

Alphabetical List of Respondents to the Hormones Consultation

1. Fiona Bottrill, Wolverhampton City Council
2. Tim Brigstocke, Royal Association of British Dairy Farmers
3. Ms Kate Burnaby
4. Mike Daniels, Deer Commission for Scotland
5. Alistair Donaldson, Scottish Association of Meat Wholesalers
6. Dr D Grant
7. Ms Lucy Harry, Foodaware
8. Dr Esther Heller, Food Standards Agency
9. Peel Holroyd & Associates
10. Ms Susan Knox
11. Ms Jeanette Longfield, Sustain
12. Dr Tom Macmillan, Food Ethics Council
13. Janice Milne, Scottish Environment Protection Agency
14. Ms Patience Purdey, National Council of Women
15. Alsaneh Roberts, Country Land and Business Association
16. Richard Young, Soil Association
17. Jane Virgoe, British Veterinary Association

1. Fiona Bottrill, Wolverhampton City Council

-----Original Message-----

From: Webb, David

Sent: 05 September 2005 08:11

To: 'Fiona Bottrill'

Cc: Sharma, Isabel

Subject: RE: Consultation on Draft Report

Dear Fiona,

I have just returned from leave and can answer your questions:

1. The purpose of the report will be to review the latest scientific evidence in this area. The UK Government will use the report to inform its own position, which has always been based on the most up-to-date and robust science. However, the EU is extremely unlikely to alter its position and all growth promotional use of hormonally active substances will remain illegal. In fact the EU has recently tightened the controls on such substances for other purposes.
2. I can see how these two statements could seem contradictory, but they are consistent. Nearly all substances, even those which at lower doses are beneficial, can exert adverse effects if we are exposed at a sufficiently high level. Any increase in consumer exposure resulting from the use of such substances is likely to be very very low. Indeed for the natural hormones, the concentrations found in treated animals would be almost identical to untreated animals. As adverse effects have generally only been demonstrated where comparatively high doses have been administered, I believe the VPC concluded that 'the weight of evidence at present available suggests that likely levels of human exposure to hormonally-active substances in meat from treated animals would not be sufficient to induce any measurable physiological effect.'

I hope this is clear, but if you have any other questions do give me a call

Regards

David Webb

Veterinary Medicines Directorate

d.webb@vmd.defra.gsi.gov.uk

GTN 3046 8327

Tel 01932 338327

-----Original Message-----

From: Fiona Bottrill [mailto:Fiona.Bottrill@wolverhampton.gov.uk]

Sent: 23 August 2005 16:53

To: d.webb@vmd.defra.gsi.gov.uk

Cc: i.sharma@vdm.defra.gsi.gov.uk

Subject: Consultation on Draft Report

David,

A Member of the Health Scrutiny Panel has raised the issue of the effect of growth hormones used in food producing animals on child and adolescent development.

While researching this issue I came across the draft report on the VPC website and would be grateful if you could clarify a couple of things.

1) The historical background refers to the ban in the use of all hormonally-active substances as growth promoters in food producing animals and that the WTO has questioned the evidence behind this. Will the outcome of the VPC report affect the UK Government's position on this matter?

2) I find it difficult to reconcile the conclusion and the overview provided in the report. Paragraph 10.2.1 states that 'The Working Group were of the view that human exposure to residues of hormonally-active substances, including growth promoters in meat, could exert biological effects if exposure was at a sufficiently high level' and that further research was needed to determine what this level would be for adults and for neonates. While the Overview states that 'the weight of evidence at present available suggests that likely levels of human exposure to hormonally-active substances in meat from treated animals would not be sufficient to induce any measurable physiological effect.'

I would be grateful if you could let me know your views by the end of 7th September since I will need to take this information to the agenda meeting for the next health scrutiny panel on 8th September.

Yours sincerely,

Fiona Bottrill
Health Policy and Scrutiny Officer
Wolverhampton City Council
01902 554065

2. Tim Brigstocke, Royal Association of British Dairy Farmers

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20 OCT 2005

RABDF

Working for British Dairy Farmers

ROYAL ASSOCIATION OF BRITISH DAIRY FARMERS

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David Webb
Veterinary Medicines Directorate
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18 October 2005

Dear Sir

CONSULTATION ON A DRAFT REPORT BY THE VETERINARY PRODUCTS COMMITTEE ON THE RISKS ASSOCIATED WITH THE USE OF HORMONAL SUBSTANCES IN FOOD-PRODUCING ANIMALS

Thank you for your Consultation re the above subject.

The Royal Association of British Dairy Farmers (RABDF) is the only UK-wide independent organisation specifically representing the dairy farming sector and thus report is of direct relevance to our members.

We very much applaud the robust and vigorous way the Veterinary Products Committee (VPC) have questioned the European Commission's Scientific Committee on Veterinary measures relating to Public Health (SCVPH) assessment of the risks associated with the use of hormonal substances. We strongly support the approach taken by the VPC which is quite correctly based on the best available science.

That said it is clearly vital that nothing should denigrate or question the safety of food available to consumers and thus the VPC conclusions that the weight of evidence suggests that likely levels of human exposure to hormonally-active substances in meat from treated animals would not be sufficient to induce any measurable physiological effect needs to be handled very carefully if this becomes a media issue.

Hopefully these comments will be of help. If RABDF can be of any further assistance then please do not hesitate to get in touch.

Yours sincerely

Tim Brigstocke
Chairman

3. Ms Kate Burnaby

-----Original Message-----

From: kate.burnby@stock1st.co.uk [mailto:kate.burnby@stock1st.co.uk]

Sent: 30 August 2005 19:11

To: i.sharma@vmd.defra.gsi.gov.uk

Subject: Oestrodial benzotae/Estradiol benzoate/Cidrol

Dear Sir/Madam

We regularly use synchronisation programs for dairy and beef cattle in our practice, and feel they are of great benefit to our producers saving labour, enabling planned breeding with generation of AI calves and more accurate calving dates and requiring them to run fewer/no bulls.

Up until recently we have been able to use CIDR devices, from ART/Interag, with Oestrodial Benzoate, from Intervet

Intervet no longer supply OB, and we are lost for an alternate.

Pregnancy rates and efficacy of the synchronisation are significantly better when using OB.

What is the position regarding use of and obtaining these medicines, and the alternative to OB, "Cidrol" that is routinely used in New Zealand? Are there any other alternates that you know of?

Thanks in advance for any assistance you may give us.

Kate Burnby

Kate Burnby BVSc CertCHP MRCVS

Veterinary Director

Stock 1st Veterinary and Livestock Services

4. Mike Daniels, Deer Commission for Scotland

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30 August 2005

Dear Mr Webb

DCS response to invitation for comment on Consultation on a draft report by the Veterinary Products Committee on the risks associated with the use of Hormonal Substance on Food-Producing Animals

I am writing to thank you for providing the Deer Commission for Scotland with the opportunity to respond to the Consultation on a draft report by the Veterinary Products Committee on the risks associated with the use of Hormonal Substance on Food-Producing Animals.

On this occasion, DCS feels it has no comment to make on this consultation at the present time but would wish to be kept informed of developments.

Yours sincerely

[*Signed*]

Mike Daniels
Research and Data Manager

5. Alistair Donaldson, Scottish Association of Meat Wholesalers

25 August 2005

David Webb
VMD
Woodham Lane
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Addlestone
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Dear David

Consultation on Draft SI Amending Animals and Animal Products Regulations 1997
Consultation on Draft VPC Report on Risks Associated with the Use of Hormonal Substances in Food Producing Animals

I write in response to the letters of 8 and 17 August respectively from Eric Crutcher on the above two topics.

In relation to the draft SI we note the comments made and the changes proposed but have no specific comment to offer.

With regard to the VPC report we note the developments arising from the initial SCVPH report culminating in this latest draft report and the continuing difference of opinion albeit that there are important gaps in the evidence base.

We assume that the proposed structured approach and the specific needs identified will be addressed and that a more definitive conclusion will result due course.

On the basis that the outcome supports the use of hormonal substances at some future stage a number of fundamental issues will be raised. The most important will be consumer reaction at a time when the image of red meat has been successfully rebuilt following well documented health/safety scares.

There are also trading issues linked to WTO discussions with the United States continuing to challenge the EU embargo on hormone use. We are aware that EFSA has been asked to review the hormone issue in this context.

Taking account of these points we would be pleased to discuss on going progress on this matter.

