The Government's proposals for organophosphate sheep dips : fifth report, report, together with the proceedings of the Committee, minutes of evidence and appendices / Agriculture Committee.500.

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HOUSE OF COMMONS SESSION 1999–2000

AGRICULTURE COMMITTEE

Fifth Report

THE GOVERNMENT'S PROPOSALS FOR ORGANOPHOSPHATE SHEEP DIPS

Report, together with the Proceedings of the Committee, Minutes of Evidence and Appendices

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Ordered by The House of Commons *to be printed*
17 May 2000

PUBLISHED BY AUTHORITY OF THE HOUSE OF COMMONS
LONDON – THE STATIONERY OFFICE LIMITED
£11·50

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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:

Mr David Borrow (*Labour, South Ribble*)
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*)
Mr Lembit Öpik (*Liberal Democrat, Montgomeryshire*)
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]

The Committee has the power to require the submission of written evidence and documents, to examine witnesses, and to make Reports to the House. In the footnotes to this Report, references to oral evidence are indicated by 'Q' followed by the question number, references to the written evidence are indicated by 'Ev' followed by a page number.

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. A list of Reports of the Committee in the present Parliament is at the end of this volume.

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.

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

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FIFTH REPORT

The Agriculture Committee has agreed to the following Report:—

THE GOVERNMENT'S PROPOSALS FOR ORGANOPHOSPHATE SHEEP DIPS

I. INTRODUCTION

1. On 20 December 1999, just days before Christmas and the long Millennium holiday, the Ministry of Agriculture, Fisheries and Food announced the withdrawal of containers of organophosphate sheep dip concentrate from the market.[1] The holders of marketing authorisations for such products were given until 31 January 2000 to recall all stocks, including those purchased by distributors and farmers, and were informed that the ban would last "until containers are introduced which will minimise operator exposure to OP concentrate".[2] The decision to implement such drastic action was taken by Baroness Hayman, Minister of State at MAFF, acting on advice from the Veterinary Products Committee (VPC).

2. We are naturally aware of the long history of concern about the impact of organophosphates on human health, dating back at least as far as 1951 when Lord Zuckerman recommended regular blood testing of workers regularly exposed to OPs.[3] We have confined ourselves to the *process* which effectively led to the withdrawal of OP sheep dip from the farmer's armoury against a variety of ectoparasites after 20 December 1999, and the implications of the indefinite withdrawal of OP sheep dip containers from the market. We announced our inquiry on 7 March 2000[4] and held a single evidence session with Baroness Hayman, Minister of State, Ministry of Agriculture, Fisheries and Food, Mr Ray Anderson, Director of Policy, Veterinary Medicines Directorate, MAFF and Professor Ian Aitken, Chairman of the Veterinary Products Committee, on 11 April 2000. In addition we received more than twenty written submissions from individual farmers and their representative organisations, the animal health industry, and organisations and individuals with concerns about OPs and human health. We are grateful to everyone who contributed to this inquiry. In this Report we examine first, the consultation over the withdrawal, the timing of the withdrawal and information made available following the withdrawal of OP dips. We then consider the effects of the withdrawal on farmers, on the environment and on human health, and its implications for the use of OPs in the future. Finally, we comment briefly on the role of the VPC and the Minister in the decision-making process and draw conclusions from their handling of this episode.

II. CONSULTATION AND INFORMATION

Events leading up to the recall

In its advice to Ministers, the VPC was responding to two separate but related developments as indicated in the timetable below.

1998	Working Group of the Committee on Toxicity (COT) set up "To advise on whether prolonged or repeated low-level exposure to OPs, or acute exposure to OPs at a lower dose than causing frank intoxication, can cause ill-health effects".[5]
July 1999	Report published by the Institute of Occupational Medicine (IOM). Drawing on a three year epidemiological study, it "identified the handling of concentrated OP dip as the main source of potential exposure" and suggested that such exposure "was associated with an increased likelihood of ill-health".[6] The Government referred the IOM report to (a) the COT working party for review; and (b) the VPC and the Advisory Committee on Pesticides (ACP) to examine "whether its findings affected

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[1] MAFF News Release 455/99, 20 December 1999.
[2] Ev. p. 1; PN 455/99.
[3] Ev. p. 37.
[4] Agriculture Committee Press Notice No 18, Session 1999/2000.
[5] PN 455/99.
[6] Ev. p. 1, para 3.1.

their earlier advice on the safety of OPs and whether further measures were necessary in advance of the completion of the COT's review".[7] Within the month, the VPC communicated "interim advice"[8] to manufacturers, allowing them three months to submit proposals for improved container designs and making it "clear that regulatory action would be taken if suitable alternatives were not found".[9]

26 November — Publication of the COT report with its conclusion that "the balance of evidence did not support the hypothesis that prolonged or repeated low-level exposure to OPs caused peripheral neuropathy or clinically significant neuropsychological effects" but that "There remained a question, however, over whether there might be a small group of individuals particularly susceptible to OPs".[10] Report referred to the VPC, ACP and the Committee on the Safety of Medicines (CSM).

16 December — VPC meeting to consider the COT report and the plans submitted by the marketing authorisation holders for changes to concentrate containers. In concert with the ACP and CSM, it endorsed the COT report and advised against any general withdrawal of OPs from the market. However, the VPC also found that whilst one company had been "able to demonstrate satisfactory plans for long-term improvement and a short-term, interim solution" for new concentrate containers, none of the other plans submitted by marketing authorisation holders "was fully satisfactory" and even the interim solution would take time to introduce.[11] The VPC therefore advised the Government that "all OP sheep dips should be withdrawn from the market pending the introduction of new containers which would minimise operator exposure".[12]

December 1999 — Baroness Hayman consulted the other ministers who together form the licensing authority on the VPC advice.[13] Suspension of licences was announced on 20 December by way of a parliamentary answer and a News Release.

