

**A REVIEW OF THE HANDLING OF THE
ALPHA-NORTESTOSTERONE ISSUE BY DARD
IN RESPONSE TO FINDINGS OF THE
HORMONE IN CATTLE PRESENTED AT MEAT
PLANTS AFTER ON-FARM EMERGENCY
SLAUGHTER**

**This review was prepared at the request of Michelle Gildernew MP MLA
Minister of Agriculture and Rural Development**

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Terms of Reference:

The Terms of Reference were to include specific consideration of the following aspects:

- the scientific basis for the initiation of action;
- the follow-up action on farms;
- the rationale for the decision to make an ex-gratia payment in respect of the animals condemned;
- lessons learnt.

I was also asked to make recommendations on how the handling of any similar issues in the future could be improved so that the Department can continue to discharge its statutory responsibility to protect the consumer and the reputation of the Northern Ireland agri-food industry whilst trying to minimise the disturbance to farmers.

Approach

My approach to this work was:

- (i) to review all of the documentation available within DARD relating to alpha-nortestosterone from March 2006 to June 2007;
- (ii) to meet with a selection of farmers affected by herd movement restrictions as a result of the detection of alpha-nortestosterone at the abattoir. Herd restrictions for these farmers ranged from 9 to 69 days. Farms visited included the four farms subject to on site searches;
- (iii) to meet with farmers' representative organisations – the Ulster Farmers' Union (UFU) and Northern Ireland Agricultural Producers' Association (NIAPA) – and representatives from the meat processing plant ABP (Newry) Ltd;
- (iv) to meet with relevant members of DARD personnel;
- (v) to review the findings and evidence from scientific reports including those of Professor Wall (October 2006) and material from reports produced by Agri-Food Biosciences Institute (AFBI).

Scientific Basis for Initiation of Action

1. Introduction

This section examines the scientific context in which the Department of Agriculture and Rural Development (DARD) was working, the initial questioning of the scientific evidence, the continued questioning of the

unusual pattern of results, culminating in the Wall Report, current scientific understanding, and the need for further action.

1.1 Background

The statutory analysis of steroid hormones in the urine of food producing animals has been undertaken in Europe since the 1980s. A network of laboratories: Community Reference Laboratories (CRL), National Reference Laboratories (NRL), and Routine Field Laboratories (RFL) has been developed to carry out the testing. The CRL for testing of alpha-nortestosterone is the RIVM in Bilthoven, the Netherlands. In the United Kingdom the NRL is the Veterinary Sciences Division of the Agri-Food and Biosciences Institute based in Belfast. The activities of these laboratories are established in European legislation and additionally specific technical rules govern the analysis of residues in samples taken from food producing animals (Commission Decision 2002/657/EC).

The compound alpha-nortestosterone was synthesised in the 1950s and has been used illegally in animals to promote growth. Chemically it is a male sex hormone with a very close structural resemblance to testosterone. Once thought to have no natural source, scientific opinion has altered over the years to reflect emerging observation. As scientific knowledge developed it was accepted that it occurred naturally in boars, stallions and pregnant cattle, but not in male bovines. Other hormones also once believed to be synthetic are now known to be natural – these include zeranol and boldenone. It was discovered in the mid-1990s that zeranol could occur naturally in cattle following consumption of feeds contaminated with material from the *Fusarium* fungi. It was discovered that boldenone could be synthesised from various natural constituents in animal diets.

1.2 Initial Questioning by DARD in Context of Scientific Background

It was against the background of emerging science that the Department and AFBI began to question the scientific validity of the pattern of findings emerging from the herds tested for alpha-nortestosterone. The visits by DARD officials to the source farms of positive animals did not reveal any substances containing hormones or other components that might explain the presence of alpha-nortestosterone, nor did sampling of animals in associated herds reveal any animals positive for alpha-nortestosterone. The obvious question in the context of previous findings was 'could it be that alpha-nortestosterone was present naturally in male bovines?' The question was raised early on in the investigation. The first laboratory positive confirmation was made on 27 March 2006 and a query on the possibility of natural occurrence was referred by scientists in AFBI on 13 April 2006 to the highest scientific authority in Europe – the Community Reference Laboratory in Bilthoven. The response from the Head of the Unit was that they had "*no indication or observations that alpha-nortestosterone in male animals, bulls or castrates are of endogenous nature. This until the opposite is proven. So as current scientific knowledge goes until now, findings of alpha-nortestosterone in male animals is regarded as coming from illegal treatment.*" However,