Yours sincerely

Alistair Donaldson

6. Dr D Grant

-----Original Message-----

From: Donald Grant [mailto:donald.grant2@sympatico.ca]

Sent: 24 August 2005 04:27

To: i.sharma@vmd.defra.gsi.gov.uk

Subject: VPC may 05 Report

Dear Dr Sharma

Firstly, may I thank you for sending me the VPC report. I have quickly read it and found it very informative. I am not an expert on Trenbolone and would like confirmation that on page 54 that "gestagen" and "progestrone" are correct or should it be "androgen" and "testosterone".

Regards

Don Grant

7. Ms Lucy Harry, Foodaware

CFG 28/05 rev

Foodaware comments on the draft report by the Veterinary Products Committee on the risks associated with the use of hormonal substances in food-producing animals

Foodaware; the Consumers' Food Group, coordinates the broad UK consumer movement's work on food safety, nutrition and standards. Our mission is to give UK consumers a strong voice on food policy by bringing together the organisations that represent them. We also consult and support the UK consumer representatives on food related committees, and further the public understanding of science. Our members are consumer, women's, family, ethnic minority and enforcement organisations, who also contribute time and expertise to our representations.

We understand that this draft report by the Veterinary Products Committee (VPC) represents the latest in a series of assessments, and counter-assessments, by the European Commission's Scientific Committee on Veterinary measures relating to Public Health (SCVPH) and the VPC. These have concentrated on assessing the evidence concerning the risk to human health from the use of six hormonally-active substances used for growth promotion in cattle: 17 β oestradiol, testosterone, zeranol, progesterone, trenbolone acetate and melengestrol acetate.

While the use of hormone growth promoters (HGP) in cattle has been banned in the European Community since 1988, their use has continued in the USA and Canada. Any third country that permits their use is required to guarantee that no animals, and no meat coming from animals, to which they have been administered, will be exported to the EU. In 1998 the World Trade Organisation ruled that the EU had not undertaken a proper risk assessment prior to imposing the ban. We therefore note that there is great political-economic pressure, particularly from the USA, to open up the European market that is at present closed to them. It is in this context that the European Commission SCVPH carried out its initial new risk assessment, published in April 1999, the findings of which were confirmed in 2002.

This recent VPC draft report states that:

“following a critical evaluation of the scientific reasoning and methods of argument adopted in the key papers and studies...the Working Group were unable to support the conclusion reached by the SCVPH that risks associated with the consumption of meat from hormone-treated cattle may be greater than previously thought. The weight of evidence at present available suggests that likely levels of human exposure to hormonally-active substances in meat from treated animals would be not sufficient to induce any measurable physiological effect”.

Foodaware is not in a position to comment on the scientific data on which these risk assessments have been carried out. However, it is concerned that the VPC draft report then goes on to state a number of reservations, in particular that “there

important gaps in the evidence base that preclude producing definitive risk assessments for 17 β -oestradiol or the other five hormonally active substances.” The conclusions and recommendations of the report, indeed, spell out the many uncertainties and grey areas that exist as well as the incomplete science base.

Given that there are considerable gaps in the evidence, Foodaware urges that the Precautionary Principle should be applied in the case of these substances until further, independent, research has been carried out to answer the many outstanding questions and uncertainties highlighted by this latest VPC report.

Another area of concern is that the risk assessments carried out to date on these substances have considered them as single substances while the report itself states “substances with hormonal action may be used in combination, both legally and illegally”. Further research is needed to assess their safety, taking into account all sources of exposure, as suggested by the recent WIGRAMPS report including interactions with natural hormones. It would appear that knowledge of the pharmacokinetics of synthetic hormonal products is far from complete.

The report also refers to the fact that there is considerable potential for the misuse and abuse of hormonal substances used for growth promotion compared to therapeutic uses. This is of great concern to consumers and a factor that should be taken into account when safety assessments are made. It should also be remembered, when making any risk assessment, that millions of people would be subject to any untoward effect resulting from the use of such products in a non-therapeutic manner – not only the pre-pubertal children and post-menopausal women who the report indicates would be at greatest risk.

The issue of animal welfare is of great concern to our members. The use of HGP benefits the manufacturers of the substances as well as beef producers but offers no advantage to the animals themselves. Animal health and welfare issues must be considered as part of safety assessments. These, as mentioned above, must take into account the fact that there is a high risk of abuse and misuse (higher than recommended doses being administered, drugs being used in combinations, withdrawal periods not being respected etc).

In addition, although it is not directly linked to the content of the report, it is worth mentioning that consumers’ confidence in the food supply, particularly that of meat, has been seriously undermined by BSE and other food scares in recent years. It was another such unnatural use of a food/product, when animal remains were fed to herbivores in an effort to save production costs, which led to BSE. Consumers would rather see animal production becoming less intensified and with greater consideration of animal welfare issues. Given this climate of opinion, and with such fragile consumer confidence in the meat industry, it is hard to see the use of HGPs being widely accepted by consumers now or in the foreseeable future.

In sum, the report highlights many areas of uncertainty and concern and where further research is needed to fill the gaps in the scientific evidence base. Given this situation we feel that it is premature to draw any definitive conclusions about the safety of the use of HGPs in animal production and consumers would consider that the statement in the report that “likely levels of human exposure to hormonally-

active substances in meat from treated animals would be not sufficient to induce any measurable physiological effect” to be both unfortunate and premature based, as it appears, on the absence of science.

We hope these comments are helpful. We are happy for this response to be made publicly available.

Yours sincerely

Susan Knox
Chairperson

8. Dr Esther Heller, Food Standards Agency

Mr David Webb
Veterinary Medicines Directorate
Woodham Lane
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KT15 3LS

9 November 2005

Reference: PVM/003/006

A

Dear Mr Webb

CONSULTATION ON THE DRAFT REPORT BY THE VETERINARY PRODUCTS COMMITTEE ON THE RISKS ASSOCIATED WITH THE USE OF HORMONAL SUBSTANCES IN FOOD-PRODUCING ANIMALS

We welcome the opportunity to comment on the draft Veterinary Products Committee (VPC) Report May 2005, on the Risks Associated with the Use of Hormonal Substances in Food-Producing Animals. The Agency has independently considered the current scientific evidence, and we are in broad agreement with the conclusions of the VPC draft report, that there is no scientific justification for treating the growth promoting hormones as a group. We advocate that each hormone should be considered on a case-by-case assessment of all scientific data.

We would like to offer the following comments on specific conclusions in the report.

There are important gaps in the evidence base that preclude producing definitive risk assessments for 17 beta-oestradiol or the other five hormonally-active substances.

The Agency agrees that the gaps in the data preclude a definitive risk assessment for the six growth promoting hormones. In order to make definitive statements about the safety of these substances, all of the data available on each hormone will need to be considered (including unpublished data owned by companies) not just the selection of papers seen by the European Commission's Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) and the VPC.

Metabolites of oestradiol do have the potential to be genotoxic, in vitro and in vivo. SCVPH concluded that 17 β -oestradiol is a complete carcinogen, and that it has the potential to be genotoxic as a consequence of metabolic activation to reactive substances known as quinones. Hence they have concluded that it is not possible to quantify the risk, and that no safe threshold for exposure to 17 β -oestradiol can be defined.

In contrast the VPC concluded that although metabolites of oestradiol do have the potential to be genotoxic *in vitro* and *in vivo*, it is also reasonable to consider that a

threshold for the carcinogenicity of oestradiol may exist. This view is underpinned by the UK's Committee on Mutagenicity (COM) which recognises that for some substances that act via a specific mechanism of mutagenicity, enough evidence is available to conclude that a threshold or safe level of exposure exists. Metabolites of oestradiol (i.e., quinones) fall into this category since they cause genotoxicity by a mechanism that can readily be countered by the natural defence systems of the tissues and cells in the body.

The VPC concluded that the weight of evidence indicates that it is very unlikely that the presence of 17 β -oestradiol and its metabolites in meat from treated animals would significantly increase the risk of adverse effects in consumers, unless an active implant site is ingested. In part, this is because residues of 17 β -oestradiol and its metabolites would occur at very low concentrations in comparison with the levels produced naturally by the animal, and exposure levels from other dietary sources. We support the VPC's conclusions with respect to consumer safety.

Zeranol and Zearalenone

The draft VPC Report concludes there is insufficient data to indicate zeranol is genotoxic.

In 1998 the COM considered the possible mutagenicity of the mycotoxin zearalenone, a metabolite of zeranol. It advised that zearalenone should be considered as being potentially genotoxic *in vivo*. We believe that until a definitive assessment of all scientific data on zeranol and zearalenone can be undertaken, a precautionary approach should be taken and both should therefore be considered potentially genotoxic.