Consultation before the recall

3. In the immediate aftermath of the announcement there was considerable surprise within the industry at the suddenness of the Government's decision. Representatives of farmers expressed concern at the "lack of consultation on the possible impact of the withdrawal"[14] and the failure of the Government to give "prior warning to the industry about its plans".[15] Speaking for the manufacturers, the National Office of Animal Health Limited (NOAH) made several criticisms of MAFF's "poor communication", including failure to publish openly the VPC report or to follow what NOAH described as "normal practice" by calling "a meeting to discuss and explain the implications with all affected parties".[16] NOAH found this last omission to be "the principal cause of much frustration, confusion, bitterness and extra cost".[17] The National Farmers' Union also believed that "a proper consultation of all interested parties prior to (or immediately following) any announcement could have considerably reduced the potential impact on sheep welfare".[18]

4. We raised these concerns with the Minister and the Chairman of the VPC. Baroness Hayman was adamant that "we were being advised about regulatory action. It was not, therefore, an appropriate situation in which to start consulting with people as to the way forward."[19] For his part, Professor Aitken argued that "As to warning, I can only refer back to the announcement in July of last year when it was indicated quite clearly that if there were no positive plans to improve container design and to uniform these that there was a risk that there

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[7] Ev. p. 1, para 3.1.
[8] Q 50.
[9] Q 13.
[10] Ev. p. 1, para 3.3.
[11] Ev. p. 2, para 4.1.
[12] *Ibid.*
[13] Q 40.
[14] Ev. p. 25, para 8.
[15] Ev. p. 30.
[16] Ev. pp. 47-8.
[17] Ev. p. 48.
[18] Ev. p. 30.
[19] Q 50.

would be a withdrawal of product".[20] There was some support for this view among the written evidence we received; for example, that from Paul Tyler MP who pointed out that "for very many years the dangers of exposure to OPs ... have been known" and "Therefore, the action ... could scarcely be considered precipitate".[21] However, NOAH responded to the Minister's evidence by clarifying that "Up until 20 December companies had every reason to believe that their proposals [for improvements in container design] would be accepted".[22] NOAH described the "shock" at the VPC's decision as threefold, namely that "the proposals had been rejected, ... there was no offer of further discussions on how to improve the proposals, [and] ... instead an immediate suspension was introduced".[23] We have some sympathy with NOAH. At the very least the VPC should have communicated their findings on each company's proposal to that company, within an agreed timescale, following submission of the proposal.

5. A further complaint of the lack of consultation came from the Environment Agency (EA) which has "statutory responsibilities for both environmental protection and waste-handling and yet was not involved or consulted in anyway before the decision to suspend OP dips".[24] Not only did this mean that the EA could not have any input into the decision, it also left them unable to offer advice to those who approached the Agency for information on the implications of the announcement.[25] In evidence, Baroness Hayman told us it was not necessary to consult the Environment Agency during the regulatory process.[26] Mr Anderson, Director of Policy, Veterinary Medicines Directorate, clarified that "the Environment Agency does, where appropriate, act as adviser to the VPC, as officials, but that is done through the Department of Environment, Transport and the Regions and their officials were in attendance throughout the process of the VPC's deliberations".[27] The VPC advice that emanates from these deliberations is then forwarded to Ministers who take the regulatory decisions. Professor Aitken later added that "I would suggest there is a need for dialogue between the Environment Agency and Veterinary Medicines Directorate about the severity of the review process that takes place".[28] **We agree, 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.**

6. Finally, MAFF also defended the Government against accusations of the lack of warning given to manufacturers and farmers by stating that "Companies could not be informed before Parliament" of the Government's response to the reports from the various advisory Committees.[29] We fail to see why this consideration should prevent consultation on likely actions. The TFA argued that, whilst Parliament has a right "to know the outcome of ministerial decisions prior to their wider dissemination", the Association "could have been consulted on the Government's proposals prior to a final announcement which would have at least warned us to expect change in that direction".[30] **We agree; 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 of 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.**

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[20] Q 123.
[21] Ev. p. 58.
[22] Ev. p. 59.
[23] Ev. p. 59.
[24] Ev. p. 55.
[25] Ev. p. 48.
[26] Q 46.
[27] Q 47.
[28] Q 102.
[29] Ev. p. 2.
[30] Ev. p. 30.

Consultation on the requirements for improved packaging

7. A related issue is the assistance manufacturers were given in bringing forward plans for new containers in the three months after the VPC's interim advice in July. In a letter to the Baroness Hayman of 7 January 2000, NOAH acknowledged that "We do recognise the need to improve packaging but cannot comply until VMD/VPC have explained what is required of companies."[31] The Minister held no meetings with the industry between the publication of the VPC's interim advice and the deadline for the receipt of plans for changes to packaging.[32] However, Mr Anderson pointed out that "manufacturers were allowed the facility of coming to see officials of the Veterinary Medicines Directorate in particular to establish what data they might have to produce to demonstrate the continued stability of their products in any new planned containers".[33] He added that two such meetings took place in August.[34] Professor Aitken of the VPC argued that "It was not the role of the Committee to be in any way prescriptive, but simply to identify that there was a need to improve container design to a point where it would minimise or avoid the risk of contamination by the operator". The VPC report in July had given totally closed systems and water-soluble sachets as "examples of what might be done".[35] **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 improvement.** We note that NOAH was satisfied with three meetings that took place between 10 February and 7 March 2000, and that they reported "a very positive shift in the attitude of officials" after the first of the meetings.[36] We expect this development to herald further close co-operation.

