ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

55th Meeting of ACAF on 28 September 2011

Presentation Paper: Possible controls on the presence of *Salmonella* species in animal feed

Dr Ray Smith, ACAF Secretariat

Action: The Committee is provided with an update on possible options for new controls to help prevent *Salmonella* contamination of animal feeds. The Committee is asked to re-endorse the current line taken by UK officials in negotiations.

Secretariat

September 2011

Possible controls on the presence of *Salmonella* species in animal feed

Purpose

1. This paper provides updated information concerning possible new European Union controls for the presence of *Salmonella* contamination of animal feed and it asks the Committee to re-endorse the current policy line taken by UK officials in negotiations.

Introduction

2. The Committee discussed microbiological risks associated with feed in April 2005 when it received a paper from a former ACAF Member Dr Colin Stewart (the paper is appended as Annex 1). A further discussion was held at the September 2005 meeting of ACAF, where Defra colleagues presented a position paper (Annex 2). In April 2006, Dr Linden Jack (FSA) gave a presentation (Annex 3) in which she suggested four issues that should be used when considering possible microbiological criteria for feed:

- specific criteria (e.g. limits) should be established only where they would enhance protection of public or animal health;

- risks should be assessed in context to ensure that any criteria to be applied are proportionate (e.g. whether the risk of exposure to a particular pathogen is greater through grazing than via feed);

- criteria should not place an unnecessary burden of testing on feed businesses; and

- whether the criteria could be used to verify and validate hazard analysis critical control point (HACCP) systems in place.

The Committee concluded that any criteria adopted should be proportionate to the risk and be applied sensibly. ACAF also agreed that it would be better to use preventative, HACCP-type approaches, rather than set numerical limits. This is the line that has been taken by UK officials in subsequent negotiations in Brussels.

Statutory Controls

3. There are no current specific statutory limits for *Salmonella* or other contaminating bacteria in feed. However, Article 5.3(a) of the Feed Hygiene Regulation (183/2005) requires that feed business operators shall comply with specific microbiological criteria. It is not clear whether the term 'criteria' refers to numerical limits (this might include a zero tolerance) or to risk-based controls put in place by feed businesses. While specific numerical European Union limits for bacteria in feed have not been introduced so far, there are such criteria in place for foodstuffs (Regulation 2073/2005).

Risk assessment

4. In 2008 the European Food Safety Authority (EFSA) Panel on Biological Hazards (BIOHAZ) published its microbiological risk assessment in feedingstuffs for food-producing animals.

http://www.efsa.europa.eu/en/efsajournal/pub/720.htm

BIOHAZ identified *Salmonella* species as representing the main 'in feed' biological hazard for consumers. The Panel also considered that feed was a less significant vector for *Listeria monocytogenes*, *Escherichia coli* O157: H7 and for *Clostridium* species. It was also of the view that manufactured compound feed was the feed type associated with the highest risk of *Salmonella* contamination and that oil-seed based feeds and animal-derived feeds were the feed materials most likely to introduce *Salmonella* into the daily feed ration and into feed manufacturing plant.

5. The Panel did not recommend specific numerical limits to control *Salmonella* in feed, but did consider how such contamination could be controlled or reduced (e.g. the use of HACCP and chemical and physical treatments). BIOHAZ's view is that control criteria should be applied to critical stages throughout feed production and not simply to the manufacture of the final feed product.

6. More recently in 2011, EFSA again identified commercially-produced complete feed (e.g. pelleted feed) as opposed to other feeds (e.g. home-mixed feeds) as being associated with a higher prevalence of *Salmonella* in European pig holdings.

http://www.efsa.europa.eu/en/efsajournal/doc/2329.pdf

Developments since 2006

7. In October 2009 Defra published its 'Code of Practice for the Control of *Salmonella* during the Production, Storage and Transport of Compound Feeds, Premixtures, Feed Materials and Feed Additives'.

http://archive.defra.gov.uk/foodfarm/farmanimal/diseases/atoz/zoonoses/documents/reports/salmonella-feed-cop.PDF

This non-statutory Code was drawn up in consultation with major UK stakeholder groups and ACAF, and was issued by Defra and its counterparts in the Devolved Administrations. The Code was endorsed by Defra, Devolved Administrations and by both ACAF and the FSA.