scientists in AFBI reported at the monthly DARD/AFBI/FSANI Residues Action Group (30 May 2006) their concerns that positives were still being found, despite the publicity that the issue was attracting in the farming press. AFBI scientists announced their intention to initiate a series of studies to try to identify potential natural sources of alpha-nortestosterone in male bovine urine.

1.3 Continued Questioning by DARD and AFBI Leading to the Wall Report

At this stage the Department and AFBI had not built up a sufficient body of evidence to question the highest scientific authority in Europe. The internal questioning continued within the Department. All meat plants were brought into the testing programme to determine if similar patterns would continue. This additional testing enabled a comprehensive body of information to be gathered.

Between 10 March and 29 August 2006, 56 out of 117 male On-Farm Emergency Slaughter (OFES) animals tested positive for alpha-nortestosterone. By contrast over 600 live animals were tested as part of investigations on farms of positive OFES cases but no animals positive for alpha-nortestosterone were identified. In addition, only one positive male animal was found in 279 healthy animals presented for scheduled slaughter under a random sampling of animals.

In the light of this emerging evidence the Department was not content that it fully understood the reasons for the contrasting results between OFES and "normal" slaughter male animals. One of the questions that arose was that of possible irregularities in DARD's sampling procedures and AFBI's testing procedures. The concerns were such that in July 2006 Professor Wall, an expert from University College Dublin, and former Head of Food Safety Authority of Ireland, was requested by the Permanent Secretary to carry out a root and branch assessment of the Department's own procedures for the sampling and AFBI's procedures for the testing of material from bovine animals for the presence of residues of illegal substances with particular attention to samples from animals slaughtered on farms as OFES cases.

Professor Wall published his findings in October 2006. His conclusion was that he was satisfied that all reasonable practices and procedures were in place to ensure compliance with the legislation relating to hormone residues by DARD personnel and AFBI laboratory staff and that the present methods should be continued.

Professor Wall agreed with AFBI scientists that there was a possibility of a physiological or natural explanation possibly related to stress for the positive samples in OFES animals. He met with Professor de Brabander, Dean of the Veterinary Faculty of the University Ghent in August 2006 to discuss the possibility. Professor de Brabander is a world renowned expert on hormone analysis. His view was that the scientific consensus was that there has been no evidence that alpha-nortestosterone occurs naturally in male cattle but in

light of the emerging findings by DARD and AFBI scientists this view would now have to be reconsidered.

1.4 Current State of Scientific Thinking and Further Action

As a result of the evidence produced by DARD and scientists in AFBI it is now accepted that alpha-nortestosterone is present in the urine of a significant proportion of OFES male cattle. All of the investigations carried out by DARD during follow-up actions showed no evidence of illegal administration and the hormone has also been found in the urine of OFES cattle from Great Britain, Belgium and the Republic of Ireland. It has not been found in the urine of healthy cattle tested as part of ongoing statutory surveillance schemes. Its presence in injured, but not in healthy animals, in the absence of any evidence of illegal administration is therefore now generally accepted as proof beyond reasonable doubt that this compound can occur naturally in the urine of injured animals.

There is a need now for the competent authorities in Europe to consider what additional scientific evidence is required before advice on the interpretation of the legislation can be changed. There is an established mechanism already in place to change the advice. The vehicle to achieve this is the use of a Reference Note based on advice from the Member States and the Community Reference Laboratory.

A hair test has been developed by AFBI to assist in the process of distinguishing between exogenous and endogenous production of the hormone. This is a laboratory test which has been offered to all Member States in May 2007.