8. Packaging was improved in response to concerns in 1993/94[37] but Professor Aitken indicated that "there has been a recommendation on the part of the [Veterinary Products] committee going back to about 1997 that technology has now progressed to the point where those totally closed systems for dispensing concentrates should be attainable".[38] NOAH noted that the IOM report was based on survey data from 1996,[39] so we are curious to know why problems first identified in 1996 were required to be addressed in the three months following July's interim advice from the VPC. With hindsight, progress could have been made since 1996 and the suspicion of cover-ups and then the accusation of hasty action could have been avoided. We hope that the lesson of sharing information and detailing requirements carefully is learned.

Timing of the announcement

9. The difficulties caused by the lack of consultation on the announcement were exacerbated by the timing. Baroness Hayman argued that the process following the July publication of the IOM report made it clear that a Government review would have to be taken "before the end of the year",[40] but she admitted that "I would not pretend to the Committee that doing this in the week before Christmas would have been the time I would have chosen to do it if I had complete control over the timetable".[41] Her reason for making the announcement on 20 December 1999, calling for a complete recall of OP sheep dips by 31 January 2000, was that "I felt it inappropriate, having been advised to take regulatory action to protect human health, to delay doing so".[42] We accept that the decision had to be taken and announced as soon as possible in these circumstances and that to wait until after the long public holidays could equally be seen as unjustifiable delay. However, we are less certain that the consequently truncated period to complete the recall was advisable or necessary. Lack of information over the New Year period

[31] Ev. p. 54.
[32] Q 51.
[33] *Ibid.*
[34] *Ibid.*
[35] Q 76.
[36] Ev. p. 50.
[37] Q 34.
[38] Q 35.
[39] Ev. p. 59.
[40] Q 45.
[41] Q 56.
[42] Q 56.

meant that it was well into January before action could be taken and the speed at which it was then implemented lent an unwelcome sense of danger to the operation. Given that routine dipping is not undertaken until April and that OP concentrates on farms were therefore unlikely to be used,[43] we believe a more considered approach should have been explored. As it is, we note Baroness Hayman's assurance that "we believe that all product was successfully withdrawn",[44] and we commend the industry for its co-operation with the recall. There can, however, be no certainty that some OP dip especially that which had already been opened did not remain on farms.

Information for farmers after the announcement

10. A particular concern for farmers was that information as to the implications of the recall was not made available to the agriculture industry with sufficient speed or clarity. The TFA told us that on 21 December, the day following the announcement, it was difficult "to get coherent and consistent advice from officials within the Veterinary Medicines Directorate and the Pesticides Safety Directorate". Furthermore, "the Government did not establish a helpline for farmers or give the already established MAFF helpline sufficient advice to provide callers with information on their position".[45] We asked Baroness Hayman how much information was immediately available to farmers. The Minister told us that the MAFF press release "went on to the MAFF website immediately which then takes you into the regional service centres" and she recalled "doing an interview for 'Farming Today'".[46] We were subsequently informed that "VMD officials provided Regional Directors with question and answer material in January. They were also given oral briefing at their first regular meeting after the holiday period on 20 January".[47] The delay between the announcement and furnishing one of the farmers' first points of contact with information causes us great concern. It is imperative that full information is available to those affected by decisions as quickly as possible and MAFF clearly fell below acceptable standards on this occasion. We welcome Baroness Hayman's commitment to "make sure that regional service centres are more specifically informed on such issues",[48] and **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.**

III. EFFECTS OF THE WITHDRAWAL OF OP SHEEP DIPS

11. The Farmers Union of Wales told us that "organophosphate compounds provide the most effective insecticide for the treatment and prevention of the major ectoparasitic infections in sheep".[49] MAFF countered this with the argument that "There are ... other products available (synthetic pyrethroid (SP) dips and injectables) for the control of ectoparasites including sheep scab. Pour-on products are also available for parasites other than scab".[50] Professor Aitken commented that "each of these alternatives has been through the regulatory process ... and they are only available if efficacy can be demonstrated".[51] Nevertheless, a number of concerns were expressed about the animal welfare, economic and environmental impact of the unavailability of OP sheep dip and/or the use of alternatives. The impact of OPs on human health was also raised. We discuss these issues in the following paragraphs.

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[43] Ev. p. 47.
[44] Q 70.
[45] Ev. p. 30.
[46] Q 56.
[47] Ev. p. 21.
[48] Q 57.
[49] Ev. p. 25, para 17.
[50] Ev. p. 2.
[51] Q 93.

Animal welfare and health

12. The Tenant Farmers Association believed that "There are few viable alternatives to dipping using OPs that can be used on a wide spread basis", with the consequence that "sheep health could suffer" from the OP ban.[52] Other organisations agreed, with the National Sheep Association arguing that the alternatives do not have "the same broad spectrum activity on ecto parasites",[53] and the Farmers' Union of Wales adding that pharmaceutical companies "have also expressed concern that the incidence of scab resistance to synthetic pyrethroids is likely to accelerate substantially if there is increased usage".[54] These concerns led to calls for fast-tracking approval of new packaging or to the National Farmers' Union proposal for "some sort of derogation to use OP dips under supervision in exceptional circumstances ".[55]

