

Report of

The Inter-Agency Review Group

on the

Dioxin Contamination Incident in Ireland
in December 2008

December 2009

FOREWORD

The dioxin contamination incident demonstrated that the food chain is only as secure as its weakest link and highlighted the consequences for the entire chain if something untoward happens with animal feed. To date it has cost the Irish taxpayer in excess of €100 million from the financial assistance facility made available to the industry and not to mention the cost to industry of providing contingency supplies to their customers, the costs of lost business, and the consequent damage to reputations.

This review seeks to establish what factors contributed to this dioxin contamination incident and what policies, and practices, might be put in place to prevent similar incidents from occurring in the future.

All of the evidence available suggests that the incident occurred as a result of contaminated fuel being used in an oil-fired burner (direct flame drying system) that generated the heat to dry the feed at Millstream Recycling Ltd., and a failure by the Feed Business Operator (Millstream Recycling Ltd.) to identify the potential hazards associated with the direct flame drier, and the risk of contaminating feed if inappropriate fuel was used, and to put the necessary control measures in place.

The incident arose from a failure of the FBO concerned to comply with his legal responsibility to ensure that only wholesome food fit to eat was put into circulation. Root cause analysis of the systems failure points to the inadequacy of the feed safety management system formulated by the feed business operator. The inadequacy of the FBO's feed safety management system was not identified through the official controls operated by the Department of Agriculture, Fisheries and Food. This interagency review has identified that within the international scientific and regulatory communities there was a specific concern with the use of oil fired direct flame burners as part of the manufacturing process of animal feed, specifically that dioxins could be produced at certain temperatures if incorrect fuel was used and these harmful compounds could be incorporated into the end product. As a result the Review Group believes that the official controls should have paid attention to the risks associated with direct flame drying

That contaminated oil reached the feed business in the first instance indicates that the oil purchased by, and supplied to, the feed business operator was not fit for purpose. How this occurred is the subject of an ongoing Garda investigation. That contaminated oil reached the food business operator also suggests that there were deficiencies in the oversight and control of oil, and waste oil, importation, distribution and sale.

Once the incident was identified by the national official food and feed control programmes it was managed as well, or better, than similar incidents that have occurred elsewhere. The source and extent of the contamination was identified and scientific risk assessment was undertaken rapidly. There was good collaboration with the EU Commission, the European Food Safety Authority and the regulatory agencies in other jurisdictions and within Ireland. Prompt and decisive action was taken on public health grounds as a result of the initial findings that animal feed supplied by one FBO was the source of the dioxin contamination including a total recall and destruction of all pork products from pigs slaughtered between September 1st and December 6th.

In the EU the legal limit for dioxins in pork fat is 1 picogram per gram and attempting to communicate the risks associated with this level of contamination plus the concepts of bio-accumulation and body burden and the need for continued exposure to result in adverse health effects proved extremely challenging. The adverse impact on consumer confidence, and Ireland's reputation was mitigated, when the risks were managed, and were seen to be managed, decisively and rapidly and actions taken were communicated in an open and transparent way to the public and all the stakeholders.

This review highlights many lessons that must be learnt if similar incidents are not to occur in the future.

I thank my colleagues on the review group for their input.

A handwritten signature in black ink that reads "Patrick G Wall". The signature is written in a cursive, flowing style.

Patrick G Wall
Associate Professor of Public Health
University College Dublin

INTRODUCTION

In the immediate aftermath of the dioxin contamination of pork and beef in December 2008, the Minister of Agriculture, Fisheries and Food established an inter agency review group to carry out a complete review of and report on all aspects relevant to the incident. The Joint Oireachtas Committee on Agriculture, Fisheries and Food conducted a separate enquiry and the Minister indicated that the recommendations arising from the Oireachtas Committee would be considered by this Review Group.

The membership and terms of reference of the Review Group are:

<u>Name</u>	Title
Dr. Patrick Wall Chairman	Associate Professor of Public, Health, U.C.D.
Prof. Alan Reilly	Chief Executive, F.S.A.I.
Martin Heraghty	Assistant Secretary General, Department Agriculture, Fisheries & Food
Tim Dalton	Former Secretary General of Department of Justice
John Keegan	Principal Officer, Food Unit, Department of Health & Children
Kieran O'Brien	Programme Manager, Office of Environmental Enforcement, Environmental Protection Agency
Michael Maloney	Director of Food Quality Programme, An Bord Bia

Executive Co-ordination / Secretariat: Joe Shortall, Mary Curley (Department of Agriculture, Fisheries and Food)

1. To examine and report on the sequence of events leading up to the discovery of the dioxin contamination of Irish pork and beef.
2. To assess the actions taken by the relevant authorities leading up to the withdrawal of products from the market.
3. In the light of experience gained in the incident to make recommendations on future policy in relation to food and feed safety controls.

4. To address the responsibility of all food / feed business operators along the food chain from primary production to the point of sale to the consumer to ensure full compliance with the legislative requirements to produce safe food.
5. To look at how the relevant authorities and the food and feed business operators interact and to review their respective roles.
6. To assess the manner in which any future food safety incidents can be managed so as to ensure consumer health is protected whilst minimising the economic impact.

The report is structured around the terms of reference assigned to the Review Group with a separate chapter devoted to each of the individual terms of reference. The extent to which any individuals or parties may carry legal responsibilities for what occurred in this instance was not a matter for this Review Group. A separate Garda investigation into aspects of the matter is ongoing. The focus of the Review Group was on the lessons to be learned and control adjustments necessary from the incident to reduce the likelihood of a similar incident in the future.

Working Methods of the Review Group

The Review Group examined in particular the regulatory environment for Food and Feed Business Operators (FBOs), the structure and responsibilities of the Control Authorities, the actions of the FBOs and the authorities in this particular incident and carried out an assessment of the above controls and actions. It considered also the lessons that might be drawn from this incident and the manner in which possible future risks to feed and to the food and feed chain might be addressed.

By way of public advertisement the Review Group sought submissions from interested parties. In total twenty-two submissions were received and considered by the Group (see Appendix 1). Some submissions, which were considered not to fall within the remit of the Group, were forwarded to the appropriate authority. The Review Group invited certain interested parties to elaborate on their submissions (also listed in Appendix 1). The Report of the Joint Oireachtas Committee was received on 26th May 2009 and was considered by the Review Group.

Incident Summary

The dioxin contamination incident originated in the detection of elevated levels of PCBs² in a pork fat sample taken on 19 November 2008 by the Department of Agriculture, Fisheries and Food as part of the requirement to conduct routine targeted sampling of animal products under the National Residues Monitoring Programme. This programme is described in more detail in Appendix 2. The source of the pork sample was traced to a farm in Co. Cork. Animal feed ingredients used on that farm were also positive for 'marker' PCB³s. The source of that animal feed was traced back to Millstream Recycling Ltd in Co. Carlow. Forty-eight farms were identified as receiving similar feed from this company (10 pig farms and 38 beef farms) since 1st May 2008. This company's products were also delivered to 7 farms in Northern Ireland.

Because of the potential link between the presence of PCBs and dioxins, samples of pork fat and the feed ingredients (bread crumb) were immediately taken on Tuesday 2nd December to the Central Science Laboratory in York for analysis, which confirmed on Saturday 6th December the presence of dioxins in both the pork fat and animal feed. Once the result became available on 6th December, the Food Safety Authority of Ireland recommended that Government initiate a full recall of pork and pork products manufactured from pigs slaughtered in Ireland since 1st September 2008. In making the decision for a total product recall, account was taken of the fact that the 10 pig producers affected and associated pig farms involving 17 separate production units accounted for some 10% of the national kill or approximately 50,000 pigs slaughtered between 1st September and the 1st December 2008. Taken together, they supplied eight of the ten main abattoirs in the country, which accounted for about 98% of the national throughput of pork. The decision to recall all products was taken because of the three month time period from which product had to be recalled and the degree of commingling of product in secondary processing it was not possible to readily identify contaminated pork from the 10 affected pig producers which was commingled with uncontaminated products in the market place. The date of the 1st September was chosen on a precautionary basis as all scientific data available to the FSAI indicated that the feed contamination incident started after this date. Subsequent testing of feed samples supported this decision.

² PCBs polychlorinated biphenyls.

³ Polychlorinated biphenyls (PCBs) are a group of 209 different congeners which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicological properties similar to dioxins and are therefore often termed as "dioxin-like PCBs". The other PCBs, known as "marker PCBs", do not exhibit dioxin-like toxicity but have lower and a different toxicological profile. A congener is the term used to describe different configurations of similar chemical compounds. The discovery of these marker PCBs in food or feed samples does not always mean that dioxins and dioxin-like PCBs will also be present.

Following the decision on Saturday 6th December for a full recall, Bord Bia, in consultation with the Department of Agriculture, Fisheries and Food, developed a label for pork products which could be guaranteed to have come from pigs that had not eaten contaminated ration. Such products were back on sale to the public on Wednesday 10th December. A total of approximately 30,000 tonnes of recalled pigmeat product was destroyed (including 5,000 tonnes outside Ireland) under a pigmeat recall/financial assistance scheme. The 170,000 pigs and 5,700 cattle from the farms that received contaminated product were culled on a precautionary basis. In the case of beef, the number of animals concerned represented only 0.02% of the national herd and carcasses and prime cuts from these animals were tested and removed from the food chain. The FSAI carried out a risk assessment which identified that the additional body burden from the consumption of contaminated beef was 300 times less than that for pork. In all these circumstances it was concluded that a general recall of beef was not necessary.

All of the evidence available suggests that the incident occurred as a result of contaminated fuel being used in an oil-fired burner (direct flame drying system) that generated the heat to dry the feed at Millstream Recycling Ltd., Laboratory tests carried out by the Environmental Protection Agency (EPA) showed that the oil used as a fuel in the burner at that plant was contaminated with PCBs. The composition of the PCBs found in the contaminated oil would indicate that transformer oil was the source of the contamination. It appears that the suspect oil that was used as a fuel at Millstream Recycling originated in Northern Ireland. Laboratory tests showed that the contamination profile in the oil used at the plant was similar to the profiles found in the fat and in the animal feed. The circumstances around the sourcing and contamination of this oil are under investigation by the Gardaí and the Northern Ireland authorities.

A detailed chronology of the events in the period from 19th November to 6th December is provided at Appendix 6.

Conclusions and Recommendations

The Terms of reference and the Groups findings on each are outlined below:

1. To examine and report on the sequence of events leading up to the discovery of the dioxin contamination of Irish pork and beef.

Primary responsibility under legislation to produce safe feed and food rests with feed and food business operators. (Ref. 1.1)

The Feed Business Operator should have identified the risks associated with the direct drying process in his feed safety management system based on HACCP principles. (Ref. 1.1)

The Department failed to verify that the FBO was complying with the legislation in that the HACCP Plan was not fit for purpose, and the inspection of the premises was inadequate. The Feed Inspection system operated by the Department has since been developed to include an assessment of the HACCP as fit for purpose. (Ref. 1.5)

Carlow County Council failed to carry out necessary inspections of the premises and the Council should therefore review its inspection procedures to ensure compliance with Waste Management Regulations. (Ref. 1.7)

There needs to be more effective collaboration and coordination between the official authorities involved in registration / licensing and inspection of premises. (Ref. 1.8)

All commercial Feed Business Operators should be risk assessed and if defined as high risk they should be subjected to the same supervisory regime as the current approved plants. (Ref. 1.9)

2. To assess the actions taken by the relevant authorities leading up to the withdrawal of products from the market

There was no delay in the handling of the incident from 19th November and all of the actions taken were proportionate and prompt.

The tracing of the source of the positive PCB result in the pork fat to the animal feed and the onward tracing and impounding of the potentially contaminated feed was effective.

The transfer of the samples of feed and pork fat to the U.K. for dioxin testing was effected rapidly and the analysis was commenced straight away. Notwithstanding the fact that dioxin testing capability was unavailable in Ireland at that stage, no delay occurred. (Ref. 2.2 – 2.5)

The selection of the date of 1st September for the purpose of the recall of product was justified. (Ref. 2.10)

Feed Business Operators should have sufficient levels of “own checks” to meet their obligations under feed and food legislation. Sharing of results of samples by companies and agreeing a risk based testing strategy would prevent duplication and ensure a more co-ordinated approach and better value for the resources expended on laboratory testing. (Ref. 2.12)

The experience gained during this incident should be used to strengthen collaboration and cooperation between official agencies in the future. (Ref. 2.13)

The recall action taken by the relevant public authorities was swift and decisive and led to the immediate removal of all potential contaminated products from retail outlets and the replacement of this product in the market place, and on retail shelves, as quickly as possible with product which had come from pigs guaranteed not to have eaten the contaminated ration. The action taken in Ireland was supported by the positive response from the European Commission when it welcomed the approach taken by the Irish Authorities in managing this incident. (Ref. 2.14 – 2.15)

The total recall of product recommended by the FSAI was the most appropriate response because the damage would have been far more severe and lasting had any possibly contaminated products remained on sale to consumers. Public confidence was restored quickly because of the actions taken by the Authorities and the Irish industry. (Ref. 2.21)

3. In the light of experience gained in the incident to make recommendations on future policy in relation to food and feed safety controls.

In the light of changing risks and the dynamic nature of the food industry the Review Group considers that the deployment of resources of all the official agencies are reviewed to ensure that they are delivering maximum protection to public health and to the reputation of the Irish agri-food industry. Risk categorisation along all the food chain should be further developed so as to ensure

that the level, and intensity, of inspection, is appropriate and proportionate to the risk. The inspection regime should be sufficiently flexible to allow it to adapt to emerging risks in the industry. (Ref. 3.2)

Continuing Professional development should be in place for officials in enforcement agencies and the ongoing training of staff in the food industry should be a priority for the industry. (Ref. 3.2)

A Food & Feed Safety Advisory Forum involving both industry and regulators should be established by the FSAI. It should meet 2 –3 times a year to share information on emerging risks. (Ref. 3.3). Risks identified in international fora should be fully taken account of and subject to regular review with industry. (Ref. 3.8 and 3.9)

The remit of the Food Safety Authority of Ireland should be extended to include Animal Feed. In doing so, the elements of feed to be included in the service contract between the FSAI and the Department of Agriculture, Fisheries and Food should be identified and agreed between both bodies. (Ref. 3.5)

More attention should have been given by the Department to the risks associated with direct flame drying. (Ref. 3.8)

Legislation governing the direct drying of feed ingredients or animal feed should be pursued by Ireland at European level. (Ref. 3.11)

The sampling of imported animal feed should be subject to continual review. (Ref. 3.14)

Businesses should ensure that their labelling is as informative and accurate as possible and any incidents of misleading labelling should be reported to and continue to be followed up by the FSAI and its official agencies. (Ref. 3.17 and 3.18)

4. To address the responsibility of all food / feed business operators along the food chain from primary production to the point of sale to the consumer to ensure full compliance with the legislative requirements to produce safe food.

All Food and Feed Business Operators are obliged to comply with their legal responsibility under the Food and Feed Hygiene legislation. In particular, they have primary responsibility to ensure that safe feed and food is placed on the market. (Ref. 4.1)

Food and feed business operators should ensure that their staff receive adequate training on their responsibilities under food safety legislation and in the design and implementation of food/feed safety management systems based on HACCP principles. (Ref. 4.1)

Drying food for the production of animal feed must be regarded as a Critical Control Point within the feed safety management plans. (Ref. 4.1)

If a Feed Business Operator introduces changes in any stage of the production process, the Competent Authority should be notified and permission sought to include that practice in his/her licence and appropriate controls put in place. (Ref. 4.2)

The difficulty in the dioxin incident was not the traceability system as such but the huge logistical challenge involved in recalling product produced from pigs slaughtered over a prolonged period i.e. between the 1st September and 6th December. (Ref. 4.6)

All of the relevant agencies should urgently review the controls on oils especially waste oil to ensure that adequate systems are in put place by both the industry and the control authorities (4.12)

Appropriate controls on waste oil imported into Ireland for use as fuel should be put in place and if necessary further legislative measures should be enacted . (Ref. 4.12)

The Department of Agriculture, Fisheries and Food should rigorously enforce t he requirement for operators to get written assurances from fuel suppliers and to maintain delivery documentation for at least 12 months. (Ref. 4.13)

The traceability system operating in Ireland fully conforms to EU legislation and is of the same standard as systems in other countries but the development of improved product tracking systems for meat and meat products merit further consideration. (Ref. 4.4 – 4.7)

5. To look at how the relevant authorities and the food and feed business operators interact and to review their respective roles.