8. EU feed stakeholder groups have indicated their willingness to provide the European Commission with a draft set of common principles to control the presence of *Salmonella* in feed. These principles would be inspired by those used in the UK Code of Practice.

9. In December 2008, following the publication of initial advice from BIOHAZ (see paragraphs 3 - 5), the European Commission started formal discussions with Member States in order to try to set microbiological criteria for feed. The Commission's initial approach was similar to that used for the statutory microbiological controls for food contained in Regulation 2073/2005. The UK (represented by Defra and FSA officials) and most other Member States said that they did not believe that this approach was proportionate to the risk to the consumer, and said that they preferred a HACCP-type approach as considered by EFSA. The Commission was asked by Member States to provide a Regulatory Impact Assessment to cover its preferred statutory approach; neither this nor further discussions have been forthcoming. Recent informal contacts with officials suggest that the Commission might still come forward with a proposal, but it have not indicated when a decision might be made.

Conclusion

10. The Committee is asked to:

- take note of recent developments; and

- re-endorse the line taken by Agency and Defra officials taken at discussions in Brussels, namely that a HACCP-type approach as considered by EFSA and as set out in the UK Code of Practice would be preferable. If the Commission was to press for a statutory approach containing statutory limits we (along with other Member States) would ask again that a full Regulatory Impact

Assessment be provided to demonstrate that the proposed line of action was proportionate to the risk to animal and public health.

Secretariat

September 2011

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

29th Meeting of ACAF on 19th April 2005 - Agenda Item 4

Discussion Paper

What are the microbiological risks associated with feed?

Action required: The Committee is invited to note and comment on the contents of this discussion paper.

Dr. Colin S Stewart (ACAF Member)
April 2005

WHAT ARE THE MICROBIOLOGICAL RISKS ASSOCIATED WITH FEED?

Introduction

1. Animal feeds may contain a variety of agents that cause disease in humans or farm animals. Most of these are microbiological organisms, the subject of this short discussion paper. Transmissible spongiform encephalopathy (TSE) is caused by infectious proteins (prions) present in some animal products and is not considered here.

2. Some of the micro-organisms naturally associated with growing plants and thus unavoidably present in feed, are hazardous to human health. Common soil fungi, ubiquitous in the environment, may be present in grain dust and pose a hazard to health as described below. Animal feed may be contaminated with other pathogens as a result of contamination of the raw plant materials used. Food-borne zoonotic pathogens are a good example, as many of these organisms are shed in the faeces of a wide range of animals and birds which inhabit the open environment. The use of animal manure and sewage as fertiliser presents an obvious hazard in this respect.

3. Crops may also be contaminated in the field, or at the time of harvesting, through contact with animals and by the natural movement of contaminated water through soil. Undesirable micro-organisms may also be introduced during the preparation of mixed feeds or during feed processing, sometimes via contact with contaminated machinery. For example, *Listeria monocytogenes* is able to form biofilms on metal and other surfaces, and is difficult to eradicate, even with biocides. Some recycled material incorporated into animal feed, such as straw bedding, may pose a risk through the survival of faecally-borne micro-organisms.

4. In other cases, stored feed may offer ideal conditions for the proliferation of micro-organisms, which then present a hazard for persons handing the feed on the farm or at feed processing facilities. Particular concern has been raised about the incidence of certain common human pathogens, such as *Salmonella* and others, that may be present in feed. Such organisms may colonise the farm environment, including the gut of livestock, entering the human food chain by faecal contamination when the animals are slaughtered and the carcass is processed for retail sale. These organisms may also infect persons working on the farm, or farm visitors, through

contact with infected material or contaminated surfaces. In these cases, similar pathogens may also be carried by vermin, birds, farm dogs and cats and other vectors. Therefore, it may be difficult to determine how often the feed itself acted as a primary source of the relevant pathogen. However, the presence of such micro-organisms in animal feed is clearly undesirable and the feed has to be recognised as a potential hazard in this respect. The following examples illustrate some currently recognised human health problems to which animal feeds may contribute.