13. Asked what advice had been given to farmers on the control of sheep scab in the wake of the withdrawal of OPs, Professor Aitken told us that industry figures showed that "OP dips were used for about 50 per cent of the sheep in the country" and the remaining 50 per cent were subject to other treatments, so "there is an armamentarium of specific products ... to treat ectoparasitic infestation".[56] (MAFF later clarified these figures as referring to percentage of sheep *dipped*, not the whole UK flock.[57]) Nevertheless, he accepted that "OP dips have the advantages of being broad-spectrum in their activities" and "are very effective".[58] Fast-tracking would depend upon the "plans that the manufacturers have for improving container design and thereafter it is a matter of generating stability data", testing for which "could be done in the short term in three months".[59] Baroness Hayman confirmed that "it might be that an interim solution could be provided more quickly because it did not need such long stability trials as a long-term solution".[60] However, any derogation looks unlikely since Baroness Hayman assured us that "it is not that it is impossible to find an effective mechanism for dealing even with a large-scale outbreak" in the absence of OPs.[61] We are concerned about the lack of an acceptable, effective alternative to OP dips. Whilst we welcome the fact that "the state veterinary service has set up a working group to look at welfare issues"[62] and the £1.6 million research programme for alternative strategies to control sheep scab,[63] **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.**

Economic issues

14. The sheep sector, as with the rest of agriculture, is currently in serious economic difficulty which makes additional demands on farm budgets hard to bear. Farmers find OP dips are attractive not just for their superior performance but for their lower costs compared with alternative products.[64] Longer withdrawal periods for alternatives such as injectibles make them unsuitable for use on sheep destined for early slaughter, thus restricting the marketability of the sheep where they are applied.[65] Allied to these concerns is that of the economic impact of poor quality sheep skins, i.e. those that had suffered from lice and scab, beyond the farmgate. The British Leather Confederation highlighted the increased number of damaged skins following the progressive "relaxation and abolition of compulsory sheep dipping".[66]

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[52] Ev. p. 31.
[53] Ev. p. 45.
[54] Ev. p. 26.
[55] Ev. p. 30.
[56] Q 91.
[57] Ev. p. 21.
[58] Q 90.
[59] Q 92.
[60] Q 87
[61] Q 93.
[62] *Ibid.*
[63] Q 92.
[64] Ev. p. 35.
[65] Ev. p. 45.
[66] Ev. p. 39.

15. Mr Anderson of MAFF countered that "Compulsory dipping was ended in 1992 ... [because] the policy was not working in terms of having any success in eradicating scab",[67] although Baroness Hayman was aware of "anecdotal evidence" that the incidence of scab is increasing.[68] She also assured us that the economic impact of the withdrawal of OP dips had formed "part of the context in which the decision was taken".[69] Nevertheless, she believed that "we have a responsibility to take the appropriate action to ensure that we minimise the risk that people then choose to take or not take".[70] We recognise that in the situation where a properly quantified risk to human health can be demonstrated, it should be remedied where possible. But economic factors must be considered in any impact assessment. The balance between these two considerations could be weighed more effectively if the real level of incidence of sheep scab were known, as well of course as the real risk to human health of OP dips. **We recommend that the Government assess the level of scab and evaluate the economic impact upon farmers of alternative approaches to eradicating sheep scab from the UK. We further recommend that the likely economic cost to farmers of the withdrawal of OP sheep dips be assessed and published.**

Environmental impact

16. Witnesses generally agreed that OPs have a further advantage over alternatives in that they have "the least cumulative negative side effects on the environment".[71] Synthetic pyrethroid (SP) dip compounds, for example, "are typically 100 times more toxic to many forms of aquatic life, than are OP dips", according to the Environment Agency.[72] The Agency had found that "The number of recorded pollution incidents match the usage of SP dip compounds. There were 34 incidents in 1997 and six in 1999, and the quantity of SP's as a percentage of total sheep dip compounds for the relevant periods was 38 per cent and 10 per cent respectively".[73] Questioned about the environmental impact of SP dips, Professor Aitken accepted that "the fact they are particularly toxic to aquatic environments and aquatic invertebrates is well-established and well-known".[74] The Minister agreed that "There are down sides to all the alternatives",[75] but she placed her reliance on "the environmental impact study that had been made to allow SP dips on the market".[76] She added that "I am sure as statutory advisers the Environment Agency are concerned about the growing use of SP dip and its effect on the environment and they will alert Ministers to that".[77] We are concerned that the impact of the increased use of SPs as a consequence of the withdrawal of OP sheep dips was not sufficiently acknowledged in reaching the decision, a point that closely relates to the failure to consult the Environment Agency. The Agency will no doubt monitor pollution incidents and SP usage over the period that OP dips are unavailable and we await the results with interest.

Human health implications and risk assessment

17. Organophosphate compounds have long been linked to human health problems.[78] Although this was not the main concern of our inquiry, we did raise certain aspects of the issue. On one side of the argument, we were told that "the threat of exposure lies beyond simply opening the container",[79] whilst the National Association of Agricultural Contractors' experience suggested that "OP sheep dip concentrates handled by trained operators are not a risk to the user".[80] The advice on the effects of OPs on human health makes a distinction between the

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[67] Q 119.
[68] Q 113.
[69] Q 111.
[70] Q 109.
[71] Ev. p. 45.
[72] Ev. p. 54.
[73] Ev. p. 56.
[74] Q 101
[75] Q 98.
[76] Q 99.
[77] Q 100.
[78] Ev. p. 37.
[79] Ev. p. 37.
[80] Ev. p. 54.

effect of the concentrate and low level exposure. The Institute of Occupational Medicine's report suggested that "exposure to concentrates was associated with an increased likelihood of ill-health in the groups of subjects studied".[81] Baroness Hayman interpreted it thus: "I think the weight of scientific evidence is that there is no doubt that exposure to the concentrate can be dangerous to human health and have very bad effects on human health".[82] The Committee on Toxicity reported that "the effects of long term exposure at low levels were still not certain".[83] We hope that while the use of OPs is prohibited the research into their effects will continue apace, and that the concerns raised about human health are properly examined, including any effect on those handling dipped sheep.