Communications between agencies, industry and consumers were both timely and informative. However the experience gained during the incident should be used to strengthen collaboration and communication for future situations. (Ref. 5.3 – 5.4)

The method of communication to inspection services at district level should be reviewed with a view to further strengthening communication mechanisms. (Ref. 5.5)

The Review Group has already recommended the establishment of the Food and Feed Advisory Forum to share information on emerging risks (ref. 3.3). It also believes that this Forum would be an appropriate vehicle to address further the collaboration and cooperation between the official agencies and the industry in the management of any future incidents. (Ref. 5.6)

6. To assess the manner in which any future food safety incidents can be managed so as to ensure consumer health is protected whilst minimising the economic impact.

The Review Group notes the crucial role of the F.S.A.I. in managing this incident. In that context it considers that all the consequences of the contemplated changes to the existing structure of the FSAI should be thoroughly evaluated to ensure the maintenance of the international credibility and independence of the Irish food safety infrastructure. (Ref. 6.3)

The protection of consumer health was rightly the overriding priority in the management of the dioxin contamination incident. (Ref. 6.4)

State financial assistance was provided because of the serious impact of the recall on the future viability of the industry and the necessity to ensure that the industry was in a position to effect the recall. (Ref. 6.4)

The question of financial guarantees / insurance should be pursued by Ireland at EU level. (Ref. 6.9)

The industry should consider the range of voluntary options open to them to reduce their financial exposure in the event of any future product recall of this type. This should also be considered in the context of “own checks” as referred to in Chapter 2. (Ref. 6.10)

There can be no guarantee for Exchequer support for the industry in the event of similar incidents in the future. (Ref. 6.11)

1. To examine and report on the sequence of events leading up to the discovery of the dioxin contamination of Irish pork and beef.

1.1 Rules governing the manufacture of food and feed are set out in the European Food and Feed Hygiene legislation, known as the Hygiene Package, which came into effect on 1st January 2006 (see Appendix 3). This package of legislation brought together, updated and consolidated earlier European food and feed safety legislation. It covers all food and feed business operators (FBOs) throughout the food chain from feed mills and primary producers to retailers. This legislation stipulates that the primary responsibility for ensuring that the food/feed produced is safe rests with each Food/Feed Business Operator along the food chain. The legislation also provides that operators, other than primary producers, are obliged to have in place a food/feed safety management programme based on the principles of the Hazard Analysis Critical Control Point (HACCP) system.⁴

1.2 The process of inspecting premises by the Department of Agriculture, Fisheries and Food under the new EU food and feed hygiene legislation began in 2006. The Department explained to the Group that initially the focus of inspections at feed premises, other than in feed mills using additives and medications, was on manufacturing procedures, traceability of product and labelling issues along with quality and safety issues. In 2006 and 2007 HACCP planning was a relatively new concept for FBO's and it was not in place in a large number of FBOs premises. The emphasis by the Department was on instruction and encouragement of these operators to put HACCP plans in place.

1.3 In the case of feed mills using additives and medications the HACCP plan was, from the outset, subject to a more thorough scrutiny by Department of Agriculture, Fisheries and Food officials because of the specific requirements of the Hygiene Package.

1.4 The Department of Agriculture, Fisheries and Food registered Millstream Power Ltd., Bunclody, Co. Wexford as a Feed Business Operator in March 2006 (Reg. No. IEWX1000456) under Statutory Instrument 910 of 2005 which transposed the new European Food and Feed Hygiene legislation. This company rented premises in Ballybrommell, Fenagh, Co. Carlow and

⁴ The primary requirement of HACCP is that the food and feed business operator clearly identifies risks, indicates the procedures for dealing with these risks and keeps records on the implementation of these procedures.

operated from there as Millstream Recycling Ltd. which was registered with a different number on 28th May 2008 (Reg. No IEWX236456). In accordance with EU legislation, animal feed production plants using certain feed additives and medications are required to be approved which includes a pre approval audit and annual audits rather than inspections. In this case the Feed Business Operator did not use these additives or medications so its operation was not required to be inspected prior to registration.

1.5 The Department's feed inspectorate carried out inspections in the plant in 2006 and 2007. A further inspection was scheduled for late 2008 but had not taken place when the incident occurred. The reports of these inspections noted that there was a HACCP plan in place. However the HACCP plan was not sufficiently comprehensive to address all potential hazards in the process and, most importantly, the direct flame drier was not identified as a risk in this plan. The Department failed to verify that the FBO was complying with the legislative requirements in that the feed safety management system was not fit for purpose. Since the incident, building from on-the-ground experience and from a background of a number of HACCP courses, the feed inspection system operated by the Department has been developed to include an assessment of whether the HACCP is fit for purpose.

1.6 Prior to the registration of the Millstream Power Ltd companies by the Department, Carlow County Council granted a waste management permit under the Waste Management (Permit) Regulation (S.I. 165/1998) to Millstream Power Ltd., in Ballybrommell, Fenagh, Co. Carlow on 26th February 2006⁵ to allow the facility to accept inert material. At that stage, the company dealt with surplus human food including waste bread and confectionery for conversion into animal feed mainly for the pig industry. A condition in granting this permit was that the Council should be advised of the introduction of any new equipment into the production process. The direct flame drier was not included in the permit. The permit also obliged the Feed Business Operator to produce an Annual Environmental Report by the 28th February of each year. The environmental reports for 2006 and 2007 were accepted as satisfactory by Carlow Co. Council but the Council informed the Review Group that the Operator failed to notify them of the use of the direct flame drier.

1.7 This facility was classified as a Class B installation, by Carlow Co. Council i.e. as a medium sized enterprise with lesser risk of environmental pollution. The Review Group noted that the Council should inspect such installations once a year but no inspections were carried out in 2006

⁵ The Waste Permit gives effect to the provision of: a) Council Directive 75/349/EEC of 16 June 1975 on the disposal of waste oils; b) Council Directive 75/442/EEC of 15 July 1975 on waste; c) Council Directive 80/68/EEC of 17 December 1979 on the protection of groundwater against pollution by certain dangerous substances and d) Council Directive 91/689/EEC of 12 December 1991 on hazardous waste.

or 2007. It was due for inspection during 2008, but this had not happened. The drying process was not a waste activity but the inspection by the County Council may have documented the presence of the dryer as a potential source of pollutants.

1.8 No evidence was presented of contact between the Department of Agriculture, Fisheries and Food and the County Council on their respective registration of these premises. The Review Group concluded that there needs to be more effective collaboration and coordination between the official authorities involved in registration / licensing and inspection of premises involved in feed or food production.

1.9 As referred to at 1.4 the Review Group noted a two-tier system exists for supervision by the Department of Agriculture, Fisheries and Food of the animal feed mills where some are registered and others are registered and approved, the latter receiving more thorough supervision. Under the Feed Hygiene legislation (Reg. 183/2005) 'approval' is required by certain feed business operators and is linked to the use of certain additives or pre-mixture of additives (medicated feeds). Other operators are simply required to register with the authorities as feed business operators. The difference between registration and approval is a requirement for a pre-approval inspection prior to start up of an 'approved' premises and more intense supervisory audits. The Review Group considers that all commercial Feed Business Operators should be risk assessed and if defined as high risk they should be subjected to the same supervisory regime as the current approved plants.

1.10 As indicated in the incident summary, it appears that the oil supplied to fuel the direct flame drier in the period prior to 1st September was contaminated. The failure by the FBO to adequately identify and address the risks and the inadequacies of the controls by the Department of Agriculture, Fisheries and Food and Carlow County Council was compounded by the fact that contaminated oil reached the plant and was used in this process. This indicated that there were weaknesses in the control systems for the importation and distribution and use of oil. This is dealt with in Chapter 4.

Conclusions and Recommendations:

Primary responsibility under legislation to produce safe feed and food rests with feed and food business operators. (Ref. 1.1)

The Feed Business Operator should have identified the risks associated with the direct drying process in his feed safety management system based on HACCP principles. (Ref. 1.1)

The Department failed to verify that the FBO was complying with the legislation in that the HACCP Plan was not fit for purpose, and the inspection of the premises was inadequate]. The Feed Inspection system operated by the Department has since been developed to include an assessment of the HACCP as fit for purpose. (Ref. 1.5)

Carlow County Council failed to carry out necessary inspections of the premises and the Council should therefore review its inspection procedures to ensure compliance with Waste Management Regulations. (Ref. 1.7)

There needs to be more effective collaboration and coordination between the official authorities involved in registration / licensing and inspection of premises. (Ref. 1.8)

All commercial Feed Business Operators should be risk assessed and if defined as high risk they should be subjected to the same supervisory regime as the current approved plants. (Ref. 1.9)

2. To assess the actions taken by the relevant authorities leading up to the withdrawal of products from the market

2.1 The Review Group considered the actions taken by the Department of Agriculture, Fisheries and Food, the Food Safety Authority of Ireland, the Department of Health and Children, the Health Services Executive and the Local Authorities between the first disclosure of a potential problem on 28th November and 6th December when the product withdrawal was initiated.

2.2 An officer from the Department of Agriculture, Fisheries and Food took routine samples under the National Residue Monitoring Programme, of pork fat from pigs slaughtered at a plant in Co. Longford on 19th November and submitted them for analysis at the Department's Pesticides Control Laboratory. The results of the analysis received on 28th November, indicated the presence of "marker" polychlorinated biphenols (PCBs)⁶. The source of the pork was traced back to a farm in Co. Cork. On 1st December, the Pesticide Control Laboratory confirmed this sample as positive for non-dioxin like 'marker' PCBs. On 2nd December, the Laboratory also confirmed that library samples of feed ingredient (dry bread) taken from this farm tested positive for non-dioxin like 'marker' PCBs and the source were traced to Millstream Recycling Ltd., Co. Carlow.

2.3 The Review Group noted that the detection of the PCBs/Dioxin came about as a result of an analysis of a routine pig fat sample, which was taken under Ireland's National Residues Monitoring Programme⁷. The pig farm was identified immediately, and the source of contamination was quickly traced to the Millstream Recycling plant which produced dry breadcrumb for use as animal feed. This was the first occasion since the national residues monitoring programme, incorporating PCB testing, was introduced that a positive result for marker PCBs was detected.

⁶ Polychlorinated biphenyls (PCBs) are a group of 209 different congeners, which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicological properties similar to dioxins and are therefore often termed as "dioxin-like PCBs". The other PCBs, known as "marker PCBs", do not exhibit dioxin-like toxicity but have lower and a different toxicological profile. The discovery of these marker PCBs in food and feed samples does not always mean that dioxins and dioxin-like PCBs will also be present. A congener is the term used to describe different configurations of similar chemical compounds.

⁷ The National Residues Monitoring Programme is one of two main programmes under the National Plan for Ireland. This programme monitors levels and trends in food and feed taking into account legal permissible levels. The second programme is the National Feed Inspection programme - see Appendix 4 for details.

2.4 On receipt of the first indicative PCB result on 28th November, there was immediate contact between the Department of Agriculture, Fisheries and Food and the Food Safety Authority of Ireland (FSAI) as required by the service contract⁸ and all information was shared as it emerged. The Review Group noted that there was close contact and full co-operation between the Department and the FSAI throughout the subsequent management of the incident. The time lag between the taking of the initial sample on 19th November and receipt of the analysis results on 28th November may seem inordinate but the Review Group noted that this was a routine monitoring sample, that the time period involved seven working days, and that it takes three days to complete the laboratory testing. In the period 28th November to 4th December additional animal feed samples were taken, the initial pork samples were confirmed positive for 'marker' PCBs, as were dry bread feed samples, which were traced to a registered surplus food re-cycling plant in Co. Carlow – Millstream Recycling Ltd. A listing of 48 farms receiving feed from that premises were identified and visited by inspectors from the Department of Agriculture, Fisheries and Food and feed was impounded at these sites and animal movements were restricted.

2.5 The Department of Agriculture, Fisheries and Food issued a press release (copy in Appendix 6) on the evening of 4th December drawing attention to the disclosure of marker PCBs in animal feed and the herd restrictions. The FSAI notified the EU Food and Feed Rapid Alert System (RASFF). This action served to bring the problem to the attention of the Dutch Authorities, who were investigating a contamination incident, and facilitated information sharing on this issue between the FSAI and the Dutch authorities. On receipt of information on 4th December that feed from Millstream Recycling Ltd., had been sent to Northern Ireland, the Northern Ireland authorities were advised through the normal contact point on 5th December.

2.6 Samples of feed from Millstream Recycling Ltd and library samples of feed dating back to July 2008 were submitted to the Department's Pesticide Control Laboratory for analysis on the 2nd and 3rd December respectively. On 2nd December, an official from the Department of Agriculture, Fisheries and Food brought samples of pork fat and feed to the Central Science Laboratory in York, as there was no Irish laboratory equipped to carry out tests for dioxins. On the afternoon of 6th December, the Central Science Laboratory in York confirmed the presence of dioxins in pork fat samples and animal feed (dry bread) at levels of 200pg/g and approximately 2,000pg/g

⁸ Currently the FSAI coordinates and oversees the enforcement of all food safety legislation in food businesses along the food chain from the farm gate forward. It performs its role through a series of service contracts with DAFF and other State Agencies such as the HSE and the FSAI audits these contractual arrangements.

respectively. These levels considerably exceeded the regulatory limits for dioxins in pork products and in animal feeds (1 pc/gram pig fat and 0.75 pc/gram animal feed) ⁹.

2.7 Following receipt of the positive dioxin result at 3.40pm on 6th December, consultations took place with the Taoiseach, the Minister for Health and Children, the Minister for Agriculture, Fisheries and Food, the Ministers of State for Food Safety and Food Promotion and senior Government officials. Because of commingling of product in secondary processing and the three-month time period involved, identifying the precise destination and distinguishing the contaminated product from the non-contaminated product in the market place was not readily possible. The FSAI therefore advised that all pork products from pigs slaughtered since 1st September should be removed from sale. This requirement was made on public health grounds to protect consumers from ongoing exposure to possibly contaminated Irish pork products both at home and abroad. The Review Group noted that there were discussions between the Food Safety Authority of Ireland, the Department of Agriculture, Fisheries and Food, the Department of Health and Children, the EU Commission and other European authorities prior to the decision to recall all products.

2.8 On 8th December 2008 a videoconference took place between the Irish Authorities, the European Commission and some Member States (including UK, France and Netherlands) and the European Food Safety Authority (EFSA). An outcome of this videoconference was a request by the European Commission to EFSA for advice on the risks to public health due to the consumption of pork from Ireland contaminated by dioxins. All risk assessments, including exposure data and consumption patterns, carried out by the FSAI were shared with the European Commission and the European Food Safety Authority to assist in this work. The Group noted the co-operation of the European Commission and the relevant authorities in other Member States, particularly the United Kingdom, the Netherlands and Germany during this incident.

2.9 The Group formed a view that using the laboratories in other Member States did not impact negatively on timescales. However if there was a wider incident involving other countries, Irish samples in foreign laboratories might not receive priority and it could have an adverse effect on the managing of an incident. The Review Group welcomed the fact that in February 2009, the State Laboratory initiated testing of food/feed for dioxins and is now the National Reference Laboratory for dioxin testing.

2.10 The basis for determining the period of contamination was as follows:

⁹ [Commission Regulation \(EC\) No 1881/2006 \(Section 5 of the Annex - point 5.7\)](#). The levels in pork fat are 1 pg/g (Sum of Dioxins) and 1.5 pg/g (Sum of dioxins and dioxin-like PCBs).

- (a) The FSAI was informed on 5th December by the Dutch Consumer Product Food Safety Authority (VWA) that a pork product with the same dioxin congener profile was found in a French processing plant in mid-October during routine “own checks” of pork loin which it had received from its parent company in Holland.
- (b) In addition, “own checks” monitoring in a pork processing plant in Belgium that belonged to the same Dutch company showed an increase in dioxin levels in composite fat derived from fat originating in several Member States from mid-September 2008.
- (c) The pattern of dioxin congeners detected in the pork products indicated that exposure to contaminated feed had been recent. In particular, the presence of certain congeners such as 2,4,6,7-TCDF and 1,2,3,7,8-PeCDF in the fat, along with the high level of dioxins, was indicative of recent exposure, since these congeners are considered to be less stable in pigs.

Therefore, as a precautionary measure, the date of 1st September was determined as the most appropriate date. Subsequent positive results from the testing of feed samples stored in Millstream Recycling supported this decision. Therefore the Review Group believes that the selection of this date was justified.

2.11 The implicated recycling plant was distributing contaminated feed ration from early September and a period of 3 months elapsed before the problem was identified. Although the National Residues Monitoring Programme¹⁰ identified the problem, by their very nature surveillance programmes are in place to monitor compliance, and the frequency of sampling means that low frequency of contamination may go undetected for long periods of time. This emphasises the importance for FBOs of having appropriate controls and own checks in place to ensure that they are meeting their legal responsibilities. Verification by the Department of Agriculture, Fisheries and Food of FBO controls are equally important if such incidents are to be prevented.