The time frame from first presentation in March 2006 to the publication of the Wall Report in October 2006 can appear unduly lengthy to those at the receiving end of policy. However the scientific opinion of the Community Reference Laboratory and other experts at the time was that there was no evidence that alpha-nortestosterone could occur naturally in male cattle. It was not until DARD and AFBI, over a period of time, built up an evidence base that it became possible to question the validity of the internationally accepted position that alpha-nortestosterone did not occur naturally in the urine of male cattle. This is the normal process through which scientific evidence and policy is changed by the establishment of a body of evidence of a sufficient quantum to cause opinion to be altered.

1.5 Conclusions and Recommendations

It is now important for DARD policy makers and AFBI scientists, together with local and European political representatives, to ensure that the competent authorities decide what additional scientific evidence is required before advice on the interpretation of the legislation can be changed.

It should also be recognised that there will always be unique events or sets of circumstances that will arise in the context of emerging scientific knowledge.

This awareness and a preparedness for timely action should continue to be at the forefront of the minds of senior officials using the experience gained from the alpha-nortestosterone case. It is recommended that consideration be given to a Project Management approach should new or unusual patterns of events arise. A Project Manager would be assigned at the beginning of the process to manage and coordinate events to ensure minimisation of timescales in resolution of problems and to minimise disruption to farmers.

The Follow-up Action on Farms

2. Introduction

This section examines the background to enforcement action, and the rationale for the on-site searches. It also makes recommendations for the need to examine the manner of approach to on-farm searches and to the method of implementation of policy change with a view to speeding up this process in the event of other future similar eventualities.

2.1 Background to Enforcement Action

In 1988 the EC introduced a prohibition on the use of hormonal substances for animal growth production and subsequently introduced legislation prescribing the measures to monitor for residues and the actions to be taken on the finding of positive results (96/22/EC, 96/23/EC, 2003/74/EC, 2005/34/EC). The use of anabolic steroids is prohibited for a variety of reasons including possible adverse human health implications, negative effect on animal welfare and the impact of residues on the environment.

Specific actions are prescribed on identification of a positive result. A concentration of alpha-nortestosterone above CC α , the Decision Limit of the laboratory assay, in a male bovine is deemed non-compliant under EU law and the competent authority is duty-bound to carry out an investigation on the farm of origin (Article 16 96/23/EC).

Under this legislation, once an animal has tested positive it must be excluded from the food chain and destroyed. The Department has to decide whether the animals in question have had the hormonal substances unlawfully administered and in the case of a male animal a positive result was itself strong evidence of administration. The Department must have significant evidence to the contrary, therefore before it can conclude that the farmer has not been guilty of such administration. Collecting this evidence involves addressing such issues as:

- (a) whether there was a scientific explanation for the natural presence of the hormonal substances;
- (b) whether the conformation of the animal suggested artificial administration of the substances;

- (c) whether there was evidence of artificial administration such as injection sites;
- (d) did other animals in the same herd test positive.

2.2 Rationale for Surprise On-Site Searches

The initial trigger for action was the collection, on 10 March 2006, of a urine sample from an On Farm Emergency Slaughter (OFES) steer at ABP Newry which screened positive for alpha-nortestosterone. Further tests of OFES animals at the plant also tested positive for the hormone. Subsequently all Official Veterinary Surgeons were instructed to take samples for hormone testing from OFES animals.

The decision to undertake surprise on-site searches at the first four farms detected was based on the current scientific understanding of the time and recent experience of illegal administration. The current scientific knowledge of the time at the highest European scientific reference point, the Community Reference Laboratory, concluded that the presence of alpha-nortestosterone indicated illegal administration. Also, on two recent occasions here the hormone was identified in bottles or syringes on two separate farms. Taking into account recent experience, the current scientific advice of the time and the legal obligations of the Department, the actions at the time were reasonable.

2.3 Impact of Surprise On-Site Visits

With hindsight and in the light of the now accepted scientific evidence that has emerged these actions may seem out of proportion. Contributors to a public meeting held on 6 June 2007 and residents of the four farms subject to surprise visits expressed concern about the impact of the visits and the manner in which they were undertaken.

Two issues in particular emerged. The first issue was the intrusive nature of the search. This seemed to manifest itself in the presence of numbers of DARD and PSNI personnel at the dwelling house searches. A review of contemporaneous documents revealed no major incidents or complaints about either individuals or groups of individuals. The second issue was the feeling that there was an implication of wrongdoing. The caution given during the search, and the fact that the Department has to undertake detailed investigations to explain the presence of hormones, helped to reinforce this feeling.