However, we are aware that consumer exposure to zeranol (and zearalenone) residues in food from this source are not a concern at present, as no zeranol products are authorised for use in food producing animals within the EU, and food from animals treated with zeranol cannot be imported into the EU. None-the-less, until a complete risk assessment can be undertaken, and based on the current available evidence, the FSA considers that a ban on zeranol would be prudent.

Yours sincerely

Esther Heller
Primary Production Division

Statement on Risk Assessment of *In-Vivo* Mutagens (and Genotoxic Carcinogens)

Statement - COM/01/S3 - June 2001

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Introduction

1. The general advice of the COM when considering the risk assessment of chemicals which are mutagenic *in-vivo* has been that it is prudent to assume a linear, non threshold dose response. Thus it is assumed that any exposure to an *in-vivo* mutagen is associated with some damage to DNA and consequently an increased risk of mutation leading to an increased risk of adverse health effects albeit that this may be small. In such instances the Committee has recommended that exposures be reduced to a low as is reasonably practicable. The COC has adopted a prudent approach to the assessment of chemical carcinogens which assumes that genotoxic carcinogens have the potential to damage DNA at any level of exposure and that such damage may lead to tumour development. Thus for genotoxic carcinogens it is assumed that there is no discernible threshold and that any level of exposure carries a risk. (1,2)

2. The COM agreed to review its general approach to the risk assessment of *in-vivo* mutagens following the publication of the COM guidance on a strategy for testing chemicals for mutagenicity.(3) The Committee has previously considered specific chemicals, on a case-by-case basis, with regard to deviations from its general approach to *in-vivo* mutagens. This statement summarises the conclusions reached at the February meeting 2001.

Evidence for existence of *in-vivo* thresholds for mutagenic effects

3. The Committee recalled that there were two mechanisms for which sufficient evidence is available for the COM to conclude that a threshold for mutagenicity exists namely (i) aneugenicity induction by tubulin inhibitors (specifically methyl benzimidazole carbamates (MBCs), benomyl, carbendazim and thiophanate-methyl) and, (ii) the rapid detoxication of hydroquinone and phenol via the oral route. The Committee has undertaken detailed reviews of the mutagenicity data on these chemicals and full statements have been published on the COM Website (www.doh.gov.uk/com.htm) and in the Committee's Annual Reports.(1) A brief overview is given below with the objective of providing background information on the approach used to provide the

critical data used by the COM in its evaluation.

Methyl benzimidazole carbamates (MBC) induced aneugenicity.

4. Benomyl, carbendazim and thiophanate-methyl belong to the methyl benzimidazole carbamate (MBCs) class of chemicals. The MBC class of chemicals are widely used in approved pesticide products as fungicides and also in veterinary medicines in particular as antihelmintics in both food producing and companion animals. These chemicals act by interfering with microtubule formation during mitosis. The COM has provided advice to the U.K regulatory Authorities namely the Pesticides Safety Directorate (PSD) and the Veterinary Medicines Directorate (VMD) of the Ministry of Agriculture, Fisheries and Food on the most appropriate approach for the risk assessment of MBCs. (4-6)

5. In 1993 the COM agreed that it was reasonable to assume that aneuploidy inducing chemicals (particularly those that function by interfering with the spindle apparatus of cell division) have a threshold of action.(4) The safety evaluation of aneuploidy inducing chemicals (aneugens) acting by inhibition of microtubule formation is based on the identification of a threshold dose below which aneuploidy does not occur. The Committee provided advice on methodologies for identifying thresholds in 1993, namely appropriate in-vitro experiments in human lymphocytes using the detection and quantification of non-disjunction chromosome less and centromere positive nuclei using FISH (Fluorescent in-situ hybridisation) analysis of selected chromosomes for centromeric DNA. The Committee considered that it was not possible to determine thresholds for aneugenicity using the currently available in-vivo assays. This advice was used by PSD and VMD when requesting data from approval/licence holders of products containing MBCs. In 1996, the Committee considered the results of experiments undertaken with benomyl and carbendazim and concluded that the studies had been satisfactorily conducted and the data indicated No Observed Effect Levels (NOELs) could be estimated for these two chemicals. (7-10) It was noted that that it would be difficult to define precise thresholds for activity from these data and the mathematical models that had been used for their analysis. Appropriate studies which provided evidence for a threshold effect have also been undertaken with thiophanate-methyl.(11)

Hydroquinone and phenol

6. In 1994, the COM agreed that both hydroquinone and phenol should be regarded as somatic cell *in-vivo* mutagens.(12-19) The Committee agreed that for exposure to these two compounds by the oral route there was potential for a threshold of activity as there was good evidence from appropriate toxicokinetic studies that two protective mechanisms (namely rapid conjugation and detoxification via the glutathione pathway) would substantially reduce systemic exposure to any active metabolites formed. However, Members agreed that there

were insufficient data on inhalation and dermal exposure and it was not possible to assume that a threshold existed for activity when exposure was via the respiratory tract or the skin. The Committee noted the information from one published paper that when radiolabelled phenol was given intratracheally, initially all the radiolabel in the plasma was present as phenol. (20) These data suggested that there was little conjugation of phenol on the "first-pass" from airways to the circulation. The Committee recommended that appropriate toxicokinetic studies were needed. In 1999, further data from published papers on the kinetics of hydroquinone in rats following intratracheal instillation and on its percutaneous absorption in *in-vitro* studies using rat skin and human stratum corneum were provided to the Committee. (21,22) The new toxicokinetic study in which rats were given a single intratracheal dose of ¹⁴C-hydroquinone showed detectable free hydroquinone in arterial blood within 5-10 seconds after dosing. (21) This new information suggested a potential risk of site-of- contact and systemic mutagenic effects following inhalation exposure to hydroquinone.

7. The data on MBCs and hydroquinone and phenol show that if there were specific data on a chemical to invoke such mechanisms then the possibility of threshold could be considered. Members agreed that data on threshold-related mechanisms would in most instances come from *in-vitro* studies. Any observed NOEL from such *in-vitro* mechanistic studies could be used to inform a risk assessment but it was unlikely that the data could be used in a quantitative way. In those cases where a potential threshold mechanism is based on chemical detoxication, then appropriate *in-vivo* data will be required.

Possible mechanisms for thresholded mutagenicity

8. The Committee reviewed a number of papers which reported proceedings of an international symposium held in Salzburg in September 1998. (23) Two broad categories of potentially threshold mechanisms were interaction with non-DNA targets and rapid detoxication which were consistent with the COM's experience regarding MBCs and hydroquinone and phenol. In addition further papers presented to the symposium noted that threshold dose responses could involve exposure to redundant or multiple cellular targets with inactivation or modification before a toxic response is produced. (24) Lists of potential cellular targets for threshold-related genotoxicity were presented at the Symposium which essentially identify protein targets such as microtubules, DNA synthetases, topoisomerases. (25) The Committee agreed that appropriate supporting evidence would be required in order to invoke any of these mechanisms on a chemical-by-chemical basis.

Conclusions

9. The COM reaffirmed that for *in-vivo* mutagens, it is prudent to assume that there is no threshold for mutagenicity. Where a potential

threshold related mechanism can be identified, appropriate data should be generated on a chemical-by-chemical basis. In many situations this will involve *in-vitro* studies of mechanism. An appropriate strategy should be devised for each chemical under consideration and this may, in some instances, include *in-vivo* studies. The regulatory approach to such chemicals can then be based on the identification of a critical NOAEL and use of uncertainty factors.

June 2001

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22 AUG 2005

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9. Peel Holroyd & Associates

PEEL HOLROYD & ASSOCIATES

Consultants in Agriculture and Food from the Farm to the Consumer

Senior Partners:-

Peel H. Holroyd, N.D.P., Dip, Poult (H.A.C.), Dip. Agric (Q.A.C.), Cbiol., M.J.Biol., P.A.S. (USA), F.H.A.A.C., F.R. Ag.S., FIFST, FICC.

Margot E.Telford Holroyd, N.D.P., Dip.Poult (IIAC).

Fax

Dr Steve Dean/Director VMD Addlestone KT15 3LS

Date: 22/08/05

(1) Re – your letter of 11-08-05 + use of Hormonal Substances in Food Producing Animals

(2) I note the content of the Draft VPC report. May I comment?

Item 8 - is there not an age factor involved

- i.e.
- Children
 - Adult
 - Elderly ? i.e. An individual life pattern?

Item 9 - added to age variations within any population + and inevitable individual difference across the UK on Total Human Population – what is the situation in Vegetarians versus Meat Eaters?

(3) Thank you for keeping me informed of your considerations.