2.12 In relation to “own checks” many companies are carrying out such checks without communicating the results or their sampling strategy outside their company. The Review Group believes that sharing of company results and agreeing a risk based combined sampling plan would prevent duplication and ensure a more co-ordinated approach and better value for the resources expended on laboratory testing. This is considered further at 6.11.

¹⁰ See also par. 2.3

2.13 The Review Group acknowledges that satisfactory consultation and cooperation took place between Departments and Agencies in the management of this incident. The experience gained should be used on an ongoing basis to strengthen collaboration and co-operation in the future.

2.14 The Review Group also noted that while the full recall of pork product was a very large scale operation, the prompt and decisive action taken on 6th December to implement a recall of all pork and pork products from pigs slaughtered in Ireland since 1st September paved the way for new and existing pork products, guaranteed not to have been sourced from implicated herds to be on the market by the following Wednesday 10th December.

2.15 The Review Group also noted the comments of the European Commission in its 2008 Annual Report on the Rapid Alert System for Food and Feed (RASFF) in relation to this specific dioxin incident. It states that the system triggered a large and impressive trace-and-recall operation in the EU and Third Countries involving as many as 54 countries. It also states that based on the statement from EFSA and the information provided by the delegation of Ireland and affected Member States of the European Union, the EU Standing Committee on the Food Chain and Animal Health agreed on 10th December on common risk management measures, ensuring a high level of consumer protection in the European Union and third countries.

2.16 The overall view of the Review Group is that the monitoring systems in place in Ireland worked to the extent that the dioxin problem was detected as part of routine sampling under the National Residues Monitoring Programme (described in Appendix 4). However, the time that elapsed before the contamination was detected ultimately necessitated a major product recall at very considerable cost to the pork industry at home and abroad (both in terms of sales of product and consumer confidence) and at very considerable financial cost to the State. While arguments have been made that some product could have been excluded from the recall, the Review Group considered that this may have led to uncertainty and confusion in the marketplace. The full recall had the advantage of drawing a line under the incident, maintaining consumer confidence and facilitating a restoration of product onto shelves within a matter of days. The question of limiting industry exposure to large product recalls is considered further in section 4.

2.17 Over the past ten years, the FSAI has developed comprehensive databases on food consumption patterns in Ireland by way of research projects which were funded by the Department of Agriculture, Fisheries and Food has funded into the development of. This data allowed the FSAI to rapidly determine the level of pork consumption and estimate the likely exposure to contaminated product and hence the consequent risk posed by this dioxin incident. Mathematical modelling was used to calculate potential exposure of the Irish population to dioxins

from consumption of contaminated pork. These calculations were based on the known range of intakes of fat from pork and pork products combined with information on the range of levels of dioxins contamination and a worst case scenario assumption was made that all products available that might have been consumed were contaminated.

2.18 The regulatory limits for dioxins and related contaminants are based on a lifetime exposure (40 years) and considerable safety margins are built into the levels set in regulations. The conclusion of the FSAI's risk assessment was that ongoing exposure would put consumers' health at risk. Therefore, a recall was necessary if this was to be prevented. Furthermore, it is illegal to allow products outside the regulatory limits to remain on the market.

2.19 A crucial factor for determining risks to public health in a dioxin incident such as this is to calculate the increase in the body-burden resulting from the consumption of contaminated foods. EFSA calculated that during the limited timescale of the incident if every bit of pork consumed was contaminated at the highest level, the body-burden of dioxin would increase by 10%. EFSA concluded that this increase was not of concern for human health. However EFSA was only able to reach this conclusion because exposure to these high levels was short lived due to the effective measures taken by the Irish authorities to remove the source thus prevent ongoing exposure.

2.20 Further information on product recall and the Rapid Alert System for Food and Feed (RASFF) is included in Appendix 8.

2.21 The Review Group concludes, that in the circumstances, the total recall of product was the most effective and appropriate response. The action taken demonstrated how seriously the official agencies and the Irish industry address any question over the safety of Irish food products. A similar dioxin contamination incident in 1999 in Belgium was handled quite differently. There was no initial recall, and ultimately the EU Commission had to intervene and introduce safeguard measures which included a global recall of certain European products of animal origin with severe disruption of the market and a decrease in consumer confidence. Had the Irish authorities not acted as they did, the European Commission would have intervened and may have imposed similar safeguard measures on Irish products.

2.22 While there were clearly significant financial consequences to the requirement to recall all pork and pork products, the Group believes that the damage would have been far more severe and long lasting if it had been decided to allow any possibility of contaminated products remaining on sale to consumers.

2.23 The actions taken in Ireland allowed Irish pork to be back on the shelves in one week. The full co-operation of those involved in the production, processing, and retail of pork products was critical to the success of the recall. Public confidence was restored quickly as a direct consequence of these decisive and timely follow up actions taken by the responsible public authorities and fully supported by the production, processing and retail sectors.

2.24 The effectiveness of the recall was as a consequence of the high degree of collaboration and co-operation achieved between all of the State agencies, including the FSAI, the Department of Agriculture, Fisheries and Food, the Department of Health and Children, Bord Bia, the Environmental Health Service of the Health Service Executive and the Local Authority Veterinary Service and the industry producers, processors and retailers concerned. The Review Group is also of the view that the introduction of a specific Bord Bia label played an important role in assuring customers of the safety of the pork products that went on sale after the recall was introduced.

Conclusions and Recommendations:

There was no delay in the handling of the incident from 19th November and all of the actions taken were proportionate and prompt.

The tracing of the source of the positive PCB result in the pork fat to the animal feed and the onward tracing and impounding of the potentially contaminated feed was effective.

The transfer of the samples of feed and pork fat to the U.K. for dioxin testing was effected rapidly and the analysis was commenced straight away. Notwithstanding the fact that dioxin testing capability was unavailable in Ireland at that stage, no delay occurred. (Ref. 2.2 – 2.5)

The selection of the date of 1st September for the purpose of the recall of product was justified. (Ref. 2.10)

Feed Business Operators should have sufficient levels of “own checks” to meet their obligations under feed and food legislation. Sharing of results of samples by companies and agreeing a risk based testing strategy would prevent duplication and ensure a more co-ordinated approach and better value for the resources expended on laboratory testing. (Ref. 2.12)

The experience gained during this incident should be used to strengthen collaboration and cooperation between official agencies in the future. (Ref. 2.13)

The recall action taken by the relevant public authorities was swift and decisive and led to the immediate removal of all potential contaminated products from retail outlets and the replacement of this product in the market place , and on retail shelves, as quickly as possible with product which had come from pigs guaranteed not to have eaten the contaminated ration. The action taken in Ireland was supported by the positive response from the European Commission when it welcomed the approach taken by the Irish Authorities in managing this incident. (Ref. 2.14 – 2.15)

The total recall of product recommended by the FSAI was the most appropriate r esponse because the damage would have been far more severe and lasting had any possibly contaminated products remained on sale to consumers. Public confidence was restored quickly because of the actions taken by the Authorities and the Irish industry. (Ref. 2.21)

3. In the light of experience gained in the incident to make recommendations on future policy in relation to food and feed safety controls.

Monitoring of the Food and Feed Chain

3.1 The annual total operational cost of the national food inspection service comes to €150 million involving a complement of some 2,300¹¹ staff. Some 45,000 food premises registered in Ireland are subject to controls under the Food and Feed Hygiene legislation. The resources deployed on food controls have regard to the imperative of the protection of human health. Irish food is exported to over 140 markets worldwide and that the Irish food industry generates €20 billion direct output and also impacts on the hospitality and tourist industry. The Review Group considers, therefore that expenditure of €150 million, which is less than 1% of total value of the output of the industry, represents a very necessary and worthwhile investment in the Irish food industry but the national food safety inspectorate has to be both efficient and effective and responsive to the changing profile of the Irish industry and the associated risk and to emerging threats.

3.2 Given the increasing complexity and dynamic nature of the food chain there is a necessity to ensure that there are regular comprehensive risk assessments of the entire food chain. It is vital that risk assessment is used to determine frequency and intensity of inspections, that these are proportionate to the risk involved and that the deployment of resources of all official agencies is reviewed to ensure that they are delivering maximum protection to public health and to the reputation of the food industry. The continuous professional development of staff enforcing food and feed legislation should be prioritised to maintain a modern and effective national inspectorate that can adapt to changes in both the industry profile and associated risks. Ongoing training of staff in the food industry should equally be a priority for the industry.

3.3 New risks in the food chain will inevitably arise and it is vital that attention is given to scanning the horizon for the emergence of such risks. In this regard the Review Group noted that there are a number of international networks focused on possible emerging risks. For example, the FSAI is involved with a number of international bodies including the European Food Safety Authority (EFSA). The World Health Organisation has a similar group – INFOSAN¹² which is an international network of food safety authorities. The Department of Agriculture, Fisheries and

¹¹ Source: FASI Annual Report for 2007

¹² INFOSAN International Food Safety Authorities Network

Food is involved at EU level and with Codex Alimentarius¹³ in this respect. The Review Group believes that there should be a mechanism for the sharing of information being available in these and other fora and at industry level on emerging risks between control agencies and food and feed operators. It recommends, therefore, the establishment of a Food and Feed Advisory Forum involving both industry and regulators which should meet 2 – 3 times a year.

3.4 The food chain in Ireland is supervised by many different official bodies and their activities are co-ordinated by the FSAI through a system of service contracts. These contracts stipulate a level and intensity of supervision which the FSAI audits. The service contract arrangements govern the food chain from the farm gate forward. The organisational arrangements, based on a service contract between the Department of Agriculture, Fisheries and Food and the FSAI worked well in dealing with the incident. While the organisational arrangements, based on a service contract between the Department of Agriculture, Fisheries and Food and the FSAI worked well in dealing with the incident, this service contract does not currently encompass animal feedingstuffs.

3.5 The Review Group recommends that the service contract between the FSAI and the Department should be expanded to cover feedingstuffs. The elements of the feed sector to be included in the service contract between the FSAI and the Department of Agriculture, Fisheries and Food should be identified and agreed between both parties. This would offer the same advantage of independent oversight of the Department's feed control functions similar to that in place in the case of foodstuffs. It would help ensure consistency of standards across the feed and food chain especially taking account of the impact of feed safety on the entire food chain and would be in line with the Food and Feed Hygiene legislation.

Direct drying of Animal Feed

3.6 During the deliberations of the Review Group it became clear that various authorities¹⁴ prior to the incident in Ireland had considered the issue of possible dioxin contamination of feedingstuffs arising from direct drying. The Group's attention was drawn to a European Commission paper dated 6th November 2000. This paper states among other things that *"Feed, food producing animals and finally food products of animal origin may become contaminated with dioxins through*

¹³ The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Programme. The main purposes of this Programme are protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations.

¹⁴ The Dutch Animal Feed Product Board (November 2004) on the drying processes for animal feed materials and a CODEX paper (CAC/RCP 62-2006) on a Code of Practice for the prevention and reduction of dioxin in food and feed.

e.g. deposition of emissions from various sources on farmland, burning of raw material containing potential dioxin sources for direct drying, blending of feedingstuffs with dioxin containing products and/or raw materials, application of contaminated pesticides, detergents, disinfectants etc., contact with / consumption of wooden materials treated with wood preservatives, and application of sewage sludge on fields".

3.7 The Review Group also noted that Germany introduced national legislation requiring the "authorisation" of direct drying processes in 2003 following a dioxin contamination incident which arose from the use of treated timber in a direct drying operation. On 10th February 2003, the European Commission published Recommendation EC/91/2003¹⁵ which dealt with a number of issues in relation to feed risks including the risks of dioxin contamination of animal feed from direct flame drying. This recommended inter alia that Member States pay particular attention to animal feed manufacturing processes involving flame drying of feeding stuffs. In November 2004 the Dutch Animal Feed Product Board highlighted driers as a risk to be managed as did a Codex Alimentarius paper in 2006.

3.8 The Department of Agriculture, Fisheries and Food was aware of these publications and indicated that it had at the time adapted its sampling strategy in the light of experience and in the context of these developments. For example, sampling and testing for dioxins was incorporated into the feed inspection programme from 2003 on foot of the Commission recommendation. Furthermore, particular emphasis was placed on inspecting drying of grass meal at the single plant in the country involved with this activity using coal in a direct drying system. The Department also placed additional focus on minerals, including trace elements; pre-mixtures and mineral mixtures containing trace elements from certain industrial processes which have been shown to contain dioxins from time to time. Testing for dioxin in 2008 was carried out on samples of milk-based products and seaweed in the light of references in the above publications and/or experience of potential problem areas. Emphasis was also placed on testing of fishmeal which had been shown to naturally contain elevated levels of dioxins and dioxin-like PCB's. The Review Group believes, however that more attention should have been given by the Department to the risks associated with direct flame drying.

3.9 While the Review Group noted that there is no European legislation specifically governing the use of oil in direct flame drying of animal feed the general requirement for feed businesses operators to identify hazards associated with their production processes and to identify risks posed by these hazards is clearly established by the obligation to have feed safety management

¹⁵ [Commission Recommendation EC/91/2003 of 10 February 2003 on the coordinated inspection programme in the field of animal nutrition for the year 2003 in accordance with Council Directive 95/53/EC](#)

systems in place based on the HACCP principles. It is, therefore, primarily the responsibility of the feed business operator to identify the risks associated with the fuel used in the drying of animal feed and ensure that such risks are controlled and monitored throughout the production process.

3.10 Since the incident, the Department of Agriculture, Fisheries and Food has instructed Feed Business Operators that the only fuels that should be used for the process of direct drying are gas, diesel (as used in cars or tractors) or kerosene.

3.11 It is understood that the EU Commission was to examine the control of direct flame drying after Regulation EC/183/2005 was introduced. However, this did not occur. It is understood that, as a result of the Irish dioxin crisis, the Commission is now re-examining the matter. The Review Group welcomes this and would wish to see the EU Commission initiate legislation setting out the specific types of fuel that can be used in direct flame drying burners (see section on Oil in part 4).

Imports of Feed

3.12 The attention of the Review Group was drawn to the issue of the large quantity of imported feed into Ireland. Feed is globally distributed and Member States at the point of entry into the EU are required to monitor shipments and once cleared the cargo can move freely in the single market. Therefore, Ireland and other EU member states are inter dependent on the controls operating in each individual member state on imported feed. Official Feed controls within the EU and outside it are audited by the EU Food and Veterinary Office.

3.13 As part of its strategy to eliminate BSE from the national herd, Ireland was permitted by the EU to introduce a control mechanism that required all bulk imports of animal feed and consignments of feed additives to be subject to sampling and analysis at point of import. This regime was introduced in 2001. For the period 2001 to 2007 samples were taken from each of the 800 plus consignments of animal feed that came through Irish ports annually. All samples were analysed for the presence of animal proteins (prohibited under BSE legislation) and a large percentage of the samples were also analysed for composition, heavy metals, undesirable substances, ash and protein content.

3.14 Following a review of the risks involved and the reducing number of BSE cases, the Department of Agriculture, Fisheries and Food took the decision in 2007 to reduce the level of sampling on whole grains of EU origin and, in 2009, on processed feed of EU origin given that these ingredients were now less likely to be carriers of constituents of animal origin. The Review Group was informed that following the dioxin incident the reduction in the sampling of imports for

bone spicules has been taken up by increased sampling of home produced animal feed, particularly grains which have undergone a drying process. Because of the level of trade involved additional focus has been placed on feed products coming from Northern Ireland with increased sampling for dioxins being undertaken on surplus food products imported from that jurisdiction since this incident.

BY-PRODUCTS FROM HUMAN FOOD

3.15 A survey of various food operators was carried out by the Department of Agriculture, Fisheries and Food in 2004 in order to determine the type of by-products and surplus food products that are in use in animal nutrition. Currently there are 99 food manufacturers that are also registered with the Department as feed business operators supplying food by-products or surplus food products as animal feed. The range of food by-product used in animal feed includes spent grains from the brewing, distilling and biofuel industries and milk products such as whey. The type of surplus food products used is principally bread products from bakeries/pizza manufacturers, biscuits, crisps and chocolate. Surplus food material is channelled to animal feed primarily because it does not meet food market specifications due to size, shape or colour etc.

3.16 There are two food recyclers registered with the Department of Agriculture, Fisheries and Food. In both cases they take surplus food material from food manufacturers (not retail waste) into their premises and either without further processing or following simple processing such as de-packaging, deliver the products to farms. The Group notes that, following the dioxin incident; food recyclers who channel product to animal feed have been selected for one audit and four unannounced inspections annually.