Concerns were expressed by all farmers including those not subject to surprise visits about the disruption caused by herd restrictions. The extent of concern varied in degree, depending upon the length of restriction, herd size and the stage of the production cycle which the cattle had reached. One farmer expressed a worry that the fact that he was subject to restriction might impact on other aspects of his business.

Complaints were also made at the public meeting and by contributors to this review about the speed at which herd restrictions were removed. Removal of herd restrictions was delayed at the early stages due to the fact that AFBI resources were overstretched in testing unusually large numbers of samples. AFBI responded by developing a rapid screening test which was capable of dealing with the greater volumes of samples presented by the testing programme.

The cumulative impact of the perceived sense of wrongdoing, and the intrusive nature of the search, combined with the disruption of herd restrictions, and ultimately the fact that no illegal administration was detected served to deepen the sense of annoyance for those subject to surprise searches.

2.4 Examination of the Manner in which Surprise Searches are Conducted

Surprise visits are an essential part of surveillance and enforcement and should be maintained at a high level as part of a range of activities which sustain the confidence that is enjoyed by our beef industry. Enforcement actions such as surprise searches are necessary to detect and prevent illegal administration and some elements of the procedure are unavoidable.

For example, cautions are a necessary part of the search procedure and are required to satisfy legal process. The Department has to undertake a number of detailed investigations before it can decide whether the animals in question have had the hormonal substances unlawfully administered.

However, based on the feedback from farmers and their representative organisations during the course of this review, and bearing in mind that not all individuals subject to surprise visits will have been engaged in illegal activities, it is recommended that a detailed examination of on-site visits is undertaken to develop options which would reduce such adverse reactions

Contributors to this review suggested that, in future, risk assessments of individual farmers should be undertaken before surprise searches are implemented. This concept should be considered, but extreme care would need to be taken to ensure equity of treatment, and consideration would need to be given as to how standard objective procedures might be applied in a manner that would satisfy legal considerations.

2.5 Speed of Policy Change

Contributors to the review were concerned about the speed with which policy was changed following the publication of the Wall Report. Although policy was amended in the light of evidence to reduce testing levels from 100% of all male OFES cases to testing based on the opinion of the Official Veterinary Surgeon (OVS) at the meat plant; the timescale from October 2006 to March 2007 seems unduly long. However it is recognised that this was a new and unique situation requiring an evidence base before policy could be changed. There was also the complication of the convergence of legal,

scientific and food safety competent authorities and the need for reconciliation of a variety of viewpoints before policy could be amended.

If a similar event were to occur again, the recommendation made in Section 1.5 to adopt a project management approach¹ should ensure a speedier response in bringing together this wide range of viewpoints.

2.6 Communication with Meat Processors

The meat processors are the direct link to the retailer and consumer. They were included in the formal process after the publication of the Wall Report in October 2006 in the context of seeking their views on the acceptance of OFES cattle in the food chain. The importance of the processors should be recognised and should any further similar set of circumstances recur it is recommended that the processors' representative organisation, Northern Ireland Meat Exporters Association (NIMEA), should be formally involved in discussions with senior DARD personnel.

2.7 Conclusion and Recommendation

The on-farm follow-up action was in compliance with the legislation and was reasonable in the context of the scientific evidence and experience of the time. However, it is recognised that to those affected, the actions taken may seem out of proportion. In view of the concerns expressed about the surprise on-site searches, an analysis is required into the manner in which the searches are conducted to ensure that there is a sensitivity to the potential eventuality that not all farmers subject to searches will be found to have been involved in illegal activity. Other enforcement agencies experience similar issues and it is recommended that DARD reviews how other organisations handle such events with a view to sharing and developing best practice.

In order to speed up policy change and reduce disruption to business as evidence emerges, consideration should be given to adopting a project management approach. This might offer a possible means of speedier co-ordination of differing interests should a similar issue arise again.

It is also recommended that food processors, through their representative body NIMEA, should be involved in strategic discussions in recognition of their important link in communication with the retailer and consumer.

