

Reply by the Government to the fifth report from the Agriculture Committee, Session 1999-2000 : The Government's proposals for organophosphate sheep dips (HC 425) : sixth special report / Agriculture Committee.

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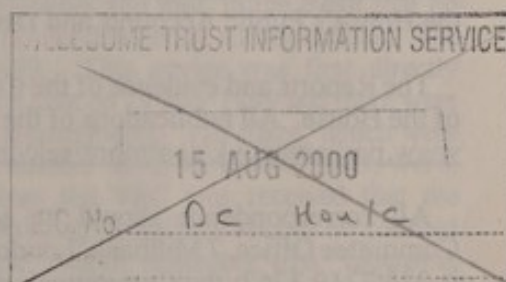


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AGRICULTURE COMMITTEE

Sixth Special Report

**REPLY BY THE GOVERNMENT TO THE
FIFTH REPORT FROM THE AGRICULTURE
COMMITTEE, SESSION 1999–2000,
“THE GOVERNMENT’S PROPOSALS FOR
ORGANOPHOSPHATE SHEEP DIPS”
(HC 425)**



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The Agriculture Committee is appointed to examine on behalf of the House of Commons the expenditure, administration and policy of the Ministry of Agriculture, Fisheries and Food (and any associated public bodies). Its constitution and powers are set out in House of Commons Standing Order No. 152.

The Committee has a maximum of eleven members, of whom the quorum for any formal proceedings is three. The members of the Committee are appointed by the House and unless discharged remain on the Committee until the next dissolution of Parliament. The present membership of the Committee is as follows:

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Mr David Curry (*Conservative, Skipton and Ripon*)
Mr David Drew (*Labour, Stroud*)
Mr Alan Hurst (*Labour, Braintree*)
Mr Michael Jack (*Conservative, Fylde*)
Mr Paul Marsden (*Labour, Shrewsbury and Atcham*)
Mr Austin Mitchell (*Labour, Great Grimsby*)
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Mr Owen Paterson (*Conservative, North Shropshire*)
Mr Mark Todd (*Labour, South Derbyshire*)
Dr George Turner (*Labour, North West Norfolk*)

On 15 February 2000, the Committee elected *Mr David Curry* as its Chairman.¹

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The Committee may meet at any time (except when Parliament is prorogued or dissolved) and at any place within the United Kingdom. The Committee may meet concurrently with other committees or sub-committees established under Standing Order No. 152 and with the House's European Scrutiny Committee (or any of its sub-committees) and Environmental Audit Committee for the purpose of deliberating, taking evidence or considering draft reports. The Committee may exchange documents and evidence with any of these committees, as well as with the House's Public Accounts and Deregulation Committees.

The Reports and evidence of the Committee are published by The Stationery Office by Order of the House. All publications of the Committee (including press notices) are on the internet at www.parliament.uk/commons/selcom/agrihome.htm.

All correspondence should be addressed to the Clerk of the Agriculture Committee, Committee Office, 7 Millbank, London SW1P 3JA. The telephone number for general inquiries is 020 7219 3262; the Committee's e-mail address is: agricom@parliament.uk.

¹On 16 July 1997, the Committee elected Mr Peter Luff as its Chairman. He was discharged on 21 February 2000.



SIXTH SPECIAL REPORT

The Agriculture Committee has agreed to the following Special Report:—

The Committee has received the following memorandum from the Ministry of Agriculture, Fisheries and Food, constituting the Government's Reply to the Fifth Report from the Committee of the 1999-2000 Session, *The Government's Proposals for Organophosphate Sheep Dips*, made to the House on 17 May 2000. A letter from Baroness Hayman, Minister of State, Ministry of Agriculture, Fisheries and Food, is appended to the Report.

* * *

Background

1. Before responding to the Committee's principal conclusions and recommendations, it should be made clear that the Government's decision to withdraw organophosphorus (OP) sheep dips was taken against a background of many years of the most intensive scrutiny of the continued use of OP dips by the Government's advisory committee, the Veterinary Products Committee (VPC). The Government sought further advice on the toxicity of organophosphorus compounds in general from the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT). In July 1999, the Institute of Occupational Medicine (IOM) completed a three-year study of sheep dippers' exposure to OPs and all the regulatory committees, the COT, the VPC and the Advisory Committee on Pesticides (ACP), were asked to consider the results of the IOM's work and report.