Sincerely

[Signed]

Peel H. Holroyd

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10. Ms Susan Knox

-----OriginalMessage-----

From: SuToKnox@aol.com [mailto:SuToKnox@aol.com]
Sent: 17 November 2005 21:16
To: e.crutcher@vmd.defra.gsi.gov.uk; dorothycraig@btinternet.com
Subject: Re: VPC meeting

In a message dated 17/11/2005 09:14:57 GMT Standard Time,
e.crutcher@vmd.defra.gsi.gov.uk writes:

Dear Eric,

Thank you. Sorry I did not stay until the bitter end; don't suppose we could have been more frozen but it was necessary to catch homeward transportation. And time was way out. I do realise that timing is the most difficult part to get right. But the last two presentations rather precluded further comment/questions on the VPC hormone report.

It is the gaps in information that concern me most. Among the reports key issues discussed in the WG They said the 17 new EU studies only partially address areas of uncertainty and major gaps still exist. I would be so bold as to say conclusions cannot be drawn if there are still major gaps. Therefore the precautionary principle needs to be applied if we are to have confidence in these areas of work. I would have liked to question the whole section Underpinning Conclusions and Recommendations (2). When I was a member of the TransAtlantic Consumer Dialogue in the early years, we had discussions with American consumer groups because CEG has always worked for the ban of hormones as growth promoters. In America you know they are widely used and the Americans were admitting that girls were maturing at 8/9 and they suspected it could be due to hormone use. But the Meat industry is powerful! That particular section says research has provided some but not all information. So obviously more needs to be done. At least it is encouraging to note the statements in Qualifications and Limitations 1 & 2 and the sections on Future Specific Research Needs. I realise that hormones as growth promoters are banned in the EU but we are not so convinced that there is not a move especially through the WTO to allow them.

I was very glad I attended and apologies again for leaving at 4:15 but time and transport waits for no one.

Best wishes,

Susan

11. Ms Jeanette Longfield, Sustain

8 November 2005

David Webb
Veterinary Medicines Directorate
Woodham Lane
New Haw, Addlestone,
Surrey KT15 3LS

Dear David Webb

Re: Comments on the draft report by the Veterinary Products Committee on the risks associated with the use of hormonal substances in food-producing animals

As you may know, Sustain: the alliance for better food and farming has a very broad membership of around 100 national organisations. Thus we would not normally write to you about a specialist issue such as this since, as a rule, our expert member organisations are happy to cover these areas. However, this draft report, which appears to underplay the risks to consumers and ignore animal welfare issues altogether, raises a number of important points of principle and some grave concerns, as follows:

- Adhering to the precautionary principle

A number of expert scientific committees have examined the potential risks to human health of six hormonally active substances used for growth promotion in cattle - 17β -oestradiol, testosterone, zeranol, progesterone, trenbolone acetate and melengestrol acetate. While the health risks appear to be low, they are not zero and some groups – for example pre-pubertal children and post-menopausal women – may be at higher risk. Moreover, there is widespread agreement that there are important gaps in the scientific evidence, including on the possible effects of such products being consumed in varying “cocktails” of combinations from a range of animal products, and from interaction with natural hormones.

It is also agreed that there are no benefits to human health from using hormone growth promoters (HGPs) in food producing animals, so the risk-benefit assessment is very clear as regards human health; it is all potential risk and no potential benefit. It seems entirely appropriate, under these circumstances, that the European Union should continue to protect its citizens from this unnecessary risk by prohibiting the use of HGPs within the EU, and ensuring that any third country that permits their use must guarantee that no animals, and no meat coming from animals to which they have been administered, will be imported into the EU.

This seems to us to be an appropriate and proportionate use of the precautionary principle.

- Taking full account of animal welfare

The report makes no mention of the impact on animal health and welfare of the use of HGP's. We are not aware of any published research on this issue, and this seems to us to be another important gap in the evidence. Experience from other, related areas, such as the use of recombinant bovine somatotropin, indicates that animal welfare is likely to deteriorate. It is very disappointing that a body specialising in veterinary issues should appear to pay so little attention to animal health and welfare.

- The influence of trade disputes with the USA

We strongly suspect that the EU continues to be under pressure from the USA to lift its ban on importing animals and meat from animals that have been treated with HGP's. We believe the reasons for this pressure are economic, and are not related to the scientific evidence on either risks to human health or on damage to animal health and welfare. Given the current scientific evidence, and the significant gaps in this evidence, we believe that both the Veterinary Products Committee and the Veterinary Medicines Directorate should be robust in defending the existing science, calling for more research, and resisting economic and political pressure from elsewhere.

We are very grateful to the Food Ethics Council for drawing this important issue to our attention, and we look forward to hearing from you shortly.

Best wishes

Jeanette

Jeanette Longfield
Co-ordinator

12. Dr Tom Macmillan, Food Ethics Council

HORMONAL SUBSTANCES

Response to VPC/VMD consultation

8th November 2005

Introduction

In April 1999, the European Commission published an Opinion of the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) on the potential risks to human health of six hormonally active substances used for growth promotion in cattle - 17 β -oestradiol, testosterone, zeranol, progesterone, trenbolone acetate and melengestrol acetate. The conclusion was that risks associated with consuming meat from cattle treated with these hormones were higher than previously thought. Assessments of the SCVPH opinion by a subcommittee of the Veterinary Products Committee (VPC) and the European Safety Working Group of the Committee for Veterinary Medicinal Products (CVMP) were unable to support its conclusions. Although upholding the EU ban on such products, the UK government accepted the view of the VPC.

Following the VPC and CVMP evaluations, the SCVPH reviewed its opinion, and stated in May 2000 that its original opinion still stood. Following the release of 17 European Commission funded research studies to evaluate health and environmental risks of the above hormones, the SCVPH published another opinion in April 2002, reiterating that its original conclusions still stand. In November 2002, the VPC Working Group on Hormones was formed to re-examine the scientific evidence for a ban on the use of hormones in food producing animals, and its findings are reported in *Risks associated with the use of hormonal substances in food-producing animals*.

We welcome the opportunity to comment on that report. This brief response is based on previous work by the Food Ethics Council.

Regulatory context

Human and animal health

The report discusses the risks to *human health* of using hormonal substances in food-producing animals. By way of context, it is important to note that human health is not the only safety issue relevant to regulation. Under European rules, regulators are also responsible for protecting animal health and welfare. Even if there were no human health concerns about the use of hormonal substances, they would be prohibited if they posed significant risks to animals.

A parallel might be drawn with the use of bovine somatotrophin, which is banned in Europe on such grounds. Like bovine somatotrophin, and unlike veterinary products used for the cure or prevention of disease, Hormone Growth Promoters (HGP) are of no benefit to the animal, being used only to increase yield.

It is also important to note that it is not only health, whether human or animal, that is at risk. The use of HGP might, in particular, poses a risk to the autonomy of treated animals, by treating them simply as means of production and failing to respect their intrinsic value. A requirement to respect the intrinsic value of animals is enshrined in the EU Treaty of Amsterdam.

Risks and benefits

The Working Group report focuses on the *risks* of using hormonal substances. Under European regulations on veterinary drugs, which entered into force in the UK in October 2005, risk managers interpreting would be required to consider these risks alongside potential benefits. Article 19 (2) (b) of the new regulations states that an application for a marketing authorisation for a new veterinary drug will be refused when “the risk-benefit balance of the veterinary medicinal product is unfavourable”.

The risks to human health of using HGPs are at best uncertain. They offer no benefits to the treated animals or to consumers. The main beneficiaries would be the farmers who adopt the technology earliest, who might see a short-term increase in competitiveness, and the HGP manufacturers. There are no benefits to the public at large against which to balance the many uncertain and potentially significant health risks that are listed in the VPC sub-group report.

The VPC is only charged with assessing risks, not with managing them or with weighing the risk-benefit balance. Nevertheless, the manner in which any expert advisory committee frames its risk assessment affects the approach taken subsequently by risk managers. It is therefore essential for the VPC to be mindful of the risk management issues we have described when they prepare their advice. In particular, they should also note that the notion risks and benefits should be weighed by decision-makers derives from the Precautionary Principle.¹ This principle, which is enshrined in European legislation, requires a presumption in favour of safety under conditions of significant uncertainty. The VPC’s advice should state clearly that the uncertainties its report identifies around human health are sufficient to trigger this presumption in favour of safety.

A clear message

Section 1.4 of the report notes that the decision about the use of HGPs is beyond the mandate of the Working Group. Nevertheless, the risk managers who make the decision must VMDhormones.doc Page 3 of 5 draw on the evidence gathered in the report and on the expert opinion of the Working Group.

If the report is ambiguous, leading to a situation where risk managers could extract contrasting expert opinions depending on the paragraphs they elected to cite, then the Working Group will have abdicated responsibility for its share in the task of evaluating HGPs in the public interest.