FOOD LABELLING

3.17 This incident brought to light the need to ensure compliance with EU food labelling legislation which states, among other things, that country of origin marking is required in cases where failure to provide such information would be likely to mislead the consumer to a material degree. It has been suggested to the Group that there were instances where consumers were misled as to the origin of product through names or imagery on labels or in advertisements. Such instances could impede identification of product in the market place or in consumer's homes in the event of a recall being necessary and, in certain circumstances, they would be in breach of labelling regulations. The Group emphasised the importance of FBOs complying with the food labelling legislation. They recommended that reports of breaches of the labelling regulations should continue to be followed up by the FSAI which is charged with the enforcement of the legislation.

3.18 There were further instances of confusion on which products were Irish; this is to a large extent reflected in the complexity of secondary processing with commingling of product at home and abroad. The Review Group believes that this situation could be improved by Food Business Operators ensuring that their labelling is as informative and accurate as possible.

Conclusions and Recommendations:

In the light of changing risks and the dynamic nature of the food industry the Review Group considers that the deployment of resources of all the official agencies are reviewed to ensure that they are delivering maximum protection to public health and to the reputation of the Irish agri-food industry. Risk categorisation along all the food chain should be further developed so as to ensure that the level, and intensity, of inspection, is appropriate and proportionate to the risk. The inspection regime should be sufficiently flexible to allow it to adapt to emerging risks in the industry. (Ref. 3.2)

Continuing Professional development should be in place for officials in enforcement agencies and the ongoing training of staff in the food industry should be a priority for the industry. (Ref. 3.2)

A Food & Feed Safety Advisory Forum involving both industry and regulators should be established by the FSAI. It should meet 2 –3 times a year to share information on emerging risks. (Ref. 3.3). Risks identified in international fora should be fully taken account of and subject to regular review with industry. (Ref. 3.8 and 3.9)

The remit of the Food Safety Authority of Ireland should be extended to include Animal Feed. In doing so, the elements of feed to be included in the service contract between the FSAI and the Department of Agriculture, Fisheries and Food should be identified and agreed between both bodies. (Ref. 3.5)

More attention should have been given by the Department to the risks associated with direct flame drying. (Ref. 3.8)

Legislation governing the direct drying of feed ingredients or animal feed should be pursued by Ireland at European level. (Ref. 3.11)

The sampling of imported animal feed should be subject to continual review. (Ref. 3.14)

Businesses should ensure that their labelling is as informative and accurate as possible and any incidents of misleading labelling should be reported to and continue to be followed up by the FSAI and its official agencies. (Ref. 3.17 and 3.18)

4. To address the responsibility of all food / feed business operators along the food chain from primary production to the point of sale to the consumer to ensure full compliance with the legislative requirements to produce safe food.

Responsibilities of Food and Feed Business Operators

4.1 The Food and Feed Hygiene regulations place the primary responsibility for the safety of food on food/feed business operators along the entire food chain. The Review Group is of the view that not all food and feed operators are sufficiently aware of the requirements of these Regulations and the actions required under that legislation as described in Appendix 3. As already pointed out, Food and Feed Business Operators are obliged to have food/feed safety management systems based on the principles of the HACCP in place. These should be detailed and constantly assessed, reviewed and updated to take account of any changed practices or new knowledge. In this specific instance, as referred to in paragraph 1.7 above the feed business operator should have identified the drying of food for animal feed as a critical control point. The Review Group considers that there is an urgent need for all feed businesses operators to ensure that they are fully aware of the legislative requirements and that they provide training to their staff in the design and implementation of feed safety management systems based on HACCP principles.

4.2 The Review Group noted that Millstream Recycling Ltd contacted the Department of Agriculture, Fisheries and Food about the use of vegetable oil for the purpose of drying food and was informed that this was acceptable. However, the Review Group was provided with no evidence that the FBO advised the Department of a change from the use of vegetable oil to mineral oil. All the feed business operators must comply with the conditions of the authorisation of the Competent Authorities. If changes are introduced to their process, the Competent Authority should be notified and permission sought to include that practice in his/her licence and appropriate controls should be put in place.

4.3 The failure of the FBO to recognise the risk associated with the direct flame drier was compounded by the fact that he received oil illegally contaminated with transformer oil, how this occurred is the subject of ongoing Garda investigation .

Traceability

4.4 Regulation (EC) No. 178 of 2002, which sets out the general principles and requirements of EU food law, stipulates among other things that food business operators at all stages of production, processing and distribution in relation to the operations under their control must ensure that they satisfy the requirements of food law. Specifically in regard to traceability, the regulations require that the operator at each and every stage in the food chain must be able to identify the source of its inputs as well as having details of the first recipient of its output. This is commonly referred to as the “one step forward one step backward” traceability system.

4.5 A detailed description of the traceability system for pigs and pigmeat in operation in Ireland is provided in Appendix 5. The Group found that the traceability system operating in Ireland fully conforms to EU legislation and is of the same standard as systems in other countries

4.6 The difficulty in the dioxin incident was not the traceability system as such but the huge logistical challenge involved in recalling product produced from pigs slaughtered over a prolonged period i.e. between the 1st September and 6th December. Having regard to the utilisation of pigmeat as an ingredient in a vast range of products, commingling of product from different processors in secondary processing and the volume of production involved, the Review Group concluded that it would have been impossible to readily isolate and specifically recall pig meat from pigs from the 10 implicated producers only.

4.7 The Review Group accepts that there are challenges to implementing a more complex traceability system in the pigmeat sector. However, the development of improved product tracking systems using modern information processes and genetic technology merits further consideration in the context of processors limiting their exposure to possible product recalls. This is considered further in Chapter 6.

Oil

4.8 The circumstances surrounding the importation and delivery of the contaminated oil to the Millstream plant is the subject of investigations by the Gardaí and the Northern Ireland authorities.

4.9 Laboratory tests conducted by the EPA showed that the oil used in the burner at the Millstream plant was contaminated with PCBs. The composition of the PCBs found in the contaminated oil would indicate that transformer oil was the source of the contamination.

4.10 The disposal of waste oil is controlled under the Waste Management Act 1996 and a number of Statutory Instruments made under that Act. The control of the use and disposal of waste oil is supervised by licensing and permitting arrangements operated by the Environmental Protection Agency and the Local Authorities. In the case of imported waste oil Dublin City Council (the National Transfrontier Shipment Office) is the Competent Authority in respect of import, export and transit of waste, including waste oil in Ireland. The Group understands that the Council did not receive any application for consent to import oil for use at the Millstream plant. The regulations governing disposal of waste oil specify that the only legal use of waste oil is as a fuel in asphalt plants in the road surfacing industry.

4.11 In the particular case of waste oil from transformers the ESB has extensive procedures in place for the disposal of such oil. These include pre-disposal checks for PCBs and the use of specialist firms for the disposal of oil found to have in excess of the legal threshold of PCBs. As is the case with other waste oils waste transformer oil is not fit for use in flame driers used in feed manufacturing.

4.12 The Review Group considers that all of the relevant agencies should urgently review the controls on oils especially waste oil to ensure that adequate systems are in place to ensure full compliance with the law by both the industry and the control authorities. If necessary further legislative measures should be enacted and procedural and organisational arrangements tightened up to ensure that all waste oil products, including imports, are properly regulated and controlled in this State.

4.13 There is no specific European legislation governing the use of oil as a fuel for direct flame driers used in the processing of animal feed. The Department of Agriculture, Fisheries and Food is examining the feasibility of introducing national legislation. Nevertheless EU Food and Feed Safety legislation already places the responsibility on all operators to ensure that they are producing safe products and that their production methods are safe. The Group therefore emphasises that it is the responsibility of the operator to identify the risks associated with the fuel used in the drying of animal feed. Since this incident occurred, the Department of Agriculture, Fisheries and Food has advised Feed Business Operators that only gas, diesel or kerosene should be used for the purpose of direct drying of feed, and that their HAACP must address this issue. The Group notes that the Department now requires each commercial Feed Business Operator and each farmer drying grain / feed to get written assurances from suppliers that the fuel supplied is of a suitable fuel type and grade, and is fit for purpose. The Feed Business operator must also declare that the fuel is used in drying equipment which is designed and

maintained to ensure the safety and quality of the feed produced. Each delivery of fuel for use in direct flame driers shall have the grade of oil clearly indicated on the delivery documentation and records shall be maintained for a period of at least twelve months. The Group recommends that this requirement be rigorously enforced by the Department's inspectors.

Conclusions and Recommendations:

All Food and Feed Business Operators are obliged to comply with their legal responsibility under the Food and Feed Hygiene legislation. In particular, they have primary responsibility to ensure that safe feed and food is placed on the market. (Ref. 4.1)

Food and feed business operators should ensure that their staff receive adequate training on their responsibilities under food safety legislation and in the design and implementation of food/feed safety management systems based on HACCP principles. (Ref. 4.1)

Drying food for the production of animal feed must be regarded as a Critical Control Point within the feed safety management plans. (Ref. 4.1)

If a Feed Business Operator introduces changes in any stage of the production process, the Competent Authority should be notified and permission sought to include that practice in his/her licence and appropriate controls put in place. (Ref. 4.2)

The difficulty in the dioxin incident was not the traceability system as such but the huge logistical challenge involved in recalling product produced from pigs slaughtered over a prolonged period i.e. between the 1st September and 6th December. (Ref. 4.6)

All of the relevant agencies should urgently review the controls on oils especially waste oil to ensure that adequate systems are in place by both the industry and the control authorities (4.12)

Appropriate controls on waste oil imported into Ireland for use as fuel should be put in place and if necessary further legislative measures should be enacted. (Ref. 4.12)

The Department of Agriculture, Fisheries and Food should rigorously enforce the requirement for operators to get written assurances from fuel suppliers and to maintain delivery documentation for at least 12 months. (Ref. 4.13)

The traceability system operating in Ireland fully conforms to EU legislation and is of the same standard as systems in other countries but the development of improved product tracking systems for meat and meat products merit further consideration. (Ref. 4.4 – 4.7)

5. To look at how the relevant authorities and the food and feed business operators interact and to review their respective roles.

5.1 The Department of Agriculture, Fisheries and Food was centrally involved from the very beginning of this incident as the positive sample taken at an Abattoir in Co. Longford was identified under the National Residue Monitoring Programme which is operated by that Department under service contract to the FSAI. In the early stages the Department of Agriculture, Fisheries and Food was leading the incident on the ground as the key matters to be clarified and proofs to be gathered were on-farm and feed related. The FSAI was notified immediately of the initial positive result and worked closely with the Department of Health and Children and the Department of Agriculture, Fisheries and Food from the outset. All actions taken were taken in the context of the possible public health implications arising. The lead organisations in the various phases of the incident are indicated below:

Issue	Lead	Time
Animal Feed	Dept. Agriculture, Fisheries & Food (FSAI)	19 th November -----
Food Safety	FSAI and Dept. Health & Children	4 th December -----
Market recovery	Dept. Agriculture, Fisheries & Food and Bord Bia (FSAI)	10 th December -----

Overall once the problem was identified the Review Group considers that the organisational response was effective with good co-ordination and communication between the relevant authorities within Ireland. The FSAI and the Department of Agriculture, Fisheries and Food were also in contact with the EU Commission, EFSA and authorities in other Member States including Northern Ireland at various stages throughout the incident.

5.2 The Northern Ireland Assembly expressed concern about a perceived time lag between the Irish Authorities becoming aware of the situation and the Northern Authorities being informed. The Review Group noted that on the evening of 3rd December the Feed Business Operator

concerned provided the Department of Agriculture, Fisheries and Food with an initial list of 8 customers covering 10 farms. None of these were located in Northern Ireland. During the course of the 4th December the operator provided information on additional customers and this was collated by the Department that evening. It transpired that some of the potentially contaminated feed was delivered to farms in Northern Ireland. This information was sent to the Department of Agriculture and Rural Affairs Northern Ireland on 5th December. The Review Group noted that the FSAI also informed the Food Standards Agency UK of the emerging incident on 4th December. The Food Standards Agency UK and the Food Standards Agency NI were also directly advised by the FSAI on Saturday 6th December.

5.3 Notwithstanding the complexity of the toxicological information on dioxins the Group found that the communication of information to the public was both timely and informative. The FSAI played a major role in advising and assuring consumers. Once the decision to recall all Irish pork and bacon products was taken, the Department of Agriculture, Fisheries and Food immediately contacted the meat distributors, processors, retailers and producers.

5.4 As the key Departments and agencies were working closely together at a central level from the beginning, the information was co-ordinated correctly and made available as the situation evolved, to the inspectorates and to the general public and key stakeholder groups in an efficient and effective manner.

5.5 The Local Authority Veterinary Service and the HSE Environmental Health Service were responsible for communicating with the retail and some of the wholesale outlets on the front line. While information was getting through to these inspectorates, some of them reported that as circumstances changed there was a degree of confusion at local level. The Review Group recommends that in such situations the method of communication to inspection services at district level be reviewed with a view to further strengthening communication mechanisms.

5.6 Once the need for the recall was identified and the decision announced there was intensive consultation with processors and retailers. Contact was maintained for the duration of the incident. With a view to preventing any such future incidents, it is important that there is a forum to discuss preventative strategies

Conclusions and Recommendations

Communications between agencies, industry and consumers were both timely and informative. However the experience gained during the incident should be used to strengthen

collaboration and communication for future situations. (Ref. 5.3 – 5.4)

The method of communication to inspection services at district level should be reviewed with a view to further strengthening communication mechanisms. (Ref. 5.5)

The Review Group has already recommended the establishment of the Food and Feed Advisory Forum to share information on emerging risks (ref. 3.3). It also believes that this Forum would be an appropriate vehicle to address further the collaboration and cooperation between the official agencies and the industry in the management of any future incidents. (Ref. 5.6)

6. To assess the manner in which any future food safety incidents can be managed so as to ensure consumer health is protected whilst minimising the economic impact.

6.1 Although the Group considers that the organisational response was effective in dealing with an unforeseen incident from the point of disclosure of the contamination onwards, the capacity, structures and practices need to be in place to minimise the likelihood of such incidents occurring in the first place and to protect public health and the reputation of the Irish food and feed industry both at home and abroad.

6.2 The independent role of the Food Safety Authority of Ireland proved to be critical in assessing and communicating the risk to public health, in providing reassurance on the controls and measures taken to safeguard public health and in coordinating the operations of the various authorities involved in managing the incident.

6.3 The Group expressed the view that the statutory independence and consumer protection focus of the FSAI should be protected and retained. The FSAI has built up credibility with Irish citizens, other EU national food agencies, the EFSA and the European Commission and the regulatory bodies in other jurisdictions. In addition, many countries within and outside of the EU have replicated the Irish model. Openness and transparency have been paramount for the FSAI since its creation as an independent, science based, consumer protection agency and its credibility nationally and internationally stems from this. The role of the FSAI and the awareness of Irish food safety regulatory system has been further increased both nationally and internationally by the publicity associated with this incident. The Report of the Oireachtas Joint Committee on Agriculture, Fisheries and Food recommended the reversal of the budget proposal to merge of the FSAI, the Irish Medicines Board and the Office of Tobacco Control as it could have the effect of diluting the FSAI's current single focus as an independent Agency focussed on consumer protection. In the light of the benefits demonstrated in this instance of having the FSAI undertake risk assessments, communicate risk to citizens and liaise with other international agencies the Review Group considers that all the consequences of the contemplated changes to the existing structure should be thoroughly evaluated to ensure the maintenance of the international credibility and independence of the Irish food safety infrastructure.

Arrangements for financial assistance

6.4 The protection of consumer health was rightly the overriding priority in the management of the dioxin contamination incident. However, the incident did give rise to very significant cost to the Exchequer. The Review Group was informed that the justification for State financial assistance in this particular circumstance was because of the serious impact of the recall on the future viability of the industry and the necessity to ensure that the industry was in a position to effect the recall. It was noted that this was a support measure and not a compensation package. Details of the scheme of financial assistance are provided at Appendix 7.

6.5 Following the announcement of the product recall, pig processing ceased in Ireland and the jobs of many employees in direct and indirect industries were suspended and/or at risk. Pigs were being held on farms, which would have caused serious economic and animal welfare consequences unless processing recommenced without delay. The threat to the survival of the Irish pig meat processors as a result of the contamination incident was considered to be real and immediate. If there had been no product recall when the results of the tests were announced, it is likely that the markets for Irish pig meat products would have collapsed.

6.6 The decision by the Irish authorities to provide a financial facility to the pigmeat sector was taken to ensure the rapid and secure disposal of eligible product in order to enable normal pig meat processing operations to resume and to bring stability to the sector. The fund was intended to provide financial assistance towards (a) the cost of removing eligible product from the market that may have originated from animals deemed unfit for the food chain due to having been exposed to, or suspected of being exposed to contaminated animal feed, and the subsequent rendering/destruction of that product; and (b) payments to producers in respect of pigs and cattle that were compulsorily slaughtered.