18. Nonetheless, we were more than a little concerned that the risk of OP contamination associated with dipping sheep had not been quantified more carefully before the withdrawal was announced. For example, we accept that the existing containers are "a source of potential contamination"[84] and that "exposure to concentrates is the greatest hazard to human health"[85] but for the Government's advisers to find it "extremely difficult to quantify" the impact of wearing protective clothing and then to provide a qualitative assessment that the risk "is very substantially reduced"[86] if it is worn seems hard to justify in this context. It is important that the action taken by Government is seen to be proportionate to the risk and this can only be done in terms of a proper risk assessment made freely available to all interested parties. We acknowledge the strength of opinion on both sides of the debate as regards a complete ban on OPs but we believe that the risk of OP concentrate to human health should have been made more explicit in the Press Release from MAFF where the message was blurred by the stress on official advice against any general withdrawal of OPs from the market.

Conclusion

19. There are strong environmental, economic and animal health and welfare arguments in favour of OP sheep dips. However, there are potential human health effects and we accept that these must carry a considerable weight in deciding whether a product should be withdrawn from the market. In this case, both sides of the argument should have been presented to the industry in a clearer fashion.

IV. USING OP SHEEP DIPS IN THE FUTURE

Re-introduction of OP sheep dips

20. OP sheep dips were withdrawn without a clear timetable for their re-introduction. This has led to fears that the announcement "may be a 'back door' route to the outright banning of the use of OP sheep dips".[87] We are satisfied that this is not the case and that the Government is prepared to issue new marketing authorisations for products in appropriate containers.[88] It is, however, far from certain when this will be. In written evidence submitted in February, MAFF admitted that "Although a satisfactory interim solution is being developed by one company, it is possible that there will be no OP dips available in time for the Spring dipping season".[89] This is now accepted as an understatement. We understand from NOAH that "The anticipated timetable is now an Appeal at the May VPC meeting to propose interim solutions to enable OP dips to return to the market for the autumn 2000 dipping season".[90] More permanent solutions will not be available until autumn 2001.[91] This estimate is broadly in line with Professor

[81] Ev. p. 1, para 3.1.
[82] Q 10.
[83] Q 2.
[84] Q 35.
[85] Q 36.
[86] Q 38.
[87] Ev. p. 30.
[88] Ev. p. 2, para 8.3; Q 86.
[89] Ev. p. 2, para 8.4.
[90] Ev. p. 50.
[91] Ev. p. 50.

Aitken's forecast that, bearing in mind the need for stability data, "it would perhaps be over-optimistic to suggest that they might be back in the autumn of this year and more realistic to anticipate it will be about this time next year."[92] It is important that there is clarity on this point. **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.**

21. Clearly, manufacturers should be and are addressing the development of both long- and short-term solutions. It is common ground among all parties to this inquiry that such packaging should offer the maximum protection to users, particularly as regards splashing.[93] Baroness Hayman assured us that "We will work with the manufacturers and give them any technical advice and support we can do to allow them to do that"[94] and that she had been advised that "there is currently technology that is applicable here that could improve safety and minimise risk through container design".[95] We expect the Government to share that information with OP dip manufacturers to allow the benefits of OPs to be used, with minimum risk, by those who want to do so, subject to the safeguards we discuss in the next section. However, we accept that new packaging will not totally eradicate the risk of contamination. We now consider briefly approaches that can be adopted alongside the new packaging to reduce the risk to sheep dippers.

Protection of dippers

22. Research reported by the Veterinary Laboratories Agency found that "farmers did not always follow dipping procedures and precautions".[96] This increases the need continuously to reinforce the importance of following the correct procedure and wearing the appropriate protective clothing in both training and point of sale material. Following a suggestion from the industry,[97] laminated sheets were sent out to all sheep farmers last November, setting out in "plain language" the dangers of handling sheep dip. AHDA has suggested that these sheets "be made legally part of the required labelling of each dip container" and therefore be handed out at point of sale with every purchase.[98] **We find some merit in this idea 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.** On the question of the label itself, we were concerned to hear of a sixteen-month delay in the revision of the wording to reflect the greater risk in handling concentrate, rather than diluted dip.[99] Professor Aitken of the VPC reported that "the label is virtually ready to go out for final consultation",[100] although Mr Anderson explained that as a result of the IOM report, "we are intending to have a final look to see whether the danger of handling concentrate should be further highlighted".[101] The distinction between concentrated and diluted dip must be made but care must be taken to avoid the implication that sheep dip in its dilute form is harmless. Progress on labelling appears to be unacceptably slow and **we recommend that the new labels be agreed as soon as possible, giving due regard in their wording and positioning to the practical circumstances in which the product is used.**

23. Another measure for the protection of dippers is the need for purchasers of sheep dips to hold a Certificate of Competence for the Use of Sheep Dips. The FUW considered it anomalous that the certificate is not required for actual use of the dip.[102] NOAH told us that all the organisations present at a meeting with Baroness Hayman on 10 February 2000 (the main farmers' unions, the National Sheep Association and the AHDA, among others) had proposed that the current requirements concerning the certificate "should be extended: (a) so that the person in charge of every dipping gang should hold the certificate; (b) that only certificate

[92] Q 49.
[93] Q 81.
[94] Q 117
[95] Q 109.
[96] Ev. p. 36.
[97] Ev. pp. 23, 53.
[98] Ev. p. 23.
[99] Ev. p. 53.
[100] Q 84.
[101] Q 84.
[102] Ev. p. 26.