It is therefore essential that the report presents a clear message, particularly in the executive summary, and the conclusions and recommendations. In its current state, however, the report could easily be cited in support of a number of contrasting regulatory outcomes. For example, the executive summary (the part of the report likely to be read the most), tells us that “The weight of evidence at present available suggests that likely levels of human exposure to hormonally-active substances in meat from treated animals would not be sufficient to induce

any measurable physiological effect". This suggests that there are no significant risks.

However, the executive summary also states "the Group acknowledges there are important gaps in the evidence base that preclude producing definitive risk assessments for 17_- oestradiol or the other five hormonally active substances".

The second statement is the more important of the two. There are no benefits against which to balance the uncertain and potentially significant risks that are discussed in the report.

These uncertainties are therefore sufficient grounds for prohibiting the use of HGP. Yet it is the first of these two statements that seems to be worded more strongly.

We recommend that the report makes it absolutely and unambiguously clear throughout that there remains serious scientific uncertainty about the safety of HGP. Set against the "important gaps in the evidence base", the "weight of evidence at present" is beside the point.

Uncertainties

The report records that "the Working Group was unanimous that all uncertainties must be made clear, especially those that were considered crucial in the risk assessment process" (Section 10.2, paragraph 5). The report as a whole notes serious uncertainties in current knowledge. For example, Section 3.1 cites Maume et al (2001), who suggest uncertainty as to whether a standard 500g portion of meat from cattle that had received multiple implants of 17_-oestradiol would exceed the ADI for pre-pubertal boys. Chapter 4 fails to rule out increased risk of breast cancer in post-menopausal women due to ingestion of 17_-oestradiol.

Paragraph 5 of the conclusions and recommendations sets out two particularly important gaps in current knowledge.

Realistic exposure scenarios

First, paragraph 5 states that "all scientific judgements made by the working group were based on the assumption that the consumer is exposed to no greater concentrations of residues than those arising from "correct" or "recommended" use of the exogenous

1 **Mepham, B.** 2005. *Bioethics: an introduction for the biosciences.* Oxford University Press, Oxford.

hormones". This is an important gap. The SCVPH (2002) report noted that misplaced implants (the residue from HGP is significantly higher in meat from the implant site) and repeated implanting occur frequently, and this is not challenged by the report. If HGP are made legal in the UK, economic considerations suggest that they will be used by a large number of meat producers. On this basis, the assumption that consumers will only be exposed to residues arising from "correct" or "recommended" of exogenous hormones seems a dangerous assumption to make. We suggest that the VPC take into account the draft Working Principles for Risk Analysis for Food Safety (CX/GP 04/20/4) of the Codex Alimentarius Commission², which highlight the importance of considering realistic exposure scenarios in risk assessment.

'Cocktail effect'

Second, the report states that “substances with hormonal action may be used in combination, both legally and illegally, while the toxicological and safety factors available (e.g. ADIs) only relate to single substances”. In a recent paper, Gray stated that “Sub-threshold Levels of two different chemicals, neither of which alone cause any observable adverse effects, can cause damaging effects when administered in combination”. [reference] One cannot assume that just because two substances have no measurable effect, the same will be true of those same substances in combination. As HGP's are likely to be used in combination with other hormonally active substances (legally and illegally) the likelihood of creating 'cocktails' is high. While the report suggests that an understanding of synergistic effects would “improve future risk assessments” (Conclusions and Recommendations, paragraph 9), it does not place sufficient emphasis on this important gap in knowledge.

Conclusion

In light of these uncertainties, the statement that “the weight of evidence at present available suggests that likely levels of human exposure to hormonally-active substances in meat from treated animals would not be sufficient to induce any measurable physiological effect” (Executive Summary) seems imprudent. Bearing in mind the important gaps in knowledge, the predominant message of this report should be that not enough is known at present to rule out serious and realistic health risks from human exposure to residues of HGP's in animal products. We recommend the VPC to amend the report to ensure that this message is absolutely clear on even the most cursory reading.

2 Codex Committee on General Principles 2004. Proposed draft working principles for risk analysis for food safety (CX/GP 04/20/4). Codex Alimentarius Commission. Paris. May 3-7. These working principles will offer guidance for member states. Codex is already committed to considering realistic exposure scenarios in its own work by its Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius adopted at the twenty-sixth session of the Codex Alimentarius Commission, Rome 30 June-7 July 2003.

The Food Standards Agency has suggested that “Should there be any move to change the current ban on the use of Hormone Growth Promoters the FSA would want a thorough review of the food safety issues”. This is something which the VPC have agreed would be appropriate (VPC minutes May 2005 item 9.6). In addition, we remind the VMD that human health is not the only issue relevant to regulation. Demonstrable harm to animal health and welfare would be a strong reason for banning HGP's.

About the Food Ethics Council

The Food Ethics Council is a registered charity (No. 1101885) which reports on ethical issues in food and agriculture. Our members are:

_ **Ms Helen Browning:** (Chair) Organic farmer; Food and Farming Director, Soil Association

_ **Prof Ruth Chadwick:** Director, ESRC Centre for the Economic and Social Aspects of Genomics, University of Lancaster

_ **Dr Elizabeth Dowler:** Department of Sociology, University of Warwick, researching food and social policy

_ **Ms Jeanette Longfield:** Coordinator of Sustain – the alliance for better food and farming

_ **Dr Peter Lund:** Senior Lecturer, School of Biological Sciences, University of Birmingham

_ **Prof Ben Mepham:** Director, Centre for Applied Bioethics, University of Nottingham

_ **Prof Kevin Morgan:** Director, Regeneration Institute, Cardiff University

_ **Dr Kate Rawles:** Freelance consultant

_ **Dr Doris Schroeder:** Reader in Ethics, Centre for Professional Ethics, University of Central Lancashire

_ **Mr Geoff Tansey:** Freelance writer and consultant

_ **Mr Colin Tudge:** Freelance writer and broadcaster

_ **Mr John Verrall:** (Treasurer) Pharmaceutical chemist

Further information about the Council, including a list of publications, is available on our web site (www.foodethicscouncil.org).

We would be glad to discuss these comments. For further information about this document

please contact Dr Tom MacMillan, Executive Director, by emailing tom@foodethicscouncil.org or telephoning 01273 766654.

13. Janice Milne, Scottish Environment Protection Agency

David Webb
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3LS

by email: d.webb@vmd.defra.gsi.gov.uk

31 October 2005

Dear Mr Webb

CONSULTATION ON A DRAFT REPORT BY THE VETERINARY PRODUCTS COMMITTEE ON THE RISKS ASSOCIATED WITH THE USE OF HORMONAL SUBSTANCES IN FOOD- PRODUCING ANIMALS

Thank you for providing the Scottish Environment Protection Agency (SEPA) with the opportunity to comment on the above consultation document.

I write to advise you that the SEPA has no comments to make on this occasion.

As a public body committed to openness and transparency, SEPA feels it appropriate that this response be placed on the public record. If you require further clarification on any aspect of this correspondence, please contact Rob Morris, Unit Manager (Land Policy), SEPA Corporate Office, at the address shown below

Yours Sincerely

Janice Milne
Head of Environmental Policy

14. Ms Patience Purdey, National Council of Women

NATIONAL COUNCIL OF WOMEN OF GREAT BRITAIN

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RISKS ASSOCIATED WITH THE USE OF HORMONAL SUBSTANCES IN FOOD-PRODUCING ANIMALS

A Veterinary Products Committee Consultation

The National Council of Women [NCW] welcomes the opportunity to comment on the draft report by the Veterinary Products Committee on the risks associated with the use of hormonal substances in food-producing animals.

The use of these substances has been of concern to NCW for some time and in our report 'Biotechnology 2000' written in that year, we stated that the use of exogenous hormones (those made outside the body) to increase food production has caused much concern and public debate, and calls for strict controls and long-term research. The VPC report covers many of the questions raised by NCW which are still relevant and as yet inadequately answered.

Extract from NCW's 'Biotechnology 2000':-

"NCW asks the questions:

- Whether residue levels in those countries using hormone growth promotion, are at an acceptable level?
- Is there a 'cocktail' effect?
- Could these extra hormones affect human DNA
- Does each animal vary in its response to these chemicals and if so is there a safe withdrawal period before slaughter
- Do hormones used in fish-farming get into the water downstream and affect the fertility of the wild fish?"

Also in 2000 The Royal Society publication 'Endocrine Disrupting Chemicals' raised many questions including:

- The interaction between chemicals
- The levels at which chemicals are likely to cause adverse effects.