6.7 The European Commission considered the aid involved to be compatible with the EC Treaty. In its decision, the Commission stated that the facts on which the Irish authorities based the aid measure were a consequence of a situation that can be qualified as an extraordinary event in the meaning of Article 87 (2) (b) of the EC Treaty. The Commission noted the necessity to avoid consumer confidence crisis and the associated adverse consequences for the producers and processors, as well as the extent of the recall measures and the fact that the contamination was caused at an entirely different level (the feed business operator) than the beneficiaries of the scheme.

6.8 The Review Group noted the statement by the European Council in the conclusions of its meeting of 11-12 December 2008: *“The European Council expresses its support to the efforts*

deployed by Ireland to deal with the pigmeat situation as well as the precautionary measures it has speedily adopted. It invites the Commission to support the farmers and the slaughterhouse in Ireland by co-financing the measures envisaging to recall from the market the concerned animals and products". As a result of these conclusions, Commission Regulation (EC) no 94/2009 was adopted, to permit the temporary exceptional support for the pigmeat market in the form of a disposal scheme in Ireland.

Financial responsibility

6.9 In the context of possible recalls as a result of contaminated feed Article 8 of EC regulation 1831/2003 on feed hygiene required the EU Commission to draw up a report, for the European Parliament and Council on the feasibility of a system of financial guarantees. The report was published in August 2007 and indicated that financial guarantees were not generally available at present but were technically feasible. The report also recommended that there should be a wider public debate on the issue and this should be completed in 2009.

6.10 A Commission Working Group on Financial Guarantees met in December 2008. The purpose was mainly fact-finding and it consisted largely of presentations from representatives of the Belgian and German feed industry, who had forms of voluntary financial guarantee systems in place. Representatives of the insurance industry also participated. In general, the meeting highlighted the difficulties in the introduction of a mandatory form of financial guarantee in the feed sector. The Review Group considers that Ireland should pursue this matter urgently at EU level so that a European wide financial guarantee system can be considered and implemented.

6.11 However persuasive the arguments, it is clear that there can be no guarantee for Exchequer support for the industry in the event of similar incidents in the future. It is important therefore, that in addition to enhancing the food safety controls along the feed and food chain, (see 2.12 re. "own checks"), Irish industry should consider the range of voluntary options, such as levies, emergency funds, insurance etc, open to them to reduce their financial exposure in the event of similar incidents occurring in the future.

Conclusions and Recommendations:

The Review Group notes the crucial role of the F.S.A.I. in managing this incident. In that context it considers that all the consequences of the contemplated changes to the existing structure of the FSAI should be thoroughly evaluated to ensure the maintenance of the international credibility and independence of the Irish food safety infrastructure. (Ref. 6.3)

The protection of consumer health was rightly the overriding priority in the management of the dioxin contamination incident. (Ref. 6.4)

State financial assistance was provided because of the serious impact of the recall on the future viability of the industry and the necessity to ensure that the industry was in a position to effect the recall. (Ref. 6.4)

The question of financial guarantees / insurance should be pursued by Ireland at EU level. (Ref. 6.9)

The industry should consider the range of voluntary options open to them to reduce their financial exposure in the event of any future product recall of this type. This should also be considered in the context of “own checks” as referred to in Chapter 2. (Ref. 6.10)

There can be no guarantee for Exchequer support for the industry in the event of similar incidents in the future. (Ref. 6.11)

APPENDIX 1

Submissions to the Group

Submissions to the Dioxin Review Group

Pat Donnelly

Martin Larkin

Tokn Grain Products Ltd.

National Transfrontier Shipment (TFS) Office

Safefood

East Galway Anti-Sludge Action Group

John O Sullivan

Mr. John W Langan

Northern Ireland Assembly

Veterinary Ireland Health Committee

Ulster Farmers' Union

Dr. Sven Huther

Confederation of European Waste -to-Energy Plants (Ireland)

Local Authority Veterinary Service (LAVS)

Health Service Executive

Irish Dairy Industries Association

Pat Doyle

Robert Hogg

Those who made a submission and were invited to the Review Group to discuss their issues further were:

Irish Association of Pigmeat Processors

Food & Drinks Industry Ireland (FDII)

Irish Grain and Feed Association (IGFA)

Irish Farmers Association (IFA)

The Review Group also met with representatives of the Animal Feed Inspectorate and the Veterinary Inspectorate of the Department of Agriculture, Fisheries and Food and a representative from the Environment Branch of Carlow County Council.

APPENDIX 2

Regulatory Authorities

Regulatory Authorities

The Department of Agriculture, Fisheries & Food is the competent authority for the development of policy, the negotiation of rules at European Community level and the implementation in national law of those rules for, primary production of food, feed safety, animal health, animal welfare and plant health. It is also the competent authority for implementation of official controls in the above areas.

The Department operates under a service contract with the Food Safety Authority of Ireland. It first entered into a service contract with the FSAI in 2000. The current contract runs until 31st December 2009 and is subject to audit by the FSAI. The sectors included in the contract are meat hygiene, milk and milk products, eggs and egg products, pesticide control service, border inspection posts, the residue monitoring programme, the zoonoses directive and food labelling

In terms of food safety, the **Department of Health and Children** is responsible for the formulation of national policy and the transposition of EU legislation with regard to the retail sectors for food and the non-retail processing and distribution of non-animal origin foods. It also oversees the implementation of food safety legislation by the FSAI.

The Food Safety Authority of Ireland (FSAI) was established in 1999 as a national body with responsibility for the enforcement of food law in Ireland. It is a statutory, independent and science-based agency, dedicated to protecting public health and consumer interests in the area of food safety. The Authority was set up to be independent of the food industry and it operates under the aegis of the Minister for Health and Children.

Enforcement of food law is carried out on behalf of the Authority by its official agencies, acting as agents of the Authority under a service contract. The main official agencies are the Department of Agriculture, Fisheries and Food, the Local Authorities, the Health Service Executive, the Sea Fisheries Protection Authority and the Marine Institute. These agencies are accountable to the Authority for their food safety programmes, standards of work and their actions in relation to food law enforcement. The Authority also co-ordinates the activities of these agencies to achieve the most effective and efficient use of these State resources in protecting public health and consumers' interests.

The Authority's remit does not cover the entire food chain. When the FSAI was established in 1999 it was given responsibility for food safety from the farm gate forwards; animal feed controls and food controls on the farm remain the responsibility of the Department of Agriculture, Fisheries and Food.

The objective of the **Health Service Executive (HSE)** is to improve, promote and protect the health and welfare of the public in an effective and efficient manner. The HSE is divided into three service delivery units:

- 1 The Population Health (PH) Directorate promotes and protects the health of the entire population;
- 2 The Primary, Community and Continuing Care (PCCC) Directorate deliver health and personal social services in the community and other settings;
- 3 The National Hospitals Office (NHO) provides acute hospital and ambulance services throughout the country.

The FSAI has a Service Contract with HSE to provide the following food control services:

- 4 Environmental Health Services from the PCCC Directorate
- 5 Food Safety Laboratory Services from the PCCC Directorate and the NHO
- 6 Public Health Medical Services from the PH Directorate

These services are provided, in the main, by Environmental Health Officers.

Carlow County Council is the administrative body with responsibility for local government in County Carlow. Among other things, it has responsibility for the issuing of Waste Permits under the Waste Management legislation¹⁶.

The Environmental Protection Agency (EPA) protects the environment through its licensing, enforcement and monitoring activities.

¹⁶ The national legislation S.I. No. 165 of 1998 as amended by S.I. 821 of 2007 give effect to the provisions of:

- a) Council Directive 75/439/EEC of 16 June 1975, on the disposal of waste oils, as amended by Council Directive 87/101/EEC of 22 December 1986;
- b) Council Directive 75/442/EEC of 15 July 1975, on waste, as amended by Council Directive 91/156/EEC of 18 March 1991;
- c) Council Directive 80/68/EEC of 17 December, 1979 on the protection of groundwater against pollution caused by dangerous substances and
- d) Council Directive 91/689/EEC of 12 December, 1991 on hazardous waste

An **Bord Bia** is the State Agency with statutory responsibility for the market development and promotion of food including seafood, horticulture, and drink products on the home and international markets. It works in partnership with industry to implement a range of programmes and activities tailored to exploit new market opportunities and increase share in existing markets.

APPENDIX 3

Regulatory Environment

Regulatory Environment

3.1 Regulations on the production of food and feed

The Food and Feed Safety legislation at European level comprises a number of regulations that include general legislation on food and feed safety and specific legislation on feed hygiene. The general legislation is Regulation EC/178/2002¹⁷ which establishes the common basis for food law in all Member States and provides the framework for the development of EU food and feed law. Regulation EC/183/2005¹⁸ covers the requirements for feed hygiene. Regulation EC/852/2004¹⁹ addresses the hygiene of foodstuffs and includes hygiene during storage and use of animal feed. Specific hygiene rules for the hygiene of foodstuffs are set down in Regulation EC/853/2004²⁰. These are transposed in Irish legislation as European Communities (Food and Feed Hygiene) Regulations 2005 (S.I. No 910 of 2005)²¹ which has since been amended by S.I. 432 of 2009)²². Regulations covering fish feed are included in the European Communities (Hygiene of Fishery Products and Fish Feed) Regulations (S.I. No 335 of 2006)²³. In addition specific regulations set maximum levels for dioxins and dioxin-like PCBs in foods and feed.

Specific requirements of Regulation EC/178/2002

This Regulation establishes the common basis for food law in all Member States and provides the framework for the development of EU food and feed law. Specific requirements for feed safety are that:

- Imported and exported feed shall comply with relevant Community feed law (Article 11 & 12 respectively);
- Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe (Article 15.1);

¹⁷ [http://www.fsai.ie/uploadedFiles/Consol_Reg178_2002\(1\).pdf](http://www.fsai.ie/uploadedFiles/Consol_Reg178_2002(1).pdf)

¹⁸ http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_035/l_03520050208en00010022.pdf

¹⁹ http://www.fsai.ie/uploadedFiles/Consol_Reg852_2004.pdf

²⁰ http://www.fsai.ie/uploadedFiles/Consol_Reg853-2004.pdf

²¹ [http://www.fsai.ie/uploadedFiles/SI910_2005\(1\).pdf](http://www.fsai.ie/uploadedFiles/SI910_2005(1).pdf)

²² [http://www.fsai.ie/uploadedFiles/SI910_2005\(1\).pdf](http://www.fsai.ie/uploadedFiles/SI910_2005(1).pdf)

²³ [http://www.fsai.ie/uploadedFiles/SI335_202006\(2\).pdf](http://www.fsai.ie/uploadedFiles/SI335_202006(2).pdf)

- Unsafe feed is feed that may have an adverse effect on human or animal health and/or feed that may make the food derived from food-producing animals unsafe for human consumption (Article 15.2);
- Feed business operators (FeBOs) shall ensure the feed satisfies requirements of food law and verify that such requirements are met (Article 17.1);
- Feed must be traceable one step up and one step down the chain (Article 18);
- FeBOs must withdraw unsafe feed, inform the competent authorities and inform the users of the feed (Article 20).

Specific requirements of Regulation EC/852/2004²⁴

Aspects of general hygiene impacting feed hygiene are covered in the Annex 1 of Regulation EC/852/2004. These include:

- As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary product will subsequently undergo. Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production and associated operations, including: (a) measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste (Annex 1 Part II)
- to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner (Annex 1 Part II, 4a);
- to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation (Annex 1 Part II 4j);

²⁴ http://www.fsai.ie/uploadedFiles/Consol_Reg852_2004.pdf

- Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on: (a) the nature and origin of feed fed to the animals (Annex 1 Part III, 8a);
- Guides to good hygiene practice²⁵ should include appropriate information on hazards that may arise in primary production and associated operations and actions to control hazards, including relevant measures set out in Community and national legislation or national and Community programmes. Examples of such hazards and measures may include: the control of feed contamination and the correct and appropriate use of veterinary medicinal products and feed additives and their traceability; (Annex 1 Part B, 2 a & d);

Specific requirements of Regulation EC/183/2005²⁶

The basic aim of this regulation is to ensure a high level of consumer protection with regard to food and feed safety. The regulation sets out specific principles, notably that the primary responsibility for feed safety rests with the feed business operator; and the requirement for the general implementation of feed safety management procedures based on the principles of the Hazard Analysis and Critical Control Points system (HACCP).

This regulation highlights that feed safety depends on a number of factors that includes the need for legislation that lays down minimum hygiene requirements, the need for official controls to be in place to check feed business operators' compliance and the need for feed business operators (FeBOs) to take measures or adopt procedures to achieve a high level of feed safety.

Specific provisions of EC/183/2005 apply to:

- All stages of feed production up to and including placing feed on the market including import and export. (Article 2.1)
- Excluded: (MS may make national rules to cover these activities) (Article 2.2)
 - Private domestic production of feed for own animals used for own consumption

²⁵ [This regulation encourages the development of national guides to good practice for hygiene and for the application of HACCP principles in Member States.](#)

²⁶ http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_035/l_03520050208en00010022.pdf

- Direct supply of small quantities of primary production of feed²⁷ at local level by the producer to local farms for use on those farms.
- FeBOs must ensure that production; processing and distribution of feed are in accordance with Community legislation, national law and good practice. (Article 4.1);
- FeBOs involved in primary production of feed and/or transport storage and handling of primary products at the place of production and/or distribution of primary products from the place of production and/or mixing of feed for use on their own holdings provided that no additives or pre-mixes are used (except silage additives) must comply with requirements of ANNEX I only and do not need HACCP plans (Article 5.1);
- Other FeBOs must comply with Annex II (Article 5.2);
- All FeBOs must comply with microbiological criteria and meet targets set down by the Standing Committee;
- FeBOs other than those covered by Article 5(1) must have a permanent written procedure(s) based on HACCP principles (Article 6.1);
 - When modification is made to product or process the HACCP must be reviewed (Article 6.3)
 - Provide evidence of compliance to the competent authorities (Article 7.1a)
 - Keep all HACCP documents up to date (Article 7.1b);
- FeBOs must be registered and the following FeBOs must additionally be approved (Article 10.1):
 - Manufacturing and/or placing on the market of feed additives, proteins obtained from micro organisms and co-products of the manufacture of amino acids by fermentation;
 - Manufacturing and/or placing on the market of pre-mixtures prepared using feed additives

²⁷ Defined as “the production of agricultural products, including in particular growing, harvesting, milking, rearing of animals (prior to their slaughter) or fishing resulting exclusively in products which do not undergo any operation following their harvest, collection or capture apart from simple physical treatment.”

- Manufacturing for placing on the market, or producing for the exclusive requirement of their holdings, compound feedingstuffs using feed additives or pre-mixtures containing feed additives.

Specific requirements of Regulation EC/882/2004²⁸

Regulation 882/2004 sets out the official controls that are required to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. This Regulation gives the general rules on national controls by competent authorities to prevent, eliminate, and reduce risks to human and animal health. The controls are to guarantee fair practices in food and feed trade. It sets out the general approach that must be taken, and the principles that must be adopted, by the authorities in EU Member States that have responsibility for monitoring and enforcing this legislation (i.e. the 'competent authorities' responsible for organising and undertaking 'official controls'). It also establishes a framework for financing of official control. In addition, it provides the legal basis for the European Commission to assess the effectiveness of national enforcement arrangements.

Article 41 of Regulation EC/882/2004 requires each Member State to produce a single integrated multi-annual national control plan. It should contain general information on the structure and organisation of the systems of controls for food, feed, animal health and animal welfare in the Member State. In addition, the plan extends to plant health controls in respect of the rules included in Council Directive 2000/29/EC²⁹.

3.2 EU Legislation on PCDD/Fs and PCBs in food and feed

In 2001 the European Commission published its Community strategy for dioxins, furans and polychlorinated biphenyls, aimed at achieving a reduction in human exposure to these chemicals and regulations have been updated on a regular basis since then. Regulations require that Member States carry out random monitoring for the presence of dioxins and dioxin-like PCBs and, if possible, non-dioxin-like PCBs in feeds. Specific maximum levels have been set in European food and feed legislation for dioxins and dioxin-like PCBs.

Directive EC/32/2002 on undesirable substances in animal feed set maximum levels for dioxins and dioxin-like PCBs. This Directive sets out the detailed scientific procedures establishing these levels.

²⁸ [European Commission Official Journal L165, p 1, 2004/04/30](#)

²⁹ [Plant Health legislation; Official Journal L169, p 1, 2000/07/10](#)

The European legislation on food contaminants was consolidated in 2006 when Regulation EC/1881/2006 was published. This has been amended by Regulation EC/1126/2007, Regulation EC/565/2008, and Regulation EC/629/2008. The currently maximum levels for PCDDs, PCDFs and the sum of PCDD/Fs and dioxin-like PCBs in food are shown in Table 1.