2. It is well known that acute exposure to OP compounds causes ill-health. The question was whether prolonged low-level exposure can cause chronic ill-health effects. The COT reported that any such ill-health effects remained unproven although there remained a question over whether there may be a small group of individuals particularly susceptible to OPs. All the regulatory committees independently advised that, on the basis of current scientific knowledge, there was no need for any general withdrawal of OPs from the market.

3 The IOM's report, which was published on 1 July 1999, identified the main risk of exposure to OP sheep dips as handling the concentrated form and the VPC was immediately asked for urgent, interim advice. The Committee advised that marketing authorisation holders should be required, within three months, to produce workable plans for the introduction of modified containers designed to minimise the risk of exposure by operators and that, in the event that no such plans were produced, action should be commenced to revoke marketing authorisations. The Government published the VPC's advice on 15 July 1999. This advice was first directly communicated to the marketing authorisation holders in letters sent on 29 July 1999 and there were subsequent discussions with officials to clarify the VPC's requirements. The plans, which were presented to the Committee by the marketing authorisation holders on 18 November 1999, were, with one exception, found to be inadequate. Advice from the VPC was received that the authorisations should be suspended and that products in existing containers should be recalled from the supply chain and from farms. Agriculture and Health Ministers (the 'Licensing Authority') accepted this advice and Parliament was informed on 20 December of the decision to suspend authorisations and, on the same day, letters were faxed to the marketing authorisation holders. The companies were given until the end of January to withdraw product from the market.

4. Since then, the companies have presented further proposals to the VPC for improvements to minimise the risk of exposure from the concentrate and the VPC has advised the Licensing Authority Ministers. That advice is currently being considered and an announcement will be made in due course.

Response to the Committee's conclusions and recommendations

Consultation before the recall

Recommendation (a): "We agree with Professor Aitken that there is a need for dialogue between the Environment Agency and the Veterinary Medicines Directorate about the review process, and believe the discussions should also examine how the Environment Agency can be directly involved in VPC processes rather than through the officials of the DETR."

Recommendation (b): "We agree that, whilst Parliament has the right to know the outcome of ministerial decisions prior to their wider dissemination, representative organisations could have been consulted on the Government's proposals prior to a final announcement; nor do we see any issues of commercial confidentiality arising since the products were to be withdrawn completely at the cost of the companies involved (hence early warning would not affect sales) or potential stockpiling difficulties for the same reason that the concentrate was to be collected from all farms. Consultation with manufacturers and farmers' organisations would have prevented the announcement from appearing to be a panic measure and would have greatly facilitated the provision of advice and the smooth handling of the withdrawal process in its immediate aftermath. In these circumstances, the culture of secrecy proved most unhelpful. We recommend that, in future similar cases, consultation be undertaken with interested parties on potential courses of action prior to the official announcement to Parliament."

Response

5. The Government agrees that there would be advantages in ensuring that the VPC has direct access to advice from the Environment Agency on subjects where this would be relevant. Such arrangements are being put in place.

6. The issue of deciding not to consult in advance of a formal announcement is not a question of commercial confidentiality or of a culture of secrecy but of acting properly within the legal framework. The withdrawal of marketing authorisations is one step in a formal, statutory process, responsibility for which rests with the Agriculture and Health Ministers acting as the Licensing Authority. It would not have been appropriate to discuss the action proposed with the authorisation holders before the Licensing Authority Ministers and Departments had agreed to take that action. The action taken by the Licensing Authority gave marketing authorisation holders a statutory right to make representations (appeal) against the action taken. It was, in any case, made fully clear to the marketing authorisation holders in July that in the event that their plans for modifications to containers were not found acceptable, the VPC was minded to advise regulatory action in relation to marketing authorisations.

Consultation on packaging improvements

Recommendation (c): "We believe that a more constructive dialogue between VPC/VMD and the manufacturers in the period after July was possible and could have led to the development of workable proposals for container improvements."

Response

7. The letter of 29 July to marketing authorisation holders set out the VPC's parameters for improved concentrate containers. It was not for the VPC to dictate how each company might wish to modify containers in order to minimise the risk to the operators. Thus it was open to each company to make commercial judgements in each case as to the best and most cost effective way to meet the requirements. Officials met with representatives of the companies, separately and together, as early as August 1999 to listen to their plans and to answer questions. However, officials rightly could not prejudge the advice of the Committee to Ministers.

Information for farmers

Recommendation (d): "We recommend that before such important announcements in the future MAFF prepare an information sheet (embargoed if necessary) that summarises the announcement and its implications for regional service centres, helpline staff and advisers within farmers' representative organisations. This information should also be made available to farmers and other organisations via the Internet."