It is noted that the report acknowledges that there are important gaps in the knowledge base that preclude producing definitive risk assessments for 17β-oestradiol or the other 5 hormonally active substances. NCW does not underestimate the difficulty of setting safe levels of use but where there is no uniform agreement between scientific bodies about the level of risk and still many uncertainties, then as consumers we would expect the most precautionary approach to be adopted.

Comments on Conclusions and Recommendations

- The acceptance that biological effects could occur if exposure were at a sufficiently high level makes the establishment of a Lowest Observable Effect Level (LOEL) urgent.
- NCW's is not only concerned about eating meat but also the drinking of milk from treated animals. This raises the question of a possible effect of the repeal of the Over Thirty Months rule. It is reported that a significant proportion of milk comes from pregnant cows where hormone levels are high. It has been suggested that with the lifting of the ban 25% of the cows will be pregnant.
- With reference to Para. 4, one is reminded of the straw breaking the camel's back. It is accepted that our individual DNA makes our reactions to substances vary. Dr George Poste giving a lecture at the Royal Society in 2000 spoke of the varying reaction of patients to medicines. He said that a recent study in the United States showed that "of the 3.1 billion prescriptions issued in the United States every year, 2.1 million of those result in people being hospitalised for adverse effects'. For some a very small amount of a substance can be the final straw. It would be more reassuring to consumers, if scientists took the view that reduction of the total intake in substances that 'could exert biological effects' was important rather than the view that a little extra intake is unlikely to make any difference.
- It is suggested that likely levels of human exposure to hormonally active substance in meat from treated animals would not be sufficient to induce 'any measurable physiological effect'. Is this a reflection on the non-availability of suitable tests rather than a measure of safety?
- The acknowledgement (5.4) that 'the many uncertainties associated with the current lack of knowledge could be addressed by further research' is welcomed, however, the following words 'where this is both feasible and affordable' implies a financial restriction to the work being undertaken. NCW opposes the view that health and safety should be traded against affordability. If sufficient knowledge to make a full favourable risk assessment is not available, the product should not be deemed 'safe'
- NCW appreciated the resume of previous reports and decisions on this subject but would also have found helpful a brief reminder of the benefits expected from the use of these substances and to who or what will be the recipients of these benefits. If there is a significant or unquantifiable risk, the benefits must be found by an alternative method.

NCW supports all the suggestions for a structured approach and for specific needs. There are many health problems such as those linked to male reproductive organs (falling sperm counts, testicular dysgenesis syndrome, hypospadias) where the cause of the increased incidence is unknown, and the statistics about the frequency of these disabilities are unavailable. There is also an increased incidence of children being born with disabling illnesses including Autism, Allergies Hyperactivity Disorder etc. The number of boys suffering from some of these illnesses is considerably greater than the number of girls.

There may be no link between the use of hormonal substances to any of these illnesses but without the necessary research a realistic risk assessment cannot be made. Further research is urgently needed

Summary.

NCW:-

- **welcomes the acknowledgement of a possible risk due to uncertainties and gaps in relevant scientific evidence,**
- **recognises the importance of regular reviews of risk analyses to take note of new research findings,**
- **recommends that where there is possible risk to human health and well-being:**
 - a) alternative action should be sought to produce the required benefits, and**
 - b) protection of human health should always take precedence over commercial factors.**
- **supports the plans for a structured approach and the noted specific needs.**

15. Alsaneh Roberts, Country Land and Business Association

COUNTRY LAND AND BUSINESS ASSOCIATION

CONSULTATION RESPONSE TO

The Draft Report by the Veterinary Products Committee on the risks associated with the use of hormonal substances in food-producing animals

Introduction

1. The Country Land and Business Association (CLA) represents 40,000 land managers and rural businesses in England and Wales who between them own some 50% of the rural land. The issue and ramifications of hormone use in food producing animals is a matter of some interest.
2. The CLA firmly believes that decisions should be made on the basis of sound science wherever possible, and so the CLA welcomes the report as a valuable contribution to the debate in this area.
3. We note that the report calls for further work to be done. While we agree that this work is important, we would also note that these hormonal substances have been used in many other countries for many years, and would suggest that every effort be made to collaborate with experts in these countries, rather than wasting time going over the same ground again.
4. The CLA would hope that this report will go some way toward clarifying issues in this field and will enable the EU to move forward on its' 'hormone ban' on a rational and internationally accepted basis.

**Country Land and Business Association
16 Belgrave Square
London
SW1X 8PQ
A09117003**

16. Richard Young, Soil Association



Soil Association submission to the consultation on a draft report by the Veterinary Products Committee on the risks associated with the use of hormonal substances in food-producing animals

Summary

The Soil Association welcomes the VPC's acknowledgment that the Committee is unable to state definitively that residues of hormone growth promoters (HGP) in meat do not cause a biological effect in humans. We are, however, concerned that this conclusion is likely to be given less emphasis in the final report than the VPC's additional claim, based on numerous assumptions, that the 'weight of evidence at present available suggests that likely levels of human exposure to hormonally-active substances in meat from treated animals would not be sufficient to induce any measurable physiological effect'. This claim cannot be supported by the evidence in view of the continuing serious gaps which exist in the safety data.

The Soil Association is furthermore concerned that:

- the draft report's Executive Summary fails to give a proper account of the science discussed in the body of the report. While the VPC disputes a number of the scientific conclusions of the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH), it also accepts the validity of some of the new science presented by that committee. Despite this, none of this important new evidence mentioned in the VPC's Executive Summary
- the VPC avoids discussing the dangers associated with the illegal or improper use of HGPs by claiming that such a discussion is beyond the remit of the group. However, the terms of reference for the VPC's report include assessing the SCVPH report and its conclusions. One of the SCVPH's conclusions is that misplaced implants and repeated implanting represent a considerable risk that highly contaminated meats could enter the food chain
- the VPC fails to give sufficient consideration to the dangers posed by residues of hormonal substances to pre-pubertal boys
- The VPC recognises that combinations of hormones will be used both legally and illegally, but that it is only able to base its scientific assessments on ADIs for individual residues considered separately. In view of the growing evidence for a 'cocktail effect' in relation to other hazardous substances we feel this serious deficiency should be reflected by greater caution in the VPC's overall conclusion

- although the SCVPH report referred to preliminary results from two studies which provided evidence of HGP use resulting in groundwater being contaminated with raised levels of hormonally active substances, and of the endocrine and reproductive systems of wild fish taken from the contaminated sites being adversely affected, the VPC decided not to check whether these preliminary findings had led to further publications since the SCVPH report was published in early 2002. The VPC then argues that the publications available to it do not provide sufficient detail on these studies for them to evaluate the quality of the work. However, both studies led to peer-reviewed papers being published in early 2004 and the VPC should have considered their findings.
- the VPC does not consider the effects of HGP implants on animal health and welfare, despite the existing evidence of adverse effects

Introduction

In April 1999, the European Commission published an Opinion of the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH), which concluded that the risks associated with the consumption of hormone-treated cattle may be greater than previously thought. The VPC was asked by the UK government to review the committee's opinion. Its response was published as a report in October 1999. This listed a number of concerns and a considerable number of scientific uncertainties surrounding the safety of HGPs. Concerning the potential for an individual to consume a high one-off dose of hormones from an incorrectly positioned implant, for example, the VPC calculated that this could give an excessive dose ranging from 111 times the Acceptable Daily Intake (ADI) in the case of progesterone to 250,000 times the ADI in the case of trenbolone. In relation to the genotoxicity of oestradiol the VPC stated that the absence of 'a "standard" cytogenetics assay, such as one using human lymphocytes ... is a major deficiency in the available data set'

Despite this, the VPC's overall conclusion was that it had 'sufficient concerns about the scientific reasoning in a number of key areas [of the SCVPH report] to throw serious doubt on [its] conclusions'. This was interpreted by ministers as 'the scientific evidence in the SCVPH report did not support the Community ban on the use of HGPs' and that 'the UK expert committee, the VPC, considers that the available science did not support the need for such a ban in order to protect animal and public health'. This statement has allowed Britain to escape its share of the approximately £100 million annual trade sanctions imposed by the US, after the World Trade Organisation ruled in its favour on this issue.

Following this the SCVPH reviewed 17 new scientific studies and published a further report in April 2002, upholding all its original conclusions and setting out further findings including, for example, convincing new data showing that two of the synthetic HGPs had a high level of persistence in the environment.

History is now repeating itself as the current draft report from the VPC is a response to the second SCVPH report and the evidence on which it is based. The VPC's position is similar to the one it took six years earlier: while it continues to

acknowledge the scientific uncertainties, overall it again rejects the conclusions reached by the SCVPH.