Table 1 Maximum Levels for dioxins, furans and dioxin-like PCBs in food

FOOD	Maximum levels Sum of dioxins and furans (WHO-PCDD/F-TEQ) (1)	Maximum levels Sum of dioxins, furans and dioxin-like PCBs (WHO-PCDD/F-PCB- TEQ) (1)
5.1.1 Meat and meat products (2) - of ruminants (bovine animals, sheep) - of poultry and farmed game - of pigs	3 pg/g fat (3) 2 pg/g fat (3) 1 pg/g fat (3)	4.5 pg/g fat (3) 4 pg/g fat (3) 1.50 pg/g fat (3)
5.1.2 Liver and derived products of terrestrial animals	6 pg/g fat (3)	12 pg/g fat (3)
5.2 Muscle meat of fish and fishery products and products thereof with the exception of eel (4) (5) - Muscle meat of eel (<i>Anguilla anguilla</i>) and products thereof	4 pg/g whole weight 4 pg/g whole weight	8 pg/g whole weight 12 pg/g whole weight
5.3 Milk (6) and milk products, including butter fat	3 pg/g fat (3)	6 pg/g fat (3)
5.4 Hen eggs and egg products (7)	3 pg/g fat (3)	6 pg/g fat (3)
5.5 Oils and fats - Animal fat - of ruminants - of poultry and farmed game - of pigs - mixed animal fats - Vegetable oil and fats - marine oil (fish body oil, fish liver oil and oils of other marine organisms intended for human consumption)	3 pg/g fat 2 pg/g fat 1 pg/g fat 2 pg/g fat 0.75 pg/g fat 2 pg/g fat	4.5 pg/g fat 4 pg/g fat 1.5 pg/g fat 3 pg/g fat 1.5 pg/g fat 10 pg/g fat

- (1) Upperbound concentrations: Upperbound concentrations are calculated on the assumption that the values of the different congeners below the limit of quantification are equal to the limit of quantification.
- (2) Meat of bovine animals, sheep, pig, poultry and farmed game as defined in Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council (OJ L 139, 30.4.2004. Corrected version in OJ L 226, 25.6.2004, p. 22) but not including edible offal as defined in that Annex.
- (3) The maximum levels are not applicable for food products containing < 1 % fat.
- (4) Muscle meat of fish and fishery products as defined in categories (a), (b), (c), (e) and (f) of the list in Article 1 of Council Regulation (EC) No 104/2000 (OJ L 17, 21.1.2000, p. 22. Regulation as amended by the 2003 Act of Accession). The maximum level applies to crustaceans, excluding the brown meat of crab and excluding head and thorax meat of lobster and similar large crustaceans (Nephropidae and Palinuridae) and to cephalopods without viscera.

- (5) Where fish are intended to be eaten whole, the maximum level applies to the whole fish.
- (6) Milk (raw milk, milk for the manufacture of milk-based products and heat-treated milk as defined in Annex I to Regulation (EC) No 853/2004.
- (7) Hen eggs and egg products as defined in Annex I to Regulation (EC) No 853/2004.

Appendix 4

Control Systems

Control Systems

4.1 The National Control Plan for Ireland

A National Control Plan for Ireland has been developed and submitted to the European Commission as required by Article 41 of Regulation EC/882.2004. The primary objectives are to ensure feed and food is safe and wholesome and to protect consumers' interests, this is achieved through:

- Ensuring that food and feed business operators' fulfil their primary legal responsibility to ensure food and feed safety
- The enforcement of food and feed law, animal health and animal welfare rules and plant health rules
- The organisation of official controls to monitor and verify that the relevant legislative requirements are fulfilled by food and feed business operators at all stages of production, processing and distribution.
- The co-ordination of official controls, to ensure
 - effective and efficient implementation at national, regional and local level
 - official controls are carried out regularly, on a risk basis and with appropriate frequency
 - impartiality, quality and consistency of official controls
 - activities are carried out to a high level of transparency

The **National Residue Monitoring Programme** and the **Animal Feed Inspection Programme** are two main elements of the National Control Plan.

4.2 The National Residues Monitoring Programme involves a risk-based sampling regime, where upwards of 30,000 samples are taken from across the food chain and tested for over 200 possible contaminants. The purpose of the programme is not to sample all food products but rather to check the work practices of the FBO to ensure that certain foods are not contaminated with residues that would pose a health risk to consumers. Implementation of the programme involves taking samples of food of animal origin and from food producing species at both farm and primary processing plant levels. Samples are generally taken in accordance with criteria designed to target animals or products, which are more likely to contain illegal residues. The range of products sampled includes red meat, white meat, milk, fish and fish products, wild game and poultry. However, the results also reflect the outcome of sampling conducted in specific cases where the presence of illegal residues was suspected by Department inspectors. Where a positive result is detected in the laboratory, a follow-up is conducted at the farm of origin

with a view to taking the necessary enforcement measures up to and including legal action where appropriate.

Since 2000, official testing has been complemented by a legislatively -based regime under which meat processors are individually obliged to implement approved residue monitoring measures in respect of animals supplied to them. This regime, which involves the submission to the Department by each processor of an annual residue monitoring plan (which requires the approval of the Department), makes it mandatory in cases where animals test `positive` for each processor to apply significantly increased levels of testing (up to a level of 100%) to subsequent consignments of animals from the suppliers in question. This initiative significantly increases the protection from illegal residues afforded to consumers of Irish food products. It also enables each processor and, indeed supplier, to deal effectively and in a timely manner with any problems which might from time to time emerge and equips Irish processors with another valuable and credible means of assuring consumers in an increasingly competitive marketplace of the quality and safety of their products.

As required by EU legislation (Directive 96/23), Ireland has an infrastructure of National Reference Laboratories and Approved Laboratories in place to carry out testing of samples taken under the National Residue Plan (NRP). These national laboratories are overseen in turn by the four EU Community Reference Laboratories (CRLs).

Ireland has currently designated five National Reference Laboratories (NRLs) covering the range of substance groups encompassed by the NRP. The functions of the NRLs are:

- To co-ordinate the work of the approved laboratories (standards and methods of analysis),
- To assist DAFF in organising the NRP,
- To organise periodic ring tests to check the competence of the approved laboratories,
- To ensure approved laboratories observe the relevant analytical limits laid down for each residue,
- To disseminate information from CRLs,
- To participate in training organised by the CRLs.

There are twelve approved laboratories for the purposes of the NRP. Under Directive 96/23, approved laboratories are required to have external accreditation and to have appropriately validated methods for the tests carried out; in carrying out testing, laboratories must comply with the detailed requirements specified in Commission Decision 2002/657 (performance of analytical

methods and interpretation of results). The specific allocations of testing for particular substances under the NRP is detailed in each year's plan.

4.3 Animal Feed Inspection Programme

The Department of Agriculture, Fisheries and Food implements an annual animal feed inspection programme to ensure that feedingstuffs or feeding practices do not constitute a hazard to human or animal health or the environment.

The inspection programme runs from 1st January to the 31st December annually. It contains information on the scope of the inspections and on the structure and systems of the control activities. The programme provides information on the following:

- Overview of the inspection activities and the staff involved
- Scope and criteria for controls
- Type and number of inspections
- Type and number of samples
- Type and number of analyses
- Analysis methods, tolerances and designated testing laboratories
- Risk assessment for determining control activities

When drawing up the Inspection Programme each year, a detailed risk assessment is carried out to determine how resources should be used. Once this is determined, the number of inspections and analysis completed for each operator within each segment of the industry is determined using risk based criteria, which takes into account the following:

- The outcome of previous inspections
- Nature of risk to health or the environment associated with an operation or type of feed
- Auto controls of the operator and history of compliance
- Community coordinated controls
- Information on controls in other member states or scientific findings.

In addition to the 2,400 inspections per annum throughout the feed chain, 1,800 samples are taken per annum from the complete range of feed material and compound feed. These in turn undergo 7,000 laboratory analyses for composition, the absence of meat and bone meal, undesirable substances and banned substances.

Progress on the inspection programme is formally reviewed on a quarterly basis and management makes adjustments in priorities and/or resources as required. The programme for

2009 has been significantly amended to take account of the experience gained during this incident, and, in particular, to place considerably more focus on feed and other such inputs that underpin the entire food chain and, therefore, represent a significant risk to the production of safe food.

4.4 Waste disposal and recovery activities

Carlow County Council has responsibility for the issuing of Waste Permits in Co. Carlow. The permit regulations are SI No. 165 of 1998³⁰ Waste Management Permit Regulation 1998. SI No. 821 of 2007³¹ Waste Management Facility Permit and Facilities Regulation 2007 revised it. These were further amended in 2008.

SI No. 165 of 1998 is applicable to the facility operated by Millstream Power Ltd. Ballybrommell, Fenagh, Co. Carlow.

These Regulations provide for the granting of waste permits by local authorities in respect of specified waste disposal and recovery activities.

The purposes for which these Regulations are made include the purpose of giving effect to provisions of:

- a) Council Directive 75/439/EEC³² of 16 June 1975 on the disposal of waste oils, as amended by Council Directive 87/101/EEC³³ of 22 December 1986.
- b) Council Directive 75/442/EEC³⁴ of 15 July 1975 on waste, as amended by Council Directive 91/156/EEC³⁵ of 18 March 1991.
- c) Council Directive 80/68/EEC³⁶ of 17 December 1979 on the protection of groundwater against pollution caused by certain dangerous substances.
- d) Council Directive 91/689/EEC³⁷ of 12 December 1991 on hazardous waste.

The waste permit application form requires that the applicant specifies, among other matters, the classes of activity concerned in accordance with the Third and Fourth Schedules of the 1996 Waste Management Act. In this particular case there were no disposal activities under the Third

³⁰ <http://www.irishstatutebook.ie/1998/en/si/0165.html>

³¹ <http://www.irishstatutebook.ie/2007/en/si/0821.html>

³² European Commission Official Journal L194, p23, 1975/07/25

³³ European Commission Official Journal L042, p43, 1985/02/12

³⁴ European Commission Official Journal L194, p39, 1975/07/25

³⁵ European Commission Official Journal L078, p23, 1991/03/26

³⁶ European Commission Official Journal L020, p43, 1980/01/26

³⁷ European Commission Official Journal L194, p23, 1991/12/31

Schedule and the activity under the Fourth Schedule was class 2 “Recycling or reclamation of organic substances which are not used as solvents (including composting and other biological transformation substances”.

The application form is also required to specify the relevant activities in Part 1of the First Schedule of the 1998 Regulations. In this case it is class 5 “The recovery of waste (other than hazardous waste) at a facility other than a facility for the composting of waste where the amount of compost exceeds 1000 m³ at any one time).

APPENDIX 5

Traceability

Traceability

5.1 Common requirements for pigs

The identification and registration of pigs is laid down in the Council Directive 2008/71/EC³⁸, Council Directive 97/12/EC³⁹, Directive 2000/15/EC⁴⁰ and Commission Decision 2000/678/EC⁴¹. Ireland has national legislation (S.I. 341 of 2002) regulating the registration of holdings and the identification of animals.

Ireland has established a system of identification and registration of pigs based on the following elements:

1. A central database of all holdings and of all keepers of pigs
2. A central database for movement of pigs
3. A register of ear tags.

For each holding the following information is registered in the database

1. The holding number
2. The address of the holding
3. The geographical position of the holding (x and y co-ordinates)
4. The keeper's name, address and contact numbers.

5.2 Movement

Identification marks (ear tag or tattoo) must be applied before pigs leave the holding of birth.

Slaughter pigs must be marked with a tattoo if they are transported direct to the slaughterhouse.

All relevant information relating to the consignment of pigs as outlined below must be recorded on an NPITS (National Pig Identification and Tracing System) document, which must accompany the pigs to slaughter.

For each batch of pigs being moved the following information is recorded:

1. The number of pigs
2. The date and time of shipment

³⁸ [Council Directive 2008/71/EC of 15 July 2008 on the identification and registration of pigs \(Codified version\)](#)

³⁹ [Council Directive 97/12/EC of 17 March 1997 amending and updating Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine](#)

⁴⁰ [Directive 2000/15/EC of the European Parliament and the Council of 10 April 2000 amending Council Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine](#)

⁴¹ [Commission Decision of 23 October 2000 laying down detailed rules for registration of holdings in national databases for porcine animals as foreseen by Council Directive 64/432/EEC \(notified under document number C \(2000\) 3075\) \(Text with EEA relevance\)](#)

3. The holding of origin
4. The destination of the animals
5. The registration number of the vehicle used for the transport.

Pigs may not be accepted for slaughter without this accompanying document.

In addition details of the movement (origin/destination, number of pigs and date) must be supplied by both buyer and seller (by telephone or electronically) to the central movement database.

5.3 Common requirements for food

Traceability of food is described in Article 18 of Reg. (EC) No. 178/2002⁴², and the responsibility of the food business operator in respect of Articles 14 and 18 are described in Article 19. Besides these requirements Ireland has no national legislation regulating traceability concerning pig meat and pig meat products in detail.

Since Article 18 only describes external traceability “one step back – one step forward” the food business operator is left with the responsibility of assessing the risk and economical consequences concerning internal traceability in a situation of product withdrawal and recall i.e. the more robust the traceability system the less product that needs to be withdrawn from the market and lower the economic impact on the industry.

The establishment must have documented procedures in place, which ensures the ability of efficiently handling the requirement of traceability and must be able to explain these procedures to relevant Department officers upon request. The current traceability of pig -processing plants meet the requirement of EU legislation on the basis of “one step back – one step forward”

5.4 Traceability at Slaughter

Normally each pig delivered to the slaughterhouse carries a holding -specific number tattooed on the animal enabling identification of the holding throughout the process of slaughter.

Depending on the establishment procedures each carcass may also be given a code identifying it in the establishment system for registering classification, weight, veterinary inspection notes etc.

As described the slaughterhouse is required to register data with the central movement database concerning

⁴² [Regulation \(EC\) No 178/2002 of the European Parliament and of the Council of 28 January 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](#)

1. Date of slaughter
2. Number of pigs received per holding

These registrations constitute the basis of an eventual focused withdrawal from the holding -level and downstream in the food chain.

As long as the carcass remains in the slaughterhouse facility and has not been divided in more than halves, full traceability to the farm is possible.

5.5 Traceability at Cutting

It is important to note that pigs are not held in chills by farm of origin. Commercial reality dictates that pigs of the same grade, fat cover etc. are held in the same chill and de-boned on this basis (this allows the processor to produce cuts of approximately the same size, weight, grade etc.)

Establishments define batches for the purpose of tracing pig meat when the carcasses are cut up. The majority of slaughterhouses in Ireland define a batch as one day's production, equivalent to pigs slaughtered the same day in the same slaughterhouse.

Depending on the size and production of the cutting facility different systems are used.

Some establishments use voluntary procedures of internal traceability based on the information following the batch of carcasses received, i.e. one or a few ingoing batches correspond to the batch identification of outgoing products.

Other establishments use a system based on the date of receipt of the carcasses, and the time span of production to determine the batches to be included in case of withdrawal of product.

In both cases the primal cuts can be traced to a number of farms (i.e. those farms that were slaughtered on the day which is used to define a batch) but not specifically to the farm where the pig was reared.

In the current climate where the retail sector demand products to a very specific specification in terms of weight, quality etc. it is not possible to trace an individual cut back to the farm of origin.

5.6 Traceability at Further Processing

(Minced meat, meat preparations, meat products, other products containing meat)

Most establishments in this category producing products for further distribution use internal traceability systems. In general these systems are based on registering the batch identification of all ingredients used in what will later become one production batch of the final product.

Depending on the production size more production batches may constitute the final batch for further distribution. Normally only production batches from the same day will be included in the final batch.

Again this will not facilitate the tracing of a particular processed product to a farm but only to a number of possible farms.

5.7 Danish System

Denmark has a national order regulating identification and registration of animals⁴³ and a national order regulating registration of husbandries⁴⁴.

Denmark has established a system of identification and registration of pigs based on 4 elements, a central database called the Central Husbandry Register (CHR), a central database for movement of pigs, holding registers and ear tags.

For each holding the following information is registered in the CHR: Holding number (CHR number) e.g. 654321, address of the holding, geographical position of the holding (x and y co - ordinates), keeper's name, address, contact numbers and VAT or CPR number , owner's name, address, contact numbers and VAT - or civil registration (CPR)-number, number of animals and veterinary events.

Identification marks (ear tag or tattoo) must be applied before pigs leave the holding of birth. The Danish order allows slaughter pigs to be marked with a tattoo on both hindquarters if they are transported direct to the slaughterhouse. The slaughterhouse must register the number of the tattoo in the CHR together with the holding number. The registration shall be recorded in CHR before the farmers can deliver pigs to the slaughterhouse.