holders should be permitted to handle the concentrate when filling or replenishing the dip bath".[103] In addition, the Environment Agency supported their extension "to include proper disposal of used dips".[104] These initiatives have been blocked by advice from the Health and Safety Commission that "there were major drawbacks to mandatory certification" for sheep dip users.[105] Baroness Hayman paraphrased their concern to be "that the responsibility was being shifted on to the individual operator and away from the responsibility of the manufacturer."[106] It is rare indeed for an industry to ask for more bureaucracy than exists at the moment, an observation which underlines the strength of their concern about the Certificate of Competence. The Government has undertaken to improve "the guidance and the syllabus for the certificate of competence" for pesticides.[107] **We recommend that at the same time the Government reconsider the scope of the Certificate of Competence for the use of sheep dips.**

Government action plan

24. The withdrawal of OP sheep dips on 20 December was intended to be just one element in a four point plan. The other three parts were revocation of approvals for "three OP compounds for which data packages have not been submitted"; "Implementation of a range of measures aimed at continuing to promote best practice"; and "A targeted research programme to take forward the research recommendations from COT and the regulatory committees".[108] The best practice measures include those mentioned in the previous section regarding labelling, together with a continuing programme of targeted inspections by HSE inspectors and the supply of protective gloves with sheep dips.[109] Meanwhile, the research programme is to be organised in collaboration with the HSE and the Department of Health. Its contents were touched upon at various points in our evidence session with the Minister. We believe it is right that major research effort be directed in this area. We particularly welcome research into alternative strategies to control sheep scab and into the human health aspects of OPs. These are questions which need to be answered for the sake of the UK sheep industry and those who work in it.

V. THE DECISION-TAKING PROCESS

Role of the VPC

25. The VPC was established in 1970 under Section 4 of the Medicines Act 1968 with the following terms of reference:

- to give advice with respect to safety, quality and efficacy in relation to the veterinary use of any substance or article (not being an instrument, apparatus or appliance) to which any provision of the Medicines Act is applicable;
- to promote the collection of information relating to suspect adverse reactions for the purpose of enabling such advice to be given.

We have no doubt that the VPC has acted conscientiously in reaching its decisions on OP sheep dips, given the information available. However, a number of witnesses raised issues with us which suggest that there is room for improvement in the way in which the committee operates. These include criticism from the OP Information Network (Scotland) of the source of information submitted to the VPC, with the claim that "a system that relies solely on the data of producers is unacceptable towards enforcing these aims of 'safety, efficacy and quality'".[110] Others pointed to the lack of openness by the Committee which had made its advice late last year

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[103] Ev. p. 50.
[104] Ev. p. 55.
[105] Ev. p. 29.
[106] Q 125.
[107] PN 455/99.
[108] PN 455/99.
[109] PN 455/99.
[110] Ev. p. 37.

such a shock to the industry.[111] Finally, the Environment Agency argued that the VPC's membership "could be usefully extended to include a further environmental scientist",[112] thereby broadening the range of expertise and of considerations taken into account when formulating advice.

26. We raised these matters with the VPC Chairman, Professor Aitken, who accepted that information supplied by manufacturers "constitutes a considerable part of the information presented", albeit not "exclusively".[113] Other information came from reports and questions raised by the committee.[114] In general, he argued that the VPC "does, in the process of authorising any application that comes before it, go through a very rigorous exercise of judging its quality, safety and efficacy".[115] He went on to say that information before the Committee also came "from the knowledge of its individual members".[116] We argued earlier in this Report that it would be more appropriate for the Environment Agency to advise the VPC directly to ensure that environmental issues were properly considered. We also believe that the VPC must consider how to broaden the range of information on the possible harmful effects of products under examination and that it must be more open in its approach. Its proceedings in this instance have not been conducive to a good working relationship with any part of the industry and we are further concerned by allegations that its report was made available to some but not all interested parties.[117] The VPC has an important role to play and greater transparency would encourage faith in its conclusions.

Role of the Minister

27. Ultimately, the decision on whether to act on advice from the VPC or any other such committee rests with Ministers. In this case, the advice to recall containers of OP dips went to the licensing authority, "a collection of ministers" including Baroness Hayman.[118] These Ministers "had to consider whether to take that advice: whether to do something less onerous", such as allow the products to remain in use while containers were being redeveloped, or to do "something more draconian", such as permanently revoke the licences.[119] Baroness Hayman regarded the advice she received from the VPC as "unequivocal",[120] although she also accepted that it was not "an easy decision".[121] She defined her role as "trying to get the most sensible assessment of the appropriate way forward given one's responsibilities as a licensing authority and the advice that one has a responsibility to consider".[122] There is of course little point in having expert advisory committees if their advice is constantly overruled. However, in this instance, we are concerned that insufficient attention appears to have been paid to the practical and economic consequences of the decision. On balance, we accept that the right decision was made but that it could have been handled more effectively both prior to and following the announcement and we welcome Baroness Hayman's willingness to reconsider her decision in the light of possible future advice from the advisory committees.[123]

VI. CONCLUSION AND SUMMARY OF RECOMMENDATIONS

28. **This inquiry has focussed narrowly on MAFF's announcement of the withdrawal of OP sheep dip containers from the market. In concluding, however, we draw together a number of lessons to be learnt from this event which have a wider application. First,**

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[111] eg Ev. p. 47.
[112] Ev. p. 56.
[113] Q 18.
[114] *Ibid.*
[115] Q 17.
[116] Q 18.
[117] Ev. p. 47.
[118] Q 8.
[119] Q 40.
[120] Q 40.
[121] Q 45.
[122] Q 107.
[123] Q 86.

information should be acted upon when it becomes available but only once a full impact assessment of the action proposed has been conducted. Second, processes involving government decisions should be conducted as much as possible in the open, allowing all points of view to be considered, as long as commercial confidentiality is duly respected. Third, the process of openness should extend to parties subsequently affected by decisions taken; there must be appropriate mechanisms in place to ensure that information about decisions is available quickly and accurately. Fourth, Committees and Agencies that are charged with advising Government should also have some formal mechanism of seeking or offering advice to each other when a case warrants such action.

