the results of official food controls and inspections on all infringements caused by limit values being exceeded. This will be a central component of the forthcoming amendment of the German Consumer Information Act.