Since 2002 all movements of pigs have been recorded in the central database for movement of pigs. For each batch of pigs being moved the following information is recorded: The number of pigs, the date and time of shipment, holding of origin, destination of the animals and registration number of the vehicle used for the transport. The same information is maintained in the NPIT system⁴⁵ operated by Ireland. The slaughterhouses that receive pigs shall report information to CHR about all movements from the holdings to the slaughterhouse.

⁴³ [Order 1066 of 10 November 2005 on marking, registration and movements of bovine animals, swine, sheep and goats](#)

⁴⁴ [Order 815 of 14 July 2006 on registration of husbandry in the Central Husbandry Register](#)

⁴⁵ [NPITS National Pig Identification and Tracing System](#).

Appendix 6

Chronology of the incident

Chronology of the incident

Background

The dioxin contamination incident originated in the detection of P CBs in food of animal origin by the Department of Agriculture, Fisheries and Food (DAFF), through random sampling carried out as part of the National Residues Programme.

Outlined below is the chronological order of the events which led to the detection and the identification of the source of the dioxins from the 19th November when the sample of pork fat was taken, up to mid-December. It also outlines the action taken based on the results of analysis on feed and animals. Since the initiation of the incident DAFF in collaboration with the Food Safety Authority of Ireland (FSAI) and other agencies, worked through the various priorities – protection of public health, restoration of consumer confidence, securing the future of the industry and maintenance of markets and national reputation.

Tuesday 19th November

- An officer of the Department of Agriculture, Fisheries and Food took routine samples, under the National Residue Monitoring Programme, of pork fat from pigs slaughtered at a plant in Drumlish, Co. Longford and submitted them for analysis at the Department's Pesticides Control Laboratory (PCL) in Backweston. The purpose of this programme is to check that the FBOs work practices do not expose consumers to unsafe food.

Friday 28th November

- The results of analyses indicated the presence of “marker” polychlorinated byphenols, more commonly referred to as PCBs. In accordance with standing procedures under the DAFF/FSAI service contract, FSAI was advised of these findings at this time. The source of the pork was immediately identified back to a farm in Co. Cork.

Saturday 29th November

- Samples were taken of all the different types of animal feed used on that farm – ten in all, including the dry bread, and these were sent to the PCL for priority analysis. In addition three samples of pork fat were submitted for priority analysis.

Monday 1st December

- The PCL confirmed the initial sample of pork fat (taken on 19th November) as positive for non-dioxin like 'marker' PCBs. It also indicated that the three further pork fat samples from the same farm were 'indicatively' positive for contamination.

Tuesday 2nd December

- The PCL confirmed that one of the feed ingredient samples (the dry bread) presented positive for contamination (non-dioxin like 'marker' PCBs). All others were negative.
- The source of the dry bread was immediately identified back to a registered surplus food recycling plant in Co. Carlow – Millstream Recycling Ltd. through checks on records maintained under the feed traceability system required under the Feed Hygiene legislation. Because of the potential link between the presence of PCBs and dioxins, samples of feedingstuffs and pork fat were immediately taken by a DAFF official to the Central Science Laboratory in York, UK for analysis.
- The Department of Health & Children (DHC) was informed of a possible contamination of pig meat by the FSAI.
- DAFF personnel visited Millstream Recycling Ltd. on the **2nd, 3rd, 4th, 5th and 6th December** to collect all the relevant samples and gather all the necessary information. A list of farms that received feed material from the premises since 1st May 2008 was compiled. In all 48 farms were identified (10 pig and 38 beef).
- Samples of feed manufactures in the period going back to July 2008 were taken from Millstream Recycling Ltd., and submitted to DAFF's Pesticide Control Laboratory in Backweston for priority analysis for presence of PCBs. Under the Feed Hygiene regulations, FBOs are obliged to keep library samples of all batches.
- Three pigs slaughtered and sampled from a second farm that had received the feed.

Wednesday 3rd December

- DAFF apprised the FSAI of developments at a high level meeting.

Thursday 4th December

- DAFF officials commenced visiting all of the remaining identified pig and cattle farms. All bread products remaining on these farms were impounded and restrictions were placed on the movement of animals from these herds.
- Feed samples were taken for analysis from 10 pig farm premises.
- The FSAI informed the Food Standards Agency (UK) of the emerging incident.
- The list of customers who received feed from the recycling plant in the previous six months both in Northern Ireland and Ireland was completed by the Department on the

evening of 4th December following receipt of detailed sales transactions information which form part of the traceability requirements under the Feed Hygiene Regime .

- A DAFF Press Release, prepared in conjunction with the FSAI, issued in the evening indicating that a number of herds had been re stricted following the identification of marker PCBs (copy attached at end of this appendix).

Friday 5th December

- The FSAI informed the European Commission that an investigation was underway and made them aware of the results received to date. The FSAI also informed the Rapid Alert System for Food and Feed (RASFF) of the European Commission about the investigation.
- Feed samples were taken for analysis from 38 beef farm premises.
- On the morning of 5th December, the authorities in the Department of Agriculture and Rural Development in Northern Ireland (DARDNI) were informed by DAFF and a list of farms located in Northern Ireland was forwarded to them indicating that bread product from Millstream Recycling Ltd., may have been delivered to those farms.
- In the afternoon the Dutch Food Safety Consumer Product Authority (VWA), following sight of the Department's Press Release, contacted the Department and the FSAI in relation to an independent investigation they were carrying out into the presence of dioxins in pork fat samples. The VWA informed the FSAI of a discovery in France of a high level of dioxin during a routine monitoring of pork loin supplied by a Dutch company. However the Dutch company was looking at a number of Member States to ascertain the origin of this pork and had not identified it as coming from an Irish production. The Dutch company reported these findings to the VWA on 25th November. The production date of this sample of pork was 13th October.

Saturday 6th December

- An Inter Departmental/Agency meeting was convened to assess the emerging situation. This meeting chaired by the Minister for Agriculture, Fisheries and Food, and attended by the Minister for Health and Children; the Minister of State for Food Safety; the Minister of State for Food Promotion; the Chief Medical Officer; the FSAI; and officials from the Departments of Agriculture, Fisheries and Food, and Health and Children. In light of the assessment of the position and possible implications the Taoiseach subsequently joined this meeting.
- The FSAI held a teleconference with the European Commission and the VWA to discuss the emerging incidents in Ireland and the Netherlands.

- At 3.40pm, the Central Science Laboratory in York, confirmed to the FSAI, the presence of dioxins in the pork fat samples and animal feed (bread crumb) at levels of 200pg/g and in excess of 2,000pg/g respectively. As it was not possible to identify and separate pork products from pigs from the farms that used contaminated feed from those that were free of contamination, the FSAI decided that it was necessary to request the food industry to recall all Irish pork and bacon products from pigs slaughtered in Ireland since 1st September 2008 and this was agreed by all parties present. The reason for choosing this date is outlined in par 4.2.
- In making the decision for a total product recall, account was taken of the fact that the 10 pig producers affected and associated pig farms involving 17 separate production units accounted for some 8% of the national kill or approximately 50,000 pigs slaughtered between 1st September and the 1st December 2008. Taken together, they supplied eight of the ten main abattoirs in the country, which account for about 98% of the national throughput of pork.
- A press conference was held at 19.00 in Government Buildings to announce the product recall.
- DAFF issued a Trader notice later that evening to all pig slaughtering and pig processing establishments that set out the requirements to be followed under the terms of the recall.
- Running in parallel to all of this was ongoing activity to (i) identify the cause of the contamination; and (ii) put in place arrangements for the recall of all of the feed material impounded on the farms.
- An alert notification was issued to the Rapid Alert System for Feed and Food (RASFF) by the FSAI to advise the EU Commission and all EU Member States.
- In addition, meetings were held on the weekend of the 6th and 7th December with representatives of the pig processors, producers and retailers. Meetings with the pig processors continued over the following days.
- The Chief Medical Officer (CMO) in the Department of Health and Children (Dr. Tony Holohan) advised the public and General Practitioners that, while Irish pork products produced between 1st September, 2008 and 7th December, 2008 should not be consumed, any risk to health arising from the consumption of Irish pork products prior to the product recall date was extremely low and there was no need for people to seek direct medical advice.

Sunday 7th December

- DAFF's Crisis Management Group convened throughout the day.
- An Ad hoc expert group on human health was convened by the FSAI at the request of the Chief Medical Officer in the Department of Health & Children to carry out a risk

assessment and advise on the complex technical, toxicological and medical issues arising. The Group met for the first time on Sunday morning at the FSAI Headquarters and was chaired by Dr. Iona Pratt (Toxicologist) Vice Chair of the EFSA Panel on Food Additives and evaluated all available evidence on the human health effects of dioxin exposure in consultation with the European Food Safety Authority (EFSA).

- A meeting was held in Agriculture House involving DAFF, the EPA and the National Bureau for Criminal Investigation of An Garda Síochána. At that meeting the EPA agreed to assist DAFF in their investigation and subsequently to assist An Garda Síochána. EPA was advised that a potential source of the contamination was oil used to fuel a burner at the Millstream Recycling Ltd., facility for the drying of bread to be used in animal feed. It was suspected that the oil had been originally sourced in Northern Ireland. The EPA agreed to inspect a number of facilities in addition to the Millstream Recycling Ltd., facility to investigate possible movement of oils and waste oils to and from NI.
- All retailers of pork and bacon were invited by DAFF to a meeting in Agriculture House.
- The FSAI advice-line received over 2,000 calls from consumers and industry seeking information on the recall.
- To allay public concerns, the FSAI embarked on a course of action to inform and reassure the general public which included the operation of an advice line, publication of a “Questions and Answers” sheet on its website and issuing a series of press releases aimed at providing up-to-date information to both consumers and industry. They also issued instructions to assist Environmental Health Officers (EHOs) who had been working with retail outlets on the withdrawal of unsafe products.

Monday 8th December

- Results of samples received the previous evening, taken from eleven of the forty-five⁴⁶ cattle herds initially restricted were received and on the basis of those results the FSAI on **Tuesday 9th December** concluded that there were no public health issues arising in relation to beef.
- A teleconference took place among the Irish Authorities, the European Commission, EFSA and a number of Member States. The outcome was a request by the Commission to EFSA for advice on the risks to public health.
- EPA and Carlow County Council carried out inspections at the Millstream site and other related locations on 8th and 9th December. Samples of oil were taken for further analysis

⁴⁶ The original number of cattle farms was 38. However through the animal traceability systems it was possible to ascertain that eleven herds were moved, increasing the figure to 45.

at some of these sites. A direct drying system using a n oil-fired burner was used to generate heat to dry food at the food recycling plant. Subsequent laboratory tests carried out showed that the oil was contaminated with PCBs. The congener profile of the contaminated oil indicated that transformer oil was the likely source of the contamination. Laboratory tests showed a similar PCB/dioxin contamination profile, the contaminated feed and in the fat of the affected animals.

Tuesday 9th December

- The Minister for Health & Children updated the Government on the steps taken to date to protect public health in the light of the discovery of dioxin contaminants in Irish pork and bacon products.
- The Minister of State at the Department of Health & Children with responsibility for food and the Minister for Agriculture, Fisheries & Food both made statements to the Dáil.

Wednesday 10th December

- The European Food Safety Authority issued an opinion stating that following its risk assessment there was no risk to health for anyone who had consumed potentially contaminated pork products in the three months prior to the recall of all Irish pork products. This risk assessment agreed with the risk assessment undertaken by the FSAI and reaffirmed the action taken by the FSAI which limited further exposure to pork products contaminated with dioxins.
- The Department of Agriculture, Fisheries & Food issued a Trader Notice and the Minister issued a statement, which set out the conditions under which pork production could be recommenced. He also advised the public of the special label developed by An Bord Bia as an added assurance to consumers in relation to the safety of pork and pigmeat products being placed on the market under the terms of the notice. The Bord Bia label was developed in association with DAFF and issued to factories, processing plants and retail outlets. The labels were produced for product which could be guaranteed to have come from pigs that had not eaten the contaminated ration. The labels were issued only upon verification from the veterinary inspectorate of DAFF or the local authority veterinarians/environmental health officers through the FSAI that all potentially contaminated product had been removed from the food chain. A total of 6 million labels were issued.
- The European Commission and Member States agreed on conditions that must be met for product to be placed on the market. This included rules for composite products like pizza and ready meals that have pork ingredients. Slaughter and processing resumed at pig processing plants.

- The Chief Veterinary Officer (CVO) of the Department of Agriculture, Fisheries and Food gave a formal presentation on the actions taken by the Irish authorities to the EU CVOs. The FSAI provided a similar update to the European Standing Committee on the Food Chain and Animal Health on 12th December.
- DAFF / Bord Bia Market Access Group convened a meeting.
- The Office of the CMO conducted a teleconference via EU Health Security Committee to brief appropriate Government Health officials in other EU member states and to share public health advice and the assessments on which that advice was based.

Thursday 11th December

- Irish pork products including the 90% of unaffected pork slaughtered start returning to market. Processors agree financial assistance package with Government and processing resumes.

Weekend of 13th/14th December

- Results for “marker” PCBs for samples taken in the remaining cattle herds became available the following weekend. Results for dioxins in the beef samples were subsequently received on **17th December**.
- All recalled feed material (453.66 tonnes) from farms securely returned to Millstream premises. Secured along with 190 tonnes of product already impounded on site.

Thursday, 18th December

- The FSAI on concluding its assessment of these results, published a statement which indicated, based on food consumption data, that the exposure from beef was 300 times lower than that posed by the contamination found in pork.

Additionally it was confirmed that of the 120,000 cattle farms in Ireland, only 21 had been identified as having received the implicated animal feed. As a precautionary measure, on the recommendation of the FSAI, a decision was taken to slaughter and remove from the food chain all animals in these 21 herds.

18th December to 9th January

- DAFF continued to test library samples of potentially contaminated feed to confirm the period of contamination to allow the de-restriction of certain beef herds.
- Contact with various markets was intensified to provide information on the controls and actions taken in order to ensure the restoration of market access.

- A series of Trader Notices was issued to Feed Business operators on their obligations under the Feed Hygiene Regulation in relation to having a fit for purpose HACCP in place with particular emphasis on the use of appropriate oil in direct drying processes.
- The Garda investigation is ongoing.

Statement by Department of Agriculture, Fisheries and Food

The Department of Agriculture, Fisheries and Food today stated that it is investigating, in close collaboration with the Food Safety Authority of Ireland the source of a contaminant in animal feed. This follows on from the discovery of the presence of marker PCBs in pork fat during routine monitoring of the food chain for a range of contaminants.

As a precautionary measure, a small number of farms associated with the investigation have been placed under restriction by the Department of Agriculture, Fisheries and Food. Animals from these farms will only be allowed to enter the food chain if they are shown to be free of the contaminant following laboratory testing.

A series of tests are being carried out in the Department's own laboratory complex in Backweston and additional samples have been sent to the UK for testing. The Investigation is continuing and further information will be available as soon as laboratory results, which are due at the beginning of next week, are available.

Note for Editors

PCBs: Polychlorinated Biphenyls are persistent organic pollutants that are principally present in food as a result of industrial processes.

Date Released: 04 December 2008

APPENDIX 7

Scheme of Financial Assistance

Scheme of Financial Assistance

Department of Agriculture, Fisheries and Food

Pigmeat Recall Scheme

December 2008

This scheme is being funded from the Irish Exchequer with partial co -funding from the European Union

7.1 Scheme Outline and General Objectives

The Pigmear Recall Scheme is being introduced to put into effect the rapid and secure disposal of eligible product, in order to enable normal pig meat processing operations to resume and bring stability to the pigmeat sector. The Scheme is based on an emergency fund agreed between the Minister and representatives of the sector and is financed by the State, with co-financing from the European Union for certain primary product.

This fund is strictly intended to provide assistance for the cost of removing “eligible product” from the market that may have originated from pigs, deemed to be unfit for the food chain due to having been exposed to, or suspected of being exposed to, contaminated animal feed and the subsequent rendering/destruction of that product, under the direction and control of the Minister.

The Minister is not purchasing any product directly or indirectly in operating this scheme from any party and agreement to pay, or actual payment of monies by the Minister from the fund shall not vest ownership of any product, nor will any ownership of the product covered by the Scheme reside at any time, in the Minister.

The scheme shall be administered by the Minister and shall operate throughout the State.

7.2 Definitions

“**The Department**” and “**DAFF**” means The Department of Agriculture, Fisheries and Food.

“**The Minister**” means The Minister for Agriculture, Fisheries and Food.

“**Applicant**” means a natural or legal person applying for assistance under this scheme, being a primary or secondary processor of pigmeat, incorporated in Ireland.

“**Authorised officer**” means a person authorised by the Minister to carry out functions in relation to this scheme, or a Veterinary Inspector of the Department, or an Agricultural Inspector/Officer of the Department, or a local authority veterinarian.