Rationale for the decision to make an ex-gratia payment in respect of the animals condemned

3 Introduction

This section examines the legal obligation, the moral obligation and the means by which the Department was able to make an ex-gratia payment.

3.1 Statutory Obligation and Moral Obligation

A distinction needs to be made between statutory and moral obligations.

3.2 Statutory Obligation

The Department is a creature of statute and can only do what statute authorises. DARD has a statutory obligation to remove alpha-nortestosterone positive animals from the food chain and is permitted to do so without incurring liability to pay compensation. The Department acted on the best scientific advice available at the time and in compliance with its community obligations. In this instance there was no statutory provision for the authorisation of compensation.

3.3 Goodwill Payment

Whilst there was no statutory provision for the authorisation of compensation the Minister decided there was a need to consider a goodwill payment. This was a unique case. The farmers were innocent of any wrongdoing but nevertheless, through no fault of their own, had suffered loss. Given that there was no evidence of wrongdoing on the part of the farmers and that scientific evidence suggests that alpha-nortestosterone may be naturally occurring in male OFES cattle, the Minister took the view that an ex-gratia payment should be considered. Accordingly, advice was sought on the Department's discretion to make an ex-gratia payment and the legal instrument whereby this payment might be made. The advice was that the decision on whether or not to make an ex gratia payment was a matter for the Department. Given that the purpose of the Community legislation was to prevent the artificial administration of hormonal substances it would not be incompatible with the Department's Community obligations for it to make ex gratia payments to the owners of animals where it was satisfied in all the circumstances of the case that the hormonal substance was present in the animal naturally. In the absence of clear legal liability, the Department could only make payments under the Budget Order. Accordingly the decision was taken by the Minister to make ex gratia payments in respect of OFES animals condemned due to testing positive for alpha-nortestosterone and where follow up investigations on each farm indicated that other animals were clear of the hormone.

The obligation under which the ex-gratia payment was made was moral rather than statutory.

4. Lessons Learnt and Recommended Future Action

Introduction

Lessons learnt and recommended future action arising from those lessons have been described in the previous sections. The following paragraphs summarise these lessons and recommended actions.

4.1 DARD Management Response to Emerging Science

There will always be unique events or sets of circumstances that will arise in the context of emerging science and its relationship to existing legislation. These events, because of their uniqueness will always be challenging. A constant awareness of emerging science and the need for timely action should continue to be at the forefront of the minds of senior DARD professionals and policy makers. Whilst a body of evidence will always be required to change scientific opinion, it may be possible to do this earlier and with greater speed if appropriate systems are in place. It is recommended that consideration be given to a Project Management approach to future unusual events of the kind.

4.2 Action on Future Implementation of Legislation in Response to DARD, AFBI evidence.

As a result of the evidence produced by DARD and scientists at AFBI, it is now accepted that alpha-nortestosterone is present in the urine of a significant proportion of OFES male cattle. It is therefore now important for DARD policy makers and AFBI scientists, together with local and European political representatives, to work together to ensure that the competent authorities decide what additional scientific evidence is required before advice on the interpretation of the legislation can be changed.

4.3 Approach to On Farm Searches

Taking into account the feedback from farmers during the course of the Review, it is recommended that DARD examines its approach to the manner in which on-farm searches are conducted to ensure that sensitivities are built in to take account of the potential eventuality that not all farmers subject to on-farm searches will have undertaken illegal activity. Other enforcement agencies experience similar issues and it is recommended that DARD examines the approaches taken by other organisations in order to share and develop best practice.

Implementation of Policy Change

The delay in implementation of policy change from the publication of the Wall Report in October 2006 until March 2007 was due largely to the need to reconcile legal, scientific and food safety viewpoints. The recommendation in Section 4.1 to adopt a Project Management approach at the beginning to manage and coordinate responses should ensure a speedier reconciliation of a wide range of viewpoints as evidence emerges.

4.5 Communication With Meat Processors

Meat processors are a vital part of the business chain. They are the direct link between the producer and the retailer and ultimately, the consumer. The importance of the processors' role should be recognised and in the event of a similar event arising in the future, it is recommended that NIMEA should be formally involved in strategic discussions with senior DARD personnel.