Effects of airborne microbial particles from animal feed on health.

5. Concerns about the inhalation of microbial particles associated with animal feeds mainly centre on the role of airborne fungi and actinomycetes (bacteria that form branching filaments), although other micro-organisms found in feeds may also be transmitted by aerosols. For example, it is known that *Salmonella* can be transmitted between animals in airborne droplets of body fluids.

6. Fungi are ubiquitous in nature and they are likely to be present in the raw materials used in animals feeds. There are two main dangers. Firstly, dust generated during the processing and handling of the feed or feed materials is likely to contain fungal spores and fragments of biomass. Such dust can be raised even upon vigorous handling of feed, for example upon tearing open bags of feed, and may be a particular problem during the large-scale processing or transference of feed or feed materials such as cereal grains. Secondly, care must be taken during the storage of feeds to ensure that the feed is sufficiently dry to prevent the growth of storage fungi. Stored grain can be very susceptible to overgrowth of *Aspergillus* and other fungal species, which may present respiratory and other hazards.

7. Airborne fungal spores, fragments of hyphae and the metabolites present in these particles can adversely affect human health in four main ways:

    - they can infect humans, particularly the lungs ;
    - they may be allergenic;
    - they may be toxigenic; and
    - they may cause inflammatory reactions [1].

8. Many ubiquitous soil fungi that are likely to occur naturally on some raw materials used for animals feeds do not colonise human hosts, but may be allergenic, or may produce mycotoxins. Mycotoxins that can accumulate to toxic concentrations in food are already widely recognised as being hazardous to human health. However, evidence is emerging that mycotoxins may be found in association with airborne fungal spores and fragments of fungal biomass. For example, airborne grain dust has been shown to contain aflatoxin B1 from fungi including *Aspergillus flavus*. It has been estimated that during the working week, workers exposed to grain dust might inhale up to several thousand ng of aflatoxin [1]. Farmer's lung disease is an example of allergic alveolitis that can be caused by exposure to thermophilic actinomycetes and fungi such as *Aspergillus flavus*, *A. versicolor, Eurotium rubrum* and other species that occur frequently in feed or feed components, especially stored grain.

Animal feeds and food-borne zoonoses

9. The faeces of farm animals may contain pathogens which infect humans and animals. Salmonella, verocytotoxic E. coli, Campylobacter and Listeria are among those organisms which cause the most widespread and severe illness. Direct or indirect contact with faeces and other body fluids is therefore a common route of transmission of these pathogens, but other routes also exist. For example, Salmonella can be transmitted from animal to animal in airborne droplets of body fluids. In several of these examples, animal feed has been implicated as a source of infection, whilst in other cases, the potential exists for animal feeds to harbour these organisms.

<u>*Salmonella* species.</u>

9. Members of the genus Salmonella are responsible for human and animal disease. Some species, such as *S. typhi*, produce enteric fever in humans, but have little effect on animals. *S. enteritidis* and *S. typhimurium* cause foodborne gastrointestinal infections of varying severity. These species are most commonly associated with eggs or poultry and other farm products; they may also be isolated from pets such as cats and dogs and cold-blooded pet animals (reptiles). Other species are adapted to animals; these include *S. dublin* (cattle) and *S. gallinarum* (poultry). Salmonellosis is the zoonotic human disease with the highest reported

incidence in most European countries. For example, in 1998 the infection rate ranged from approximately two persons per 100,000 in Portugal, to approximately 136 persons per 100,000 in Belgium. [2].

10. *Salmonella* species are found in animal feeds, where they can survive for several years. Infection of cattle and chickens by consumption of contaminated feed has been demonstrated [3]. The implementation of HACCP in feed manufacturing, including verification tests on the final feed product, has been regarded as instrumental in the improved *Salmonella* status of primary poultry production seen in some EU countries [2]. It has been pointed out that tests to detect *Salmonella* in feeds may not be targeted at the species that cause most health problems in humans. However, the current culture-based detection methods are crude, and may not necessarily rule out the presence of species pathogenic to humans. For several of the most common human pathogens, cultural detection can involve an enrichment step, which will tend to select strains best adapted for growth in culture media.