Response

8. The Government accepts that information for farmers about the announcement could have been better handled. In particular, Regional Service Centres and helpline staff should have been provided with detailed advice on the practicalities of the recall once the Licensing Authority Ministers had taken their decision. Such information can, in future, be made available on the

MAFF and VMD websites. It might also have been helpful to facilitate an early meeting at which marketing authorisation holders could have discussed their plans for recalling products with VMD and other officials.

Animal Welfare and Health

Recommendation (e): "We believe that there should be a 'Plan B' in case of a major outbreak of sheep scab during the period of time farmers are without OPs. We recommend that MAFF consult on and publish such a plan as a matter of urgency."

Response

9. The Government recognises the real concern of sheep farmers to have the full armoury of controls, including OP dips, available and the VPC are providing every assistance to the companies to enable OP dips to return to the market once the concerns of the VPC have been addressed. It is hoped that OPs may again be available to the industry within 12 months.

10. The Government does not believe that any contingency plan for the period in which OPs are not available is necessary. Even though OP dips have been withdrawn from the market, there are other dip and injectable products available. These, if used according to the manufacturers' instructions, are effective and we anticipate will be sufficient to deal with the disease situation in the Autumn. It would not be possible, having withdrawn OP dips from the market on safety grounds, to return them to the market unless the concerns of the VPC had been satisfactorily addressed.

11. The Sheep Scab Order 1997 was introduced at the industry's request for legislation so that the industry could deal with those less responsible individuals who did not treat their sheep against scab. It is an offence for sheep farmers to have scabby sheep and not treat the whole flock. Any sheep farmers aware of scabby flocks can report the matter to the local authority who are responsible for enforcement. Therefore the industry has the legislative means and alternative products to deal with any significant increase in the incidence of sheep scab.

Economic issues

Recommendation (f): "We recommend that the Government assess the level of scab and evaluate the economic impact upon farmers of alternative approaches to eradicating scab from the UK. We further recommend that the likely economic cost to farmers of the cost of withdrawal of OP sheep dips be assessed and published."

Response

12. Sheep scab is not a notifiable disease and no precise information on its occurrence is held centrally. The Sheep Scab Order 1997 gives powers to Local Authorities to investigate cases of scab and to require control measures under the supervision of a private veterinary surgeon. In such cases, samples taken by Local Veterinary Inspectors for diagnosis are examined by the Veterinary Laboratories Agency (VLA). This information provides some evidence of the occurrence of scab. The VLA report that the number of cases referred to them for diagnosis has declined recently. It is not clear whether this is due to a reduction in scab or a reduction in the reporting of possible scab to Local Authorities. Surveillance for sheep scab will be considered as part of on-going work to develop a coherent strategy for veterinary surveillance.

13. The Government has funded work since 1996 to explore non-chemical methods as alternative approaches to sheep scab control. One avenue of approach is based on earlier published work funded by MAFF at the Royal Veterinary College. The earlier results showed evidence of an immune response in the blood of sheep affected by sheep scab mites. A four-year programme, costing £1.6m, investigated the significance of this. The results in 1999 showed that the approach to the immunological control of sheep scab is complex and requires an understanding of a number of key elements if a vaccine is to be developed. A further, three-year study focussing on these elements is in hand.

14. A major effort to eradicate sheep scab was undertaken between 1976 and 1992. This included supervised national dipping during specified periods, movement controls, and segregating dipped and non-dipped sheep in markets. Fleece samples were checked for evidence of dipping. Where outbreaks occurred, there was full tracing of contact sheep by the State Veterinary Service. Eradication was not achieved despite this intensive effort. The reasons were attributed to a major increase in the size of the national flock, from 27 million in 1976 to 45 million in 1992, greater movement of sheep around the country, and a lack of commitment by some sheep farmers. A contributory factor was the difficulty of ensuring a complete gather on common or open grazing land and the impossibility of gathering feral sheep. None of these factors has changed and the reintroduction of a national eradication plan is not considered feasible.

15. The economic cost to farmers of the withdrawal of OP sheep dips is marginal. Alternative products are more expensive – the cost of OP dip per sheep treated is around 30p, whereas the cost per sheep of an injectable and a pour-on product is around 80p. However, the labour costs of dipping sheep are considerably higher since more people are needed.