The differing conclusions between the two committees is illustrated by the issues relating to 17 β -oestradiol. The SCVPH concludes that 'Convincing data have been published confirming the mutagenic and genotoxic potential of 17 β -oestradiol' and that '*In vitro* experiments indicated that oestrogenic compounds *might* alter the expression of an array of genes.'

In contrast, the VPC draft report concludes, 'When it came to the current evidence base for 17 β -oestradiol, however, in spite of certain data gaps, the view of most of the Working Group was that there is ample information to show that zootechnical and therapeutic uses of 17 β -oestradiol do not pose any risk to humans unless an active implant site is ingested'.

It is pertinent to consider why two independent scientific committees should repeatedly present such differing conclusions after an analysis of the same scientific evidence. Perhaps the most significant reason is a difference of approach. The VPC appears to start from the position of the Lamming Committee in 1982 and the WHO/FAO Joint Expert Committee on Food (JECFA) in 1988, which both reviewed the safety data and concluded that the use of HGP's posed no risks for consumers. As such, in reviewing the most recent research the VPC is looking to see if any of the studies provide conclusive evidence which overturns the general assumption of safety.

It is relevant to note, as other reviewers have done before (European Environment Agency 2001), that the basic safety data on which these earlier committees made their positive assessments was mainly generated by the manufacturers in support of their original licensing applications. The studies designed by the manufacturers were frequently unpublished, and there was no obligation on them to record or publish all related studies they had undertaken and which may have yielded unfavourable results. For this reason, the manufacturers' data (which is still not publicly available) should be treated with caution and scepticism, particularly when uncertainties remain regarding safety.

On the other hand the SCVPH starts from the perspective of European consumers who in large numbers forced the EU-wide ban on to regulators against their scientific advice, because of intuitive concerns about such widespread and poorly controlled use of hormones in food production. In contrast to the VPC, therefore, the SCVPH looks at the latest evidence to see whether it demonstrates conclusively that the use of HGP's is safe.

Both committees highlight broadly the same shortcomings in the evidence, but they consider it from different perspectives. In the view of the Soil Association the more precautionary approach of the SCVPH is more appropriate in this instance, since the case for using HGP's is purely a commercial one. Until the many significant unknowns regarding the effects on human and animal health and the environment can be eliminated, the benefits cannot be said to outweigh the risks.

The motivation for HGP use is economic so the precautionary principle should be applied

HGPs promote faster animal growth and greater 'feed conversion'. The motivation for using them is therefore economic rather than therapeutic. Since there is no shortage of meat being produced without HGPs, those who benefit most from their use are the manufacturers of the products, whereas those most likely to be harmed are the animals being implanted and the meat consumer when residues of hormones or their metabolites are consumed in food.

HGPs are of no therapeutic benefit to the animals, and may indeed ultimately be found to harm animals health and welfare, as was finally established in the case of the genetically modified hormone which increases milk production, recombinant bovine somatotropin (rbST). Although denied for many years by the manufacturers, it was eventually shown that the manufacturers had withheld key study data from the VPC, which demonstrated that rbST increased lameness, mastitis and infertility (Millstone et al 1994). It was on this basis that the licence for this product was withdrawn in the EU.

Since there are no welfare gains for animals, the possible increased risk to human health from residues is not counterbalanced by benefits, as is the case with the use of some potentially toxic veterinary medicines with therapeutic value. As such, the need to apply the 'precautionary principle' and to eliminate scientific uncertainty regarding the adverse effects to humans, the environment and animal welfare are all the greater.

The Executive Summary does not provide a useful assessment of new science

The Executive Summary of the draft report fails to provide a useful assessment of the most up-to-date science concerning the safety and environmental impact of HGPs. In particular the Executive Summary makes no mention of:

- the published scientific evidence suggesting that 17β -oestradiol and its metabolites are a complete carcinogen, despite the VPC having concluded on p. 36 that it would be prudent to assume that they are.
- the fact that the VPC accepts that the weight of evidence indicates that the metabolites of 17β -oestradiol may be genotoxic, nor of the fact that there is evidence of 17β -oestradiol being clastogenic (causing harm to chromosomes) (p. 27).
- the newly available evidence that steroid metabolites, previously considered to be nothing more than inactivation products, may have patho-physiological actions themselves (see p. 36).
- the fact that pre-pubertal boys are a high-risk category.
- the existence of evidence that the use of HGP causes environmental damage or has the potential to cause such damage, including:
 - the evidence from published peer-reviewed papers of detrimental effects on hormone levels in water downstream from cattle feedlots and on the fish taken from that water (see below for further details)

- the fact that it has now been established that certain HGP's can be detected in soil several months after manure, which has itself been stored for several months, has been applied (pp 32–3). The half-life of the derivatives of one synthetic HGP was found to be over 250 days in liquid manure (see p. 24 of SCVPH report), but this is not mentioned anywhere in the VPC report.

These omissions are hard to understand, particularly in view of the fact that the SCVPH refers to so many of these facts in the conclusions of its report, and the VPC's draft report is an assessment of the former. Publishing a summary which fails to address so much of the newly available science in a satisfactory way can only bring into question the VPC's willingness to present the facts as openly, as scientifically and as objectively as possible.

The VPC gives inadequate consideration to the possibility of illegal and improper use of HGP's

As explained by the SCVPH (pp 11–12), commercial growth promoters are over-the-counter products, so that correct implantation cannot be guaranteed – despite the existence of various guidelines defining the principles of good veterinary practice, multiple implanting occurs in the daily routine of cattle husbandry where HGP's are in use. The SCVPH also explains that implants that are not positioned correctly might be missed during post-mortem meat inspection, and that processing such injection sites can contaminate tons of minced meat, or meat products, with concentrations exceeding the ADI/MRL levels proposed by JECFA and other regulatory bodies. Multiple applications also need to be considered as unavoidable under practical conditions since, as the SCVPH explains, the practice is both advertised and even recommended in the scientific literature as producing the best results in terms of economic performance. The effects of overdosing should also be considered since the growth response is dose-sensitive.

The likelihood of illegal or improper use of HGP's is much higher than in the case of therapeutic veterinary medicines, particularly when the latter are dispensed by a veterinary surgeon. Any realistic scientific assessment of the dangers of HGP use should therefore take this into account. Despite this, the VPC claims that the illegal or improper use of hormone growth promoters is 'no different from the illegal or inappropriate use of any veterinary products and, as such, is beyond the remit of the Working Group. However, it is something that does need consideration' (p. 11).

The VPC's Terms of Reference require it to evaluate the SCVPH's opinion and advise on its conclusions (p. 3). One of the SCVPH's conclusions is that 'misplaced implants and repeated implanting, which seem to occur frequently, represent a considerable risk that highly contaminated meats could enter the food chain' (p. 21 of SCVPH report). The question of illegal or improper use is therefore clearly within the VPC's remit, and the committee's failure to address it is a sign of political rather than scientific thinking.

It is very unfortunate that the VPC have not tackled this issue despite admitting that it does 'need consideration'. When are the government's independent scientific advisors going to consider this issue if not now?

The VPC's approach to gaps in the scientific knowledge

Both the SCVPH and the VPC accept that there remain significant gaps in the scientific understanding of the potential adverse effects of hormone use. The Soil Association welcomes the fact that the VPC has made clear that it is unable to state definitively that residues of HGP in meat cannot cause a biological effect in humans, although we cannot agree with its conclusion that the weight of evidence suggests that this cannot happen. In our view the scientific evidence permitting this conclusion to be drawn does not exist.