11. Future management options identified [2] include increased testing of animals using tests that detect infections with the species of highest human significance and introducing control measures on farms with unacceptably high levels of infection. It was also recommended that feed controls should be introduced, ensuring that the feed on the farm is free from *Salmonella*. A study in Switzerland found that, for the pork and beef production sectors, lack of monitoring for *Salmonella* during animal feed production contributed to low safety assurances for this bacterium [4].

Verocytotoxic *Escherichia coli*. (VTEC)

12. Most strains and serotypes of *Escherichia coli* are harmless commensals that inhabit the gut of warm-blooded animals and man. However, a number of serotypes of this bacterium have gained important pathogenicity determinants, including, crucially, the ability to produce verocytotoxins. These VTEC bacteria are probably best known through the notorious pathogen *E. coli* O157, but O157 is not the only VTEC serotype. Some VTEC cause diseases in human but not in animals, though not all VTEC produce human disease. Certain VTEC strains can cause severe disease in animals, including pigs.

13. The clinical symptoms of VTEC infection in humans include diarrhoea, haemorrhagic colitis, haemolytic uraemic syndrome (HUS), thrombotic thrombocytopenic purpurea (TPP) and death. VTEC infection of humans is much less common than, for example, salmonellosis, but a high proportion of cases result in serious life-threatening illness and death. The EU incidence of *E. coli* O157 in 1997 was (per million inhabitants) seven VTEC cases and one HUS case; Scotland was a hot spot for VTEC at 100 cases per million inhabitants [2].

14. The main risk factors to humans are the direct or indirect exposure to faecal contents from either ruminants carrying the bacterium, or from infected humans, some of whom may be symptomless carriers. In some cases, farm pets have been implicated in the route of infection. Contamination of the human food chain can occur at abattoirs by carry-over of bacteria from infected carcasses. The importance of contamination of animal feeds by VTEC is not clear, but feed presents an obvious route of transmission to animals [5]. Attempts to detect this bacterium in the farm environment have often failed. However, very small numbers of *E. coli* O157 (perhaps as few as 10) may be needed to infect an individual and most detection methods may not be sensitive enough to detect so few bacteria. Furthermore, it is known that these bacteria can be carried by many types of wild animals and birds. There is a clear potential for the contamination of feed in storage on farms and at feed processors' premises.

Campylobacter species.

15. Pathogenic campylobacters (principally *C. jejuni* and *C. coli*) are mainly found in the alimentary tract of farm animals, wild animals and birds. They are common in poultry and game birds, cattle and pigs and have been found in rodents, insects and houseflies. *Camplyobacter* sp. may cause an acute enterocolitis in humans. On rare occasions, this can result in the development of a paralysing nerve disorder, Guillain-Barré syndrome. In 1997, the number of cases of campylobacteriosis in the EU varied widely, from about 10 persons per 100,000 in Spain, to 108 persons per 100,000 in Scotland. In general, the incidence of infection by this bacterium appears to be increasing in the EU and in some recent years has exceeded that of *Salmonella* [2]. Faecal contamination, especially at slaughter, seems to be an important route for transfer of *Campylobacter* from food animals to humans. The detection of this bacterium in rodents and insects suggest that infestation of animal feed could pose a risk of spreading *Campylobacter* species, though feeds are not at present normally seen as a major route of transmission.

Listeria monocytogenes.