“**Eligible product**” for the purposes of this scheme shall mean:

- Product manufactured from animals slaughtered in Ireland on dates between 1st September and 6th December, 2008 that had left the control of primary and secondary processors and was in free circulation on 6th December, 2008 and which was returned to the processor or his agent, receipted for and verified by the Department or sent direct by retailers for destruction, with verification documents being provided to the primary and/or secondary processors and supplied to the Department;
- Product manufactured from animals slaughtered in Ireland on dates between 1st September and 6th December 2008 that remains under the control of primary and secondary processors, which cannot be segregated to the satisfaction of the Department (i.e. that cannot be shown conclusively to be uncontaminated). Assistance will be subject to verification by the Department;
- Product manufactured from animals slaughtered in Ireland on dates between 1st September and 6th December, 2008 that remain under the control of primary and secondary processors that, due to the expiry of sell by dates could not enter free circulation. Assistance will be subject to verification by the Department;

7.3 Eligibility

This scheme covers all eligible product, for which a claim for assistance is made by 31st March 2009, with all supporting documentation .

Where this includes fresh, chilled or frozen product which was in slaughterhouses on 6th December 2008, or in coldstores under the responsibility and control of a slaughterhouse, there is a requirement that such product be secure, easily identifiable and kept apart physically from other stocks.

Any payment made to an applicant is to be net of any insurance recovered by that applicant, or any other financial recovery made by the applicant by any means. The applicant must take all reasonable steps to recover any insurance payments that are possible under any insurance policy held by it, relevant to the operation of the scheme, which leads to a recovery of monies and reduction in the claims on the State including any indemnity enjoyed by an applicant in respect of such product under a usual contract of insurance (including recovery by litigation and/or arbitration, where a commercial law senior counsel to be appointed by agreement between the applicant and the Minister or in default of agreement within 14 days by the President for the time being of the Law Society of Ireland provides an opinion that there is on the balance of probability, a reasonable chance of success in pursuing payment on foot of any insurance policy held by the applicant) and must as a condition of this scheme use its best endeavours to make such insurance recovery. An applicant shall furnish to the Minister all insurance documentation held by

it in this regard, on request being made by the Minister. The Department reserves the right to verify all aspects relating to claims, including a review of insurance cover, before all claims are reconciled and subsequent payments are made. Full co-operation in this matter is a condition of this scheme.

The standard procedure is that eligible product must be returned to the plant of origin. The Minister may be willing, in certain exceptional circumstances, to consider facilitating direct dispatch of recalled pork products for rendering from other nominated sites. The approval of the Minister must be obtained in advance, however.

7.4 Presentation and Transportation for Rendering

An applicant, must present eligible product to an authorised officer for loading and onward dispatch for rendering from the applicant's premises, on a consignment basis, i.e. in a quantity and form capable of being transported as a single load. It should be assembled and presented to an authorised officer using a PRS2 form. The product should be assembled and recorded in the form of the product categories shown at Appendix 1. Fresh, chilled or frozen product which was in slaughterhouses on 6 December 2008, or in coldstores under the responsibility and control of a slaughterhouse, must be clearly identified on the PRS2 form.

The authorised officer will supervise the identification of the product or material and will carry out the required sample checks. These will comprise of a minimum of 10% inspection of all intake per consignment.

When an authorised officer is satisfied with a consignment, the transporting vehicle may be loaded. If it is necessary to remove any boxing prior to transportation, in line with instructions from Animal By-Products Division, then this should only be done at this stage and only when the authorised officer has authorised it. The vehicle must be weighed at the site of loading using a certified weighbridge. The weight must be recorded on the left hand side of the PRS3 form. The vehicle will be sealed and the seal number recorded. A unique identifier will be created for the consignment in the following format: **Plant No./Load No./PRS**, which must be written on to both forms. The first part of the PRS3 form will be completed and signed on behalf of the Minister and the plant management.

The original form and one copy will travel with the consignment and the authorised officer will keep one copy. The load can then be dispatched to the final destination point for rendering.

Eligible product is regarded as Category 1 animal by-product (ABP) and must be accompanied by an ABP commercial document. However, as an exceptional measure, there is no requirement to transport the product/material on special Category 1 vehicles.

On arrival at the designated rendering plant the consignment shall be weighed on intake under the supervision of an authorised officer and the second part of Form PRS3 completed and signed. The original documents, which have accompanied the load should be retained by the authorised officer and forwarded with a copy of the weighbridge docket to Pig Meat Recall Section, Department of Agriculture, Fisheries and Food, Johnstown Castle, Co. Wexford. Copies should be retained by the Department representative. A copy of the Form PRS3 should be retained by plant management, as this document will form the basis of their claim for payment at a later date.

7.5 General Conditions of the Scheme:

The following general conditions apply: -

- 1) Adequate notice must be given to DAFF to enable adequate authorised officers to be present to supervise movements of product/material from an applicant's premises to the designated rendering plant for destruction (in the case of abattoirs, processing plants and renderers, at least 24 hours notice must be given; a shorter period may be possible in the case of smaller operators or retailers).
- 2) Work on the scheme shall not commence, until adequate DAFF staff is available to give supervision.
- 3) Applicants must facilitate all sample and other checks being carried out.
- 4) Weighing scales must be calibrated and certified.
- 5) Tares must be accurate.
- 6) Payments shall only be processed and made after receipt and verification by authorised officers of all required and validated documents.

The secure disposal of all by-products of rendering will be the responsibility of the designated rendering plant. All resultant tallow and or MBM shall be incinerated on site, if permitted or removed to an authorised incineration plant.

7.6 Payment

Payment to applicants shall be made on the basis of the rate fixed by the Minister for eligible product.

In general, a claim for payment may only be made after the product has been delivered and accepted for destruction by rendering (subject to section 7 below). Claims for payment shall be made in the format specified by the Minister and with the required supporting documentation. Once-off claims may be made immediately.

Claims over a sustained period should be made at no more than weekly intervals.

In all cases, final payment will be made solely on the basis of volumes rendered and validated by the DAFF. Where there is a discrepancy between the applicant's claim and the Department's records, payment will be made on the lesser of the two figures. Before all claims are reconciled and final payment made, all aspects relating to the claim, including a review of insurance cover will be undertaken. An appeal/review process from any decision shall be provided for.

7.7 Advance Payment

Provision will be made for advance payment in certain circumstances, on the basis of an inventory of stocks proposed for destruction. The inventory must be submitted in the format laid down by the Minister. On receipt of the application for advance payment, the Minister shall assess the claim and make a payment not exceeding a fixed percentage of the value of the claim, on the basis of the rates established by the Minister for the categories of product concerned.

7.8 Taxation Requirements

All activities the subject of payment under the terms of this Scheme shall be conducted in compliance with the laws of the State relating, inter alia, to tax and employment. Applicants are expected to be tax compliant and all payments are made strictly subject to provision on request of a tax clearance certificate.

7.9 Keeping of records

Applicants of this scheme shall ensure that proper records are kept and made available to the Minister on request. As with company records generally, all such original documents shall be maintained for a period of six years and shall be produced to the Minister's authorised officer on written demand and copies provided where required.

7.10 Provision of False or Misleading Information

By signing the required forms the applicant confirms that all information is true and accurate to the best of his or her knowledge. Where, for the purposes of obtaining payment under this Scheme, the applicant or a person acting on his/her behalf knowingly makes a false or misleading statement or declaration, or includes ineligible material or withholds essential information, the claim in question shall be rendered ineligible for payment and the applicant may be precluded from making any further claims. A deliberate attempt to obtain monies by fraudulent means may render the applicant and any others involved liable to prosecution.

7.11 Amendment of Terms, Conditions and Procedures

The Minister reserves the right to alter the terms and conditions of this scheme and/or the procedures to be followed subject to State Aid rules.

Any monies that may be payable pursuant to this scheme is strictly subject to a determination by the Commission of the European Union that such payments are consistent with Community law. The Minister reserves the right to recover any and all monies paid pursuant to this scheme in the event that the Commission of the European Union determines that such payments are unlawful having regard to Community law.

7.12 Information and Data Protection

The Minister reserves the right to make public information in relation to payments and beneficiaries under this scheme, having regard to the provisions of the Freedom of Information Act and the Data Protection Act.

7.13 General Indemnity

Any payments made to an applicant pursuant to this Scheme shall preclude any claims and the applicant shall fully indemnify the Minister and the State in respect of any such claims howsoever arising against the Minister and the State (the existence of which is denied) in relation to the removal and disposal of product or material that may have originated from pigs, deemed to be unfit for the food chain due to having been exposed to, or suspected of being exposed to, contaminated animal feed and participation by an applicant in the Scheme. Any payment made there under shall be deemed as full acceptance by the applicant that the Minister has no liability whatsoever to the applicant.

By way of example and explanation, but without prejudice to the generality of the preceding paragraph, the indemnity referred to in the preceding paragraph relates *inter alia* to claims taken against the applicant and/or the Minister and the State to include any injury, loss, or damage caused to a third party by the applicant, or to any member of staff of the applicant in dealing with the return, collection, unwrapping, loading, unloading, removal, transport, delivery disposal, ultimate destruction of and/or payment for Product pursuant to the Scheme and to any claim taken by a party to whom the applicant may have an existing, or as yet unascertained financial liability relating to, or connected with Product covered by the Scheme or payments made under it by the Minister to the applicant. This indemnity does not relate to, or exclude claims for assistance, by the applicant limited to Product only, as set out at paragraph 4 of the overarching Framework Agreement concluded between the processors and the Minister on the 10th day of December 2008. Any such claims will be dealt with by the Minister, but within the strict parameters of what is set out in paragraph 4 of the Framework Agreement.

The applicant shall be fully responsible for the onward payment of all monies received by the applicant under this scheme which:

- (i) is due to retailers or other creditors of the applicant,
- (ii) arises from the receipt of eligible product for destruction by the applicant and
- (iii) for which the Minister has provided payment to the applicant.

7.14 Further Information/Queries

Any queries in relation to this Scheme should be referred to:

Pigmeat Recall Section

DEPARTMENT OF AGRICULTURE, FISHERIES AND FOOD

Johnstown Castle,

Co. Wexford.

PRIMARY PROCESSOR CATEGORIES**Fresh, chilled or frozen product in store on 6 December 2008**

Carcases	fore-end	middle	legs	tenderloin	by-product	manufacturing (trims/fat)	Offal (red)
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Product acquired/returned after 6 December 2008

Carcases	fore-end	middle	legs	tenderloin	by-product	manufacturing (trims/fat)	Offal (red)
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SECONDARY PROCESSOR CATEGORIES

Finished Goods & Work In Progress		
Ser	Product Category	Incl in Category
1	Bulk Cooked Hams	
2	Small Goods (Various)	Sausages, Puddings, Rolls, Sausage Rolls, Savouries, Pies, Ready Meals
3	Pre-Sliced Pre-packed Rashers	
4	Pre-Sliced Bulk Rashers	
5	Bacon Joints	Ham Fillets, BI Gammon, BR Gammon, Horseshoe Gammon, Others
6	Pre-pack Sliced Ham	
7	IQF Diced Ham	Individually Quick Frozen
8	Fermented & Dried Meats	Pepperoni/Salami/Merguez/ Chorizo/Other
9	Cooked Back Rasher	
10	Cooked Streaky Rasher	
11	Cooked Sausage/Pork	
12	Hand Held Snacks	"Attack a Snack", "Rustlers"/ Others

Raw Material		
Ser	Product Category	Incl in Category
1		Legs Bone In
2		Boneless Leg Meat
3		Loin/Backs
4		Bellies

5		Shoulder Bone In
6		Boneless Shoulder Meat
7	Pork Manufacturing Meat	Belly Meat, Trim, Fat

APPENDIX 8

Rapid Alert System for Food and Feed (RASFF)

and

Product Recall

Rapid Alert System for Food and Feed (RASFF) and Product Recall

8.1 Legislative background

Regulation (EC) **178/2002** lays down the principles and requirements of food law, it established the European Food Safety Authority and it lays down procedures in matters of food safety. The following Articles form the basis of product recall and the Rapid Alert System for food and feed.

Articles 19 and 20 are very specific about the responsibility of Food and Feed Business Operators FBOs to ensure that food or ingredients imported, produced, manufactured or distributed complies with food safety requirements. Where the FBO believes there to be a non-compliance, s/he must immediately move to withdraw the food or feed in question and advise the competent authorities accordingly.

Traceability – Article 18 stipulates among other things, that food business operators at all stages of production, processing and distribution within the businesses under their control must ensure that foods satisfy the requirements of food law and that these requirements are met. With regard to traceability this Article requires that the operator must have systems in place that can identify any person from whom they have been supplied with a food. They must also have a system in place to identify the other businesses to which their product has been supplied.

8.2 RASFF

The scope and procedures of the Rapid Alert System for Food and Feed (**RASFF**) are defined in **Articles 50, 51 and 52**. Article 50 establishes RASFF as a network involving the Member States, the Commission as a member and manager of the system and the European Food Safety Authority (EFSA). The EEA countries⁴⁷ are also longstanding members of the RASFF.

Whenever a member of the network has any information relating to the existence of a serious direct or indirect risk to human health deriving from food or feed, this information is immediately notified to the Commission, using a common template, under the RASFF. The Commission immediately transmits this information to the members of the network. The contact for Ireland is the Food Safety Authority of Ireland.

⁴⁷ EEA – European Economic Area: Norway, Liechtenstein and Iceland

There are four types of notifications to the Commission that can be identified in the following manner:

- **Market Notifications.**

These notifications report on risks identified in products that are placed on the market in the notifying country. That country reports on the risks it has identified, the product and its traceability and the measures it has taken. According to the seriousness of the risks identified and the distribution of the product on the market, the market notification is classified after evaluation by the Commission services as alert notification or information notification before the Commission transmits it to all network members.

- **Alert Notifications**

An 'alert notification' or 'alert' is sent when a food or feed presenting a serious risk is on the market or when rapid action is required. Alerts are triggered by the network member that detects the problem and has initiated the relevant measures, such as withdrawal/recall. The notification aims at giving all the members of the network the information to verify whether the concerned product is on their market, so that they can take the necessary measures.

- **Information Notifications**

An 'information notification' concerns a food or a feed on the market of the notifying country for which a risk has been identified that does not require rapid action, e.g. because the food or feed has not reached the market or is no longer on the market (of other member countries than the notifying country).

- **Border Rejection Notifications.**

This relates to a food or a feed that was refused entry into the Community for reason of a risk.

- **News Notifications.**

This concerns any type of information related to the safety of food or feed which has not been communicated as an alert, information or border rejection notification, but is judged interesting for the food and feed control authorities in the member states. These are often made based on information picked up in the media or forwarded by colleagues in food or feed authorities in third countries⁴⁸, EC delegations or international organisations, after having been verified with the Member States concerned.

As far as market and border rejection notifications are concerned, two types of notifications are identified:

- An 'original notification' is a notification referring to one or more consignments of a food or a feed that were not previously notified to the RASFF;
- A 'follow-up notification' is one that is transmitted as a follow-up to an original notification.

⁴⁸ [Third Countries and countries outside the European Union.](#)

An original notification sent by a member of the RASFF system can be **rejected** from transmission through RASFF, after evaluation by the Commission, if the criteria for notification are not met or if the information transmitted is insufficient. The notifying country is informed of the intention not to transmit the information through RASFF and is invited to provide additional information allowing the rejection to be reconsidered by the Commission.

8.3 Non-member countries

An alert or information that was transmitted through RASFF can be **withdrawn** by the Commission at the request of the notifying country if the information, upon which the measures taken are based, turns out to be unfounded or if the transmission of the notification was made erroneously.

8.4 International collaboration

If a risk is identified in a food or feed product that came from or was exported to a non-RASFF member, The European Commission informs the country in question. In this way it can take corrective measures and thus avoid the same problem in the future. For example, it may remove a business from the list of approved companies that fully comply with EU legislation requirements and are allowed to export to the EU.

In addition, the European Commission and RASFF work with the World Health Organisation (WHO) alert system called the 'International Food Safety Authorities Network' (INFOSAN). This network comprises contacts or national focal points in over 160 member countries that receive information from the WHO in the form of INFOSAN notes about food safety issues and disseminate it to all relevant ministries in their respective country. RASFF works with INFOSAN and the two share information on a case-by-case basis.

8.5 This incident

When the contamination incident was identified, the FSAI (being the Irish contact point) informed the Commission through RASFF on 5th December 2008. It also initiated a comprehensive recall of all Irish pork produced since 1st September 2008.

In less than two weeks more than 100 follow-up measures were received tracing the products – from raw meat to processed products containing Irish pork as one of many ingredients – involving as many as 54 countries among which 27 were RASFF member countries. Because of the system described above, these countries were able to take immediate action and to trace and recall pork and processed products that were possibly contaminated with dioxins before they were consumed.