29. **In this specific case, we further conclude that the Minister knew when the issue appeared before her in urgent form that the approaching Christmas and Millennium holidays presented a particular problem in terms of the dissemination of any decision she would take and the making available of information which flowed from it. Precautionary steps should have been taken much earlier to alert RSCs to the issue and mechanisms put in place to brief RSCs on the practical steps which the decision would impose. We do not believe that the decision raised issues of confidentiality. The Minister therefore could have discussed in advance with interested parties the steps which would be necessary if a decision to ban OP dip concentrates were taken. We remain concerned that users of sheep dips are without their preferred means of combatting sheep disease for the foreseeable future and that there are likely to be severe economic, environmental and animal welfare implications as a result. We do not dismiss the sufferings of those whose ill-health has been linked to OP sheep dips but we believe it to be to the general benefit that OP sheep dip concentrates are restored to the market in suitably designed containers, together with all other practical precautionary measures, as soon as possible and that all sides should work together to make this happen.**

30. Our other principal conclusions and recommendations are as follows:

Consultation before the recall

(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 (paragraph 5).**

(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 of 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 (paragraph 6).**

Consultation on packaging improvements

(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 improvement (paragraph 7).**

Information for farmers

(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 (paragraph 10).**

Animal welfare and health

(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 (paragraph 13).**

Economic issues

(f) **We recommend that the Government assess the level of scab and evaluate the economic impact upon farmers of alternative approaches to eradicating sheep scab from the UK. We further recommend that the likely economic cost to farmers of the withdrawal of OP sheep dips be assessed and published (paragraph 15).**

Re-introduction of OP sheep dips

(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 (paragraph 20).**

Protection of dippers

(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 (paragraph 22).**

(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 (paragraph 22).**

(j) **We recommend that the Government reconsider the scope of the Certificate of Competence for the use of sheep dips (paragraph 23).**

ABBREVIATIONS USED IN THE REPORT

ACP	–	Advisory Committee on Pesticides
AHDA	–	Animal Health Distributors Association (UK) Ltd
COT	–	Committee on the Toxicity of Chemicals in Food, Consumer Products and the Environment
CSM	–	Committee on the Safety of Medicines
DETR	–	Department of the Environment, Transport and the Regions
EA	–	Environment Agency
FUW	–	Farmers' Union of Wales
HSE	–	Health and Safety Executive
IOM	–	Institute of Occupational Medicine
MAFF	–	Ministry of Agriculture, Fisheries and Food
NOAH	–	National Office of Animal Health
OP	–	organophosphate
RSC	–	regional service centre (MAFF's offices in the regions)
SP	–	synthetic pyrethroid
TFA	–	Tenant Farmers Association
VMD	–	Veterinary Medicines Directorate (of MAFF)
VPC	–	Veterinary Products Committee

PROCEEDINGS OF THE COMMITTEE RELATING TO THE REPORT

WEDNESDAY 17 MAY 2000

Members present:

Mr David Curry, in the Chair

Mr David Drew	Mr Lembit Öpik
Mr Alan Hurst	Mr Owen Paterson
Mr Michael Jack	Mr Mark Todd
Mr Paul Marsden	Dr George Turner
Mr Austin Mitchell	

The Committee deliberated.

Draft Report [The Government's Proposals for Organophosphate Sheep Dips], proposed by the Chairman, brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 30 read and agreed to.

Annex agreed to.

Resolved, That the Report be the Fifth Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House.

Ordered, That the provisions of Standing Order No. 134 (Select committees (reports)) be applied to the Report.

Ordered, That the Appendices to the Minutes of Evidence taken before the Committee be appended to the Report.

[Adjourned till Tuesday 23 May 2000 at ten minutes to Two o'clock.

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Tuesday 11 April 2000

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Rt Hon Baroness Hayman and Mr Ray Anderson 3

VETERINARY PRODUCTS COMMITTEE

Professor Ian Aitken 3

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UNPRINTED MEMORANDA

Additional memoranda have been received from the following and have been reported to the House, but to save printing costs they have not been printed and copies have been placed in the House of Commons Library where they may be inspected by Members. Other copies are in the Record Office, House of Lords, and are available to the public for inspection. Requests for inspection should be addressed to the Record Office, House of Lords, London SW1 (Tel 020 7219 3074). Hours of inspection are from 9.30 am to 5.30 pm on Mondays to Fridays.

1. Farmers' Union of Wales (Annex) (B3)
2. Veterinary Laboratories Agency (Annex) (B12)
3. National Office of Animal Health Limited (Annex) (B17)

MINUTES OF EVIDENCE

TAKEN BEFORE THE AGRICULTURE COMMITTEE

TUESDAY 11 APRIL 2000

Members present:

Mr David Curry, in the Chair

Mr David Borrow
Mr David Drew
Mr Michael Jack
Mr Austin Mitchell
Mr Lembit Öpik
Mr Owen Paterson
Dr George Turner

Memorandum submitted by the Ministry of Agriculture, Fisheries and Food (B 10)

1. Issue

1.1 The Government has required the holders of marketing authorisations for organophosphorus (OP) sheep dips to withdraw their products from the market by 31 January pending the introduction of new containers designed to minimise the risk of operator exposure to concentrated dip.