16. The bacterium *Listeria monocytogenes* is widespread in nature, being found in the soil, on foliage and in animal and human faeces [6]. *Listeria* infections result in meningitis or septicaemia, or both conditions may occur. Infection of pregnant women may result in miscarriage, still birth or premature birth of a gravely ill child. In ruminants, *Listeria* primarily causes encephalitis and uterine infections resulting in late-term abortions and septicaemia. A wide range of food products has been associated with outbreaks and sporadic cases of listeriosis, including cheeses (particularly soft cheeses), poultry, seafood and vegetables. The incidence of human listeriosis is low (2-15 per million inhabitants world-wide), but the proportion of cases that die is between 20% and 40%. Listeria is able to grow at refrigerator temperatures and can become established in food processing factories and slaughterhouses. Thus, re-infection of food may occur following treatments to reduce the numbers of bacteria associated with food. Fish processing factories may be at particular risk, as *Listeria* can form stable viable biofilms on stainless-steel work-surfaces and equipment held at low temperatures.
17. The animal feed most often associated with listeriosis in ruminants is improperly fermented silage (pH > 5.0 to 5.5) [7]. Recently, it has been suggested that animal farms may provide a reservoir that could act as a source for the environmental contamination of food processing establishments. A survey of the incidence of *L. monocytogenes* on ruminant farms in New York State (USA) revealed that this bacterium was detected in around 21% of animal feed samples from farms with recent cases of listeriosis. In this study, the comparable incidence in animal feeds from farms without reported cases of listeriosis was around 13%. Bovine hosts in particular appeared to amplify the numbers of *Listeria* in the farm environment. The subtypes of *Listeria* found on the farms overlapped with those detected in human cases that were recorded in the same geographical area [7].

Conclusions.

18. Ubiquitous fungi, naturally present in soil or on plants fed to animals, may pose a risk to health through the generation of airborne dust containing spores and biomass.

19. If grain of other animal feed is stored wet, overgrowth of fungi can result in exposure of workers in the vicinity to the risk of developing alveolitis and other conditions.

20. The presence of *Salmonella* in some animal feeds is probably a factor in the human incidence of salmonellosis.

21. *Listeria monocytogenes* may survive on herbage and it has been suggested that incomplete fermentation of silage on farms may result in the occurrence of listeriosis in the human population in the same geographical area.

22. It is not yet clear if animal feeds play a part in the spread of *Escherichia coli* O157 and *Campylobacter* infections to humans, but the use of manure and slurry as fertilisers for plants incorporated into animal feeds may pose a risk.

Action required

23. The Committee is invited to note and comment on the contents of this discussion paper.

Dr. Colin S Stewart (ACAF Member)
April 2005

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ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

31st Meeting of ACAF on 20 September 2005 - Agenda Item 3

Discussion Paper

Microbiological Risks Associated With Feed – Defra Position Paper

Action required: The Committee is invited to note and comment on the contents of this Defra position paper.

Defra Secretariat
September 2005

MICROBIOLOGICAL RISKS ASSOCIATED WITH ANIMAL FEED - DEFRA POSITION PAPER

Introduction

1. At the ACAF meeting on 19 April 2005 the Committee received a paper on the microbiological risks associated with animal feed from Dr. Colin Stewart.

2. Dr. Stewart had been asked to write a paper to stimulate discussion on this important issue. The Committee subsequently had a wide-ranging discussion (extract of minutes attached at Annex I) and it was agreed that a further paper would be produced by Defra. The aim of this paper, therefore, is to outline Defra's strategy on microbiological risks associated with feed.

Policy aims

3. Defra's policy aims in this area are:

- to minimise the risk to public and animal health from animal feedingstuffs in a proportionate way, taking account of the costs and benefits of control measures employed;

- to use a risk based approach and, where appropriate, HACCP principles to achieve the minimisation of risk posed by feedingstuffs; and

- to work with other Government departments and relevant stakeholders to implement EU legislation in this area in an appropriate and proportionate way.

Scope

The scope of Defra's policy covers:

Animal Groups

- Cattle
- Sheep/ goats
- Pigs
- Poultry
- Horses
- Companion animals

Animal Feed

- Grass and other forage crops
- Harvested fodder (silages, etc.)
- Compound Feed
- Feed containing additives

Microbiological agents

- Bacteria
- Viruses
- Fungi
- Parasites
- Toxins
- Genetically Modified Organisms (GMOs)

Defra Strategy

Risk

4. Defra favours adopting a risk management approach to prioritising issues such as microbiological levels in animal feed. This involves identification of hazards, assessing risks, managing risks through interventions, communication and education. Interventions need to be proportionate to the risk. As part of the Defra Evidence and Innovation Strategy, tools are

being developed to help better assess where input of resources will have the greatest effect on the desired outcome of improving animal health and welfare. Where there is a lack of data on which to base assessments, consideration is given to funding research to generate the information required.