The VPC admits that it is making a variety of assumptions when it concludes that it is very unlikely that residues of HGP in meat could cause a biological effect on humans. Some of these assumptions are unrealistic, and others remain to be demonstrated in a serious and scientific way. In particular:

- The VPC admits that 'all scientific judgements made by the Working Group were based on the assumption that the consumer is exposed to residues at no greater concentrations than those that would be caused by the "correct" or "recommended" use of the exogenous hormones, be it for growth promotion or other permitted zootechnical uses or therapeutic purposes' (p. 4). This, however, is very unrealistic and even the VPC accepts that the likelihood of hormones being misused for growth promotion is higher than it is when they are being used for therapy. In practice many consumers would undoubtedly be exposed to concentrations higher than these.
- The VPC admits that 'substances with hormonal action may be used in combination, both legally and illegally, while the toxicological and safety factors available (e.g. ADIs) only relate to single substances' (p.4). In other words, the VPC's scientific assessment is based on the assumption that consumers will not be exposed to a 'cocktail' of HGPs, or their metabolites, as residues. This is not, of course, a realistic assumption and, since it is known that substances can be more toxic when ingested together, this is a serious gap in the scientific assessment which should lead to a more cautious overall conclusion.
- The VPC admits that when it used one 6-day study in rats to conclude that '17 β -oestradiol-implanted cattle is unlikely to provide biologically significant oestrogenic exposure', it is basing its assessment on 'numerous assumptions'. These include 'assuming similar absorption and metabolism profiles in humans and rats' and assumptions about 'bioavailability'. It also admits that its conclusion takes no account of the possibility that lipoidal oestrogens might bioaccumulate over time in fatty tissues, such as in the breast (p. 20).
- Members of the VPC accept that metabolites of 17 β -oestradiol have the potential to be genotoxic *in vivo* (p. 36) and accept the evidence showing that these metabolites can form DNA adducts *in vivo* (p. 27). However, the VPC questions the quality of further studies which show genotoxicity *in vivo* for both 17 β -oestradiol and its metabolites, and uses some theoretical considerations to argue that there might be a 'thresholded response' (p. 27). This again seems to be a case of the VPC making assumptions, which are

clearly scientifically unproven, about the products' safety, instead of erring on the side of caution.

As a general rule, the VPC should not be using the existing gaps in the scientific knowledge about the safety of HGP's to apply the principle which states that 'absence of evidence is evidence of absence'. Instead, when the science has not yet been fully explored, and the potential risks to human health are real, the precautionary principle should be applied. It is surprising and disappointing, therefore, that apparently only one member of the committee expressed the view that the precautionary principle should be applied (p. 4).

The VPC does not give sufficient consideration to dangers to pre-pubertal boys

Pre-pubertal boys have been identified as particularly at risk from the ingestion of residues of hormonal substances in food.

One reason for this is that their endogenous levels of, and production of, oestrogens is extremely low, so that any additional exogenous oestrogen represents a relatively high percentage of the total body oestrogen. This is particularly relevant in the context of the safety criterion applied by the FDA, that intake of any hormone from food should constitute less than 1% of the individual's daily endogenous production (European Environment Agency 2001, p. 152–3).

A second reason is that, whereas the body generally contains a 'feedback balancing system' which checks hormonal levels and adjusts the concentrations accordingly, this is thought to be lacking in the foetus, post-menopausal women and in pre-pubertal children (p. 12 of the VPC report). In the absence of a feedback system, the VPC accepts that any ingestion of hormones in food has to be viewed as additive increments of exposure (p. 21).

In spite of this, the VPC concludes: 'Despite its possible genotoxicity, it is reasonable to consider that 17 β -oestradiol may have a threshold for carcinogenicity due to the presence of homeostatic feedback mechanisms, the requirement for activation pathways to exceed inactivation pathways and the presence of antioxidants *in vivo*' (p. 35). No mention is made in this conclusion of the lack of feedback mechanisms in pre-pubertal children.

The VPC describes a study showing that the intake of hormonal substances by pre-pubertal boys consuming a standard proportion of meat from animals receiving multiple implants might exceed the ADI, as being 'well conducted' (p. 20). Nevertheless, in the Executive Summary, the VPC only refers indirectly to the existence of the study by calling for more research.

In view of the above, it is hard to see how the VPC's conclusion that residues are unlikely to cause a physiological effect on humans can still be supported.

The VPC's failure to consider evidence of environmental damage adequately

The SCVPH report presents evidence of surface water downstream of cattle feedlots where HGPs are used having higher levels of compounds with oestrogenic and androgenic activities. It also presents evidence of alterations in the reproductive biology of native fish taken from the contaminated water: male fish were de-masculinised whereas female fish were masculinised (pp 26–7 of SCVPH report). The SCVPH, however, admits that the preliminary evidence available to it did not permit it to establish a direct link between HGP use and hormone levels in surface water and abnormalities in fish from that water.

The VPC response is to say that the SCVPH conclusions 'are based on Study 15, which has apparently not been published in the peer-reviewed literature, except for a brief summary in Jégou *et al.* (2001). The conclusions are also based on Study 16, which has only been published briefly as part of a review (Orlando and Guillette 2001). These published papers do not provide sufficient information to judge the quality of the work, although the researchers involved are acknowledged leaders in the field' (p. 33).

Unfortunately, the VPC's response on this point is completely inadequate and hard to understand. Both Study 15 and Study 16 led to peer-reviewed papers which were published in early 2004 (see Soto et al 2004 and Orlando et al 2004). Oddly, one of these two papers, (Soto et al 2004) is even listed in Appendix B (p. 51) of the VPC report, but it seems that members of the VPC have not read it, or at least they do not discuss it.

The VPC admits that it did not attempt to find out whether Study 15 or 16 had led to any peer-reviewed papers being published when it says 'The Working Group evaluated the SCVPH's conclusions and compared these with the published evidence from the three cited studies. Additional information was not sought, and it is possible that further publications have emerged from the three SCVPH studies' (p. 32). It seems extraordinary, therefore, that the VPC should claim that it is not able to evaluate the research because of a lack of information when it chose not to seek any further information.

If the VPC had studied the paper by Soto and co-authors it would have seen that they conclude that their data indicates that 'significant oestrogenic and androgenic activity is released into water by feedlot operations' and that 'feedlot effluents contain sufficient levels of hormonally active agents to warrant further investigation of possible effects on aquatic ecosystem health' (Soto et al 2004).

In addition, Orlando and co-authors report that their study 'is the first study demonstrating that the endocrine and reproductive systems of wild fish can be adversely affected by feedlot effluent'. One reason they were not able to demonstrate beyond doubt that the HGPs used were responsible for the adverse effects on the fish was that they were not able to find cattle kept in feedlots which were not treated with HGPs to use as a control (Orlando et al 2004).

Orlando et al say that their data demonstrates the androgenic activity of water obtained below feedlots and that this could be due to natural androgens found in

faecal material or to pharmaceutical androgens found in HGP. The authors note, however, that the synthetic androgenic HGP trenbolone acetate is known to be 8–10-fold more potent than testosterone in cattle (Orlando et al 2004). Furthermore, the half-life in liquid manure of two of its derivatives has been shown to be over 250 days, whereas the half-life of natural hormones appears to be much shorter, being measured in days or hours (see SCVPH 2002 report and Orlando 2004). The authors could not find any literature regarding the relative persistence of the two other synthetic HGPs, zeranol and melengestrol.

No consideration is given to the effects on animal welfare and health

The Soil Association believes it to be unfortunate that no consideration has been given in either the SCVPH or VPC reports to effects on animal health and welfare. Since HGPs are not used for therapeutic purposes, it appears particularly important that the effect of their use on animal health and welfare be considered. Little research on this topic appears to be available in the peer-reviewed journals, although one paper published in 1976 reports that: 'the weight of uterus was not affected by the different doses of 17 β -oestradiol or trenbolone acetate, but a combination 17 β -oestradiol + trenbolone acetate led to a surprising weight increase. The proliferation of uterine glandular cells was responsible for the increased uterine size. The lumen of uterus was partially filled with a watery liquid.' A high dose of trenbolone acetate was also found to cause 'an abnormal size of the clitoris and led to a reduction of the size of the thymus' (Gropp et al 1976).

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17. Jane Virgoe, British Veterinary Association

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8th November 2005

Dear Mr Webb

CONSULTATION ON A DRAFT REPORT BY THE VPC ON THE RISKS ASSOCIATED WITH THE USE OF HORMONAL SUBSTANCES IN FOOD PRODUCING ANIMALS

I am writing in response to Mr Crutcher's letter of 17th August inviting comments on the draft report by the Veterinary Products Committee on the risks associated with the use of hormonal substances in food producing animals. The British Veterinary Association has consulted with its divisions in considering this issue. Comments have been received from the British Cattle Veterinary Association (BCVA) and the Society of Practising Veterinary Surgeons (SPVS) which have informed this response.

It is unclear from the consultation document whether the Veterinary Products Committee is attempting to make a case for the reintroduction of these products or highlighting the need for further research. There is no real doubt that the use of hormones in food producing animals is potentially harmful but there are uncertainties about the levels at which an effect becomes significant. There are also differing opinions on the scale of the risk.

The BVA accepts that there were, and still are, misgivings about the science behind the European ban and, given these uncertainties, it seems the safer route to follow, particularly as there is no real need, other than economic gain, to use these hormones.

What is of concern, however, is that the current application of the regulations may allow meat to be imported from Third Countries, where animals have been treated with hormonally-active substances, without indication that it may contain levels of hormone prohibited in the EU. This is a situation which the BVA believes should be urgently addressed.

I hope you will find these comments helpful.

Yours sincerely

Jane Virgoe
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