4.6 Actions

It is recommended that:

- (i) DARD acts with AFBI scientists and political representatives to ensure a speedy response to the question of what additional scientific evidence is required by Competent Authorities before advice on the interpretation of the legislation can be changed;
- (ii) DARD examines the mechanisms which can be built in to the management process to facilitate an earlier and speedier response to findings arising from emerging science and that the adoption of a Project Management approach be considered;
- (iii) DARD examines the manner in which it approaches on-farm searches with particular emphasis on communication, taking into account that it may be that not all farmers subject to surprise searches will have engaged in illegal activity;
- (iv) DARD ensures that processes are in place to allow for speedier implementation of policy change in response to evidence and that as in recommendation (ii), consideration be given to a Project Management approach to facilitate action;
- (v) DARD ensures that processors, through NIMEA, are formally involved in strategic discussions in any future similar event.

5. Conclusions

- 5.1 DARD acted upon the highest level of scientific advice available at the time from the Community Reference Laboratory in Bilthoven. When the pattern of results appeared unusual the Department and AFBI scientists questioned the advice and were informed that alpha-nortestosterone could not occur naturally in male bovines. The testing was expanded and with AFBI a body of evidence was established. When the unusual patterns continued the Department brought in an expert to review its own procedures for sampling and those of AFBI for testing. The expert concluded that he was satisfied that all reasonable practices and procedures were in place and agreed with AFBI scientists that there was a possibility that alpha-nortestosterone in male bovines could occur naturally due to stress or some other physiological explanation. The quantum of evidence established by DARD and AFBI has convinced scientific opinion to accept that the presence of alpha-nortestosterone in male bovines may be due to natural occurrence.

These were new and challenging circumstances in which the Department had to deal with its legislative responsibilities and the findings arising from emerging scientific evidence. Scientific knowledge is an evolutionary process and DARD is likely to meet new and unique situations in future. It is recommended that when these new and unique events arise that a project

management approach is adopted to ensure a focus on scientific issues and a co-ordination of actions to ensure minimum disruption to farmers in the course of their business. It is also recommended that DARD policy makers and AFBI scientists work with political representatives to ensure that the competent authorities in Europe make a decision on what further scientific evidence is required before advice on interpretation of the legislation can be changed.

- 5.2 The actions taken by DARD in respect of the surprise on-farm searches were in compliance with legislation. The actions were reasonable in the context of the scientific evidence of the time which was confirmed at the highest level in Europe, and also in the context of recent experience of illegal administration.

Enforcement actions such as surprise searches are essential to ensure the prevention and detection of illegal activity and to maintain the confidence enjoyed by our beef industry. Many elements of search procedure have to be maintained to comply with legislation and to satisfy legal process.

It is, however, recommended that the Department takes into account the concerns expressed by farmers subject to on-site searches. It is recommended that DARD examines the manner of its approach to future such searches to take into account the possibility that it may be that some farmers subject to such a search will not have been engaged in illegal activity. It is also recommended that DARD examines the approach taken by other enforcement agencies in order to share and develop best practice.

- 5.3 DARD amended policy in response to emerging evidence and in doing so had to reconcile its legal obligations, scientific advice, and public health and food safety considerations.

Concerns were expressed by farmers about the speed at which policy change was executed. The recommendation that in future a Project Management approach be adopted at the beginning of the process should provide sufficient focus to ensure that these complex issues are reconciled more quickly.

- 5.4 The Department acted on the best scientific advice available at the time and in compliance with the Community obligations. In this instance there was no statutory provision for the authorisation of compensation. In view of emerging scientific evidence and no evidence of wrong-doing by farmers, the Minister decided that an ex-gratia payment should be made in respect of condemned cattle. This payment was made under the Budget Order, the only legal instrument available to undertake such payment. The Department, having no statutory obligation, made the payment as a goodwill gesture.

- 5.5 It is recognised that there will always be unique events or sets of circumstances arising in the context of emerging science. This awareness and preparedness for timely action should continue to be at the forefront of minds of senior officials using the experience gained and the lessons learned from the alpha-nortestosterone case.

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