Working in partnership

5. Defra recognises that industry has a large part to play in ensuring products are safe and its strategy includes adopting a 'Working in Partnership' approach, which encourages the use of best practice plans and the setting of industry standards through organisations such as the Agricultural Industries Confederation (AIC). These also support another of Defra's strategy directions, 'Prevention is better than cure', which aims at changing the farmers approach to disease management. There is a need to consider with partners the cost/ benefit of delivering the policy in terms of both gains in public health and animal health.

6. The feed industry has a clear self interest in producing clean feedstuffs and for many sectors, particularly where high value stock is involved, producers are requiring that, for example, feed is guaranteed *Salmonella* free.

Surveillance

7. The UK Veterinary Surveillance Strategy, led by Defra, is seeking to enhance all veterinary surveillance through a range of initiatives, including improved collaboration and sharing of information between all those involved in surveillance, and enhancing the management, use and dissemination of surveillance information through its new IT system Rapid Analysis and Detection of Animal related Risks (RADAR) project. This project will, over a ten-year implementation period, bring together key surveillance information collected in other systems about animal diseases and conditions in a structured and consistent way. RADAR will also contain current, accurate information about the number and location of animals. This will allow a better understanding of animal disease in the UK and the risks posed by them.

Antimicrobial resistance

8. Antimicrobial resistance of organisms in animals is of increasing interest and it is appreciated that feedingstuffs can pose a source of new antimicrobial resistant strains to the livestock and other animal populations. Limited monitoring for *Salmonella* is carried out on a statutory basis and industry carries out wider monitoring on a non-statutory basis. The European Commission has included monitoring in the new Zoonoses Directive 2003/99/EC and Regulation (EC) 2160/2003.

Delivery

9. Defra aims to work with industry as well as internal (Government) stakeholders to develop and deliver this strategy. It is in the interests of feed producers that they produce products which are acceptable to the food business operator and which are not going to have an ill effect on the health and welfare of the animals, or on anyone consuming animal products.

10. Measures supporting Defra's strategy include:

- Codes of Good Agricultural Practice for the Protection of Water, Air and Soil to reduce contamination of pastures and forage have been produced along with advice on minimising water pollution farm waste and manures;

- codes of good practice for the control of *Salmonella* in feed during manufacture, storage and transport have been produced and widely adopted;

- codes of practice on the use of animal protein in animal feeds, where permitted, have been produced to ensure that *Salmonella* and other micro-organisms are not introduced into the feed;

- information is published annually on the findings of *Salmonella* in feed and feed materials ('*Salmonella* in Livestock Production in GB');

- a legislative basis for some further hygiene measures on farm will be introduced with the implementation of the requirements of Regulation 852/2004 on the hygiene of foodstuffs;

- work is in hand to produce public health improvements in the important areas of *Salmonella* and *Campylobacter* – with Defra leading on *Salmonella* and the Food Standards Agency leading on *Campylobacter*; and

- codes of practice have been produced aimed at providing constructive advice to producers on such things as clean pastures, and manure management.

Cost

11. It is vital that any changes made are proportionate to the benefit they deliver. The cost of testing for micro-organisms is relatively high in animal feed – particularly if the range of organisms to be tested for is not clearly defined.

Action

12. The Committee is invited to note and comment on the contents of this Defra position paper.

Defra Secretariat

September 2005

Annex I

Extract taken from minutes of ACAF meeting held on 19 April 2005

Agenda Item 4 – What are the Microbiological Risks Associated With Feed? (ACAF/05/08)

The Chairman outlined the background to this paper. The European Community Feed Hygiene Regulation (183/2005) states that feed business operators should comply with specific microbiological criteria. Dr Colin Stewart had been asked to write a paper to stimulate discussion on the microbiological risks associated with feed. The Chairman stated that it was important that ACAF should provide a view to aid the FSA's negotiating line in Brussels, therefore this item would likely to be on the agenda for the next two meetings with a 'position paper' being the ultimate aim. Dr Stewart then led the Committee through the detail of the paper, following which a wide-ranging discussion took place.