Re-introduction of OP sheep dips

Recommendation (g): “We recommend that the VPC and MAFF prepare and publish a timetable for the re-introduction of OP dips, in both interim and permanent container designs, subject to the achievement of necessary safety measures, in order to reduce uncertainty in the industry.”

Response

16. The timing of the reintroduction of OP sheep dips has been largely in the hands of the marketing authorisation holders. However, as already indicated, officials and the VPC will co-operate fully to assist their return at the earliest opportunity.

17. Unfortunately, plans developed by one company for a change to containers in the short term and closed transfer systems as long term solutions, which were found acceptable by the VPC at its meeting in November 1999, were not taken forward because of the merger of the company with another. Marketing authorisations for the products in question were terminated at the request of the company which held them after the merger. Had these plans gone forward, then improved containers for OP dips would probably have been available in the Summer of 2000 and closed transfer systems might have been developed by the end of the year.

18. The Ministers who jointly form the Licensing Authority are currently considering advice from the Veterinary Products Committee (VPC) on the return of OP sheep dips onto the market.

Protection of dippers

Recommendation (h): “We find some merit in the idea of making laminated sheets part of the required labelling of each dip container and recommend that the Government consider making it a legal requirement that laminated sheets be given out to purchasers of OP sheep dip at the point of sale.”

Recommendation (i): “We recommend that the new labels for OP sheep dip concentrate be agreed as soon as possible, giving due regard in their wording and positioning to the practical circumstances in which the product is used.”

Recommendation (j): “We recommend that the Government reconsider the scope of the Certificate of Competence for the use of sheep dips.”

19. New labels for sheep dips are well advanced and marketing authorisation holders will be expected to adopt the new labels as part of the process of an eventual return of their products to the market. We agree that the provision of a laminated sheet at the point of sale has attractions and we will shortly consult on ways to bring such a requirement into effect.

20. The Government received advice from the Health and Safety Commission in November 1999 against a statutory requirement for users of sheep dips to hold Certificates of Competence. The HSC, which has the responsibility for advising the Government on such matters, advised that

there is already extensive legislation, including the COSHH Regulations, requiring dippers to be fully trained and competent and that requiring mandatory certification would not necessarily improve practice. On the contrary, mandatory certification may lead dippers to consider that certificates discharge them from their responsibility to work safely every time they dip and would not assist enforcement. The Government accepts the Committee's recommendation that the scope of the Certificate of Competence Scheme should be reconsidered. The Government is currently considering whether to consult interested parties on making it an offence if the person supervising the dipping operation and/or the principal concentrate handler do not hold a Certificate of Competence.

Ministry of Agriculture, Fisheries and Food
July 2000

APPENDIX

Letter to the Committee Chairman from Baroness Hayman, Minister of State, Ministry of Agriculture, Fisheries and Food (B25)

I was interested to read your Committee's report on how the Government's decision temporarily to withdraw OP sheep dips was handled. The Government will respond in due course but the purpose of this letter is to clear up an issue with which I was not able to deal in full when I gave evidence to your Committee on 11 April.

The issue, which was raised by Lembit Öpik, concerned the development of improved containers by one of the marketing authorisations, Vericore Limited. I had to be circumspect because, although Vericore had been bought by Novartis, the marketing authorisations for OP sheep dips had not been acquired and they remained with Grampian Pharmaceuticals Limited. That company wrote to the Veterinary Medicines Directorate (VMD) on 6 April and asked for the marketing authorisations in question to be terminated. Once that action had been completed, VMD sought the permission of Grampian Pharmaceuticals to disclose it to your Committee in advance of it being made public through Gazetting the expiry of the authorisations. Permission has now been granted and I can, therefore, confirm that this is the reason why changes in container design for the products Ectomort Centenary and Paradip 8% and Flyte 1250, Seraphos, Downland Seraphos and Paradip 40% will not, now, take place.

This is disappointing because the plans submitted by Vericore and considered by the Veterinary Products Committee in November were acceptable to the Committee. Had the developments gone ahead, Vericore had estimated that an interim solution could have been on the market by this summer at latest and that completely developed closed delivery systems might have been available before the end of the year.

This, I think, demonstrates that, with the necessary will, marketing authorisation holders could have developed plans which would have ensured that containers which met the objective of minimising the risk of operator exposure to OP concentrate were brought rapidly to the market. Unfortunately, the plans originally submitted by the other companies involved were not acceptable.

The Veterinary Products Committee has now considered revised plans and we expect to receive the Committee's advice shortly. Naturally, we will ensure that reference to this advice is included in the Government's response to your Committee's report.

22 June 2000

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