It was suggested that the main focus should be on areas which where significant to human and animal health and Members agreed that Dr Stewart's paper had done this. The point was made that the market already demanded safe feed and therefore any criteria set should be proportionate to risk and applied sensibly. Members noted that no matter how sterile feed was, animals with access to pasture were always going to be subjected to contaminated material. Furthermore, it was not clear to what degree problems in the human food chain related back to animal feed.

Some members were concerned at any mention of maximum limits being set for particular agents. It was pointed out that industry is generally very close to its customer base and they already work together on these issues. It was

suggested that rather than looking at maximum levels regarding hazards, it would be better to identify the risks and *where* hazards are most likely to occur (e.g. a HACCP approach). It was also suggested that by focussing on controlling the risks of one microbiological agent, e.g., Salmonella, one could also expect a level of control of the risks of other microbiological hazards too.

Dr Lucy Foster informed the Committee that she and her colleagues in the Agency's Microbiological Safety Division were working on parallel requirements for food and the Commission were due to come forward with proposals by June 2005 for implementation in January 2006.

The Chairman brought this initial discussion to a close by thanking Dr Stewart for his paper and by stating that a further paper would be tabled for consideration at the next ACAF meeting in July.

Microbiological Criteria

Linden Jack
Food Standards Agency

Microbiological Criteria in food and possible application to feed

- Why do we have criteria for food?
- Regulation 2073/2005 Microbiological criteria for foodstuffs
- How criteria are established for food
- Developing new criteria (an example)
- Issues to consider for animal feeds

Why do we have criteria for food?

- Food safety is mainly ensured by preventative approaches such as HACCP-based procedures.
- Microbiological testing cannot guarantee food safely because of limitations in sampling, testing and uneven distribution of microorganisms throughout the food
- Testing does not guarantee a pathogen is not present.

Why do we have criteria for food?

Harmonised microbiological criteria have been established to:

- Contribute to the protection of public health
- Prevent differing interpretations across member states
- Give guidance on the acceptability of the foods and manufacturing process

• Be an integral part of HACCP-based procedures and are used in validation and verification of these procedures

Regulation 2073 Microbiological criteria for foodstuffs

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• Has been developed in support of the food hygiene legislation.
• Reviews and consolidates criteria in EU vertical Directives.
• In many cases food businesses operators do not need to test to demonstrate compliance.
• In most cases businesses are able to establish their own testing regime according to their HACCP-based procedures.

Regulation 2073/2005 Microbiological criteria for foodstuffs

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• Criteria should be used within context of food safety management procedures (HACCP)
• Flexibility or food business operator to apply criteria within their own controls e.g. include in HACCP plan
• Validate food safety management systems and assess acceptability of certain batches
• Should not mean increased reliance on end product testing or positive release
• Flexibility to adjust sampling requirements according to the nature and size of the business.

Regulation 2073/2005 Microbiological criteria for foodstuffs cont

• Competent authority must ensure food business operators comply with the Regulation.
• Verification will include an assessment of the food safety management procedures in place, including the sampling regime and results of any testing.
• Expect the CA will only take additional samples if they have concerns about the fbos procedures or it considers there has been insufficient testing.
• CA should apply the proposed safety criteria to imported foods e.g. at BiPs

Regulation 2073/2005 Microbiological criteria for foodstuffs (cont)

Regulation 2073 contains 2 types of criteria.
• **FOOD SAFETY CRITERIA** define the acceptability of the batch and apply to products on the market.
The product will not be placed on the market or will be withdrawn/recalled from the market if criteria are exceeded
• **PROCESS HYGIENE CRITERIA** indicate the process is functioning correctly. They apply during the process or at the end of it. It they are not met, improvements in process hygiene are required
• All failures should result in a review of the food safety management procedures.

How are the criteria established?

• Commission have a published strategy
• Criteria should only be established and applied where they enhance food safety and their application is practical

• Food safety criteria should only apply where there are no other more effective tools available and where they are expected to improve public health protection
• The intention is not to create unnecessary burdens and testing for food businesses
• Must be based on risk assessment or internationally recognised principles and EFSA must be consulted before new criteria can be included in the Regulation.

How are the criteria established?

Each criterion is composed of:
• a statement of justification
• analytical method
• sampling plan - number of samples and size each analytical unit
• microbiological limits and number of analytical units to comply
• Foodstuff and point in the food chain where applies
• corrective action

Listeria monocytogenes criteria

Food Category	Micro-organisms	Sampling plan		Limits		Analytical Reference Method	Stage where the criterion applies	Action in the case of unsatisfactory results
		n	c	m	M			
1.2 Ready-to-eat foods able to support the growth of *L. monocytogenes* other than those intended for infants and young children and ready-to eat-foods for special medical purposes[3]	*Listeria monocytogenes*	5	0	Absence in 25g[5]		EN/ISO 11290-1	Products ready to be placed on the market	The batch shall not be placed on the market[4]
		5	0	100 cfu/g[6]		EN/ISO 11290-2	Products ready to be placed on the market and during their shelf-life	The batch shall not be placed on the market or it shall be withdrawn from the market[4]

[3]

Developing new criteria

•The Agency was very actively involved and influential in the negotiations on the

Regulation and brought about a number of significant changes to obtain the best outcome possible for UK fbos.
•Stakeholders involved throughout.
•Some successful outcomes (prevented disproportionate controls for infant formula) others less successful (Salmonella in minced meat and meat preparations)

Developing new criteria: Bacillus

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•Several Member States have national criteria for Bacillus cereus in Food, especially infant formula and have EFSA opinion on Bacillus in food.
•Commission established an expert group to consider harmonised criteria for Bacillus cereus
•Reviewed all background information (Infectious intestinal diseases study, NZ/Aus assessment of infant formula, data from industry)
•UK view - no clear evidence that criteria for Bacillus cereus would meet requirements in strategy

Developing new criteria: Bacillus (cont)

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•First meeting of Expert Group concluded there was sufficient evidence to support a proposal for a process hygiene criterion but not a food safety criterion
•Commission would prefer food safety criterion so asked Expert Group to reconsider.
•We assessed additional info provided by Commission and circulated all the background information we had available to reinforce our position.

Developing new criteria: Bacillus (cont)

•Expert Group maintained their position and this was reported to the Working Group (7th April).
•Commission request information from Member States so can prepare impact assessment before making proposals to the Working Group meeting
•UK will work with the industry to collate and provide information for impact assessment as required

Issues to consider for animal feeds

•Criteria should only be established where they will enhance protection of public health or animal health
•Assess risks in relation to other risks to ensure controls would be proportionate - is the risk of exposure greater through tar example grazing or other environmental exposure.
•Will controls in feed have a significant effect e.g. criteria for Campylobacter not appropriate for broiler feed as Campylobacter does not survive the dry conditions in feed.

Issues to consider for animal feeds (cont)

•Are more appropriate controls available, e.g. there is a potential risk of C.botulinum growth in silage but control of the silage process is more effective than testing for botulinum which may be present in 'hot spots'
•If considering food safety need to consider whether controls in another part of the food chain might be more

effective
•Criteria could help verify and validate HACCP-based systems used by feed producers

Salmonella in feed for housed poultry - an example

•Evidence is available to support feed as a source of Salmonella infection in broilers
•Controlled environment- can control other sources of Salmonella so could have an impact
•Controlling Salmonella in feed could offer enhanced animal and public health protection
•Monitoring is likely to provide meaningful results as Salmonella is found in feed

Salmonella in feed for housed poultry - an example (cont)

•Corrective action is available (review of process control) as Salmonella free poultry feed can be produced and best practice advice is available
•A criterion may be useful to help verify and validate the HACCP-based principles being operated by feed producers
•Is a requirement for Salmonella free feed a proportionate control? Are the benefits proportionate to the cost?
•Is there a validated test method for Salmonella in feed?

Salmonella in feed for housed poultry - an example (cont)

A food safety type criterion for Salmonella is probably not currently

justified
A process hygiene type criterion might be appropriate with detection of Salmonella leading to improvements in process with the aim of reducing the levels of Salmonella contamination in feed.

Closing remarks

•Have highlighted issues and provided comments based on experiences in developing micro criteria for food
•Any criteria must be established according to risk and supported by evidence which suggests their application may be beneficial to public or animal health
Criteria must not place an increased burden of testing on a business and must be applied as part of the HACCP-based procedures

Thank you for listening