2. Background

2.1 OP dips for use against sheep scab were introduced in the 1980s, replacing organochlorine dips, which were persistent in the environment. They are effective against serious sheep ectoparasites, including the scab mite, blowfly, ticks, keds and lice. OPs are toxic chemicals and must be handled with care. They are absorbed through the skin and measures must be taken to prevent exposure.

2.2 Advice on sheep dipping is provided in booklet, AS29(rev2), in the Agriculture Safety series, issued jointly by the Health and Safety Executive (HSE), the Veterinary Medicines Directorate (VMD), the Environment Agency and the Scottish Environment Protection Agency (SEPA). The booklet has been sent free to all registered sheep farmers in Great Britain. It sets out a hierarchy of safety measures to be taken when dipping, including properly designed and sited dipping baths, engineering controls (eg screens and splash boards), and personal protective equipment (PPE).

2.3 Warnings and advice are included on the labels of containers of sheep dips. Proposals for simplified, more easily understandable labels are under preparation and will be widely circulated for comment.

2.4 An interdepartmental high-level group of officials ("'the official group'") was set up in December 1997 to monitor information sharing on OPs and to draw together scientific evidence. Its report—"Official Group on OPs—Report to Ministers"—was published on 25 June 1998.

3. Research and Committees' Advice

3.1 A report of a three-year epidemiological study by the Institute of Occupational Medicine (IOM), published in July 1999, identified the handling of concentrated OP dip as the main source of potential exposure. It suggested that exposure to concentrates was associated with an increased likelihood of ill-health in the groups of subjects studied. The report was referred to the Department of Health's Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT), which had been asked in 1998 to review the evidence of possible ill-health effects of OPs and to advise on whether prolonged or repeated low-level exposure could cause chronic ill-health effects. The IOM's report was also referred to the Veterinary Products Committee (VPC) and the Advisory Committee on Pesticides (ACP) for urgent advice on whether its findings affected their earlier advice on the safety of OPs and whether further measures were necessary in advance of the completion of the COT's review.

3.2 In an interim report, also published in July, the VPC advised that marketing authorisation holders should be asked to submit practicable plans to improve and standardise the design of sheep dip containers, with the objective of minimising operator contact with OP concentrate. Plans were to be submitted within three months and if they were not, action would begin to revoke marketing authorisations.

3.3 The COT's report, published in November, concluded that the balance of evidence did not support the hypothesis that prolonged or repeated low-level exposure to OPs caused peripheral neuropathy or clinically significant neuropsychological effects. It indicated that, if such effects did occur, they must be relatively uncommon. There remained a question, however, over whether there might be a small group of individuals particularly susceptible to OPs.

4. FURTHER ADVICE FROM THE VPC

4.1 The VPC and other regulatory committees were asked to consider the regulatory implications of the COT's report and all advised against a general withdrawal of OPs from the market. The VPC had also considered plans submitted by the marketing auhorisation holders for changes to concentrate containers. One company was able to demonstrate satisfactory plans for long-term improvement and a short-term, interim solution. None of the other plans was fully satisfactory. Time would be needed to introduce even the interim solution and the VPC therefore advised that all OP sheep dips should be withdrawn from the market pending the introduction of new containers which would minimise operator exposure.

5. THE ANNOUNCEMENT

5.1 The Government's response to the committees' reports was announced to Parliament on 20 December. Companies could not be informed before Parliament but were informed of the withdrawal by letter immediately after the announcement, and a News Release was also issued. Marketing authorisations were immediately suspended pending the introduction of new containers. This meant that no OP sheep dips could legally be sold or used from that date.

5.2 All companies co-operated. Sales were stopped immediately and marketing authorisation holders took action to comply with the requirement to withdraw products from the market by 31 January. Withdrawing products from the sales chain is straightforward but retrieving products from farms presents greater difficulties.

6. EFFECT ON SHEEP WELFARE

6.1 It will take time to introduce new containers of concentrated dip. The interim solution proposed by one company could be introduced relatively quickly but it is possible that there will be no OP dip available for the Spring dipping season. There are, however, other products available (synthetic pyrethroid (SP) dips and injectables) for the control of ectoparasites including sheep scab. Pour-on products are also available for parasites other than scab.

7. FURTHER WORK

7.1 The Government announced a four-point plan for further work arising from the committees' report. This includes measures to promote best practice in sheep dipping, including improvements to labelling, targeted inspections by Health and Safety inspectors, and the development of a research programme to take forward the research recommendations of the COT and regulatory committees.

8. SUMMARY

8.1 Following a report from the Institute of Occupational Medicine, the VPC advised that marketing authorisation holders for OP sheep dips should submit plans for improvements to the containers of concentrated dip. Plans were submitted within the three month deadline but only one was satisfactory. Even the satisfactory solution would take time to introduce and the VPC advised that all OP sheep dips should be removed from the market pending the introduction of improved containers.

8.2 The Government could not delay action in the light of the VPC's advice and companies were required to withdraw products from market by 31 January.

8.3 OP sheep dip products will be permitted to return to the market once satisfactory improved containers, designed to minimise the risk of operator exposure, have been introduced.

8.4 Although a satisfactory interim solution is being developed by one company, it is possible that there will be no OP dips available in time for the Spring dipping season. There are, however, alternative products available.

15 February 2000

Examination of Witnesses

BARONESS HAYMAN, a Member of the House of Lords, attending by leave of that House, Minister of State, Ministry of Agriculture, Fisheries and Food, MR RAY ANDERSON, Director of Policy, Veterinary Medicines Directorate, Ministry of Agriculture, Fisheries and Food, and PROFESSOR IAN AITKEN, Chairman, Veterinary Products Committee, examined.

Chairman

1. Minister, Professor Aitken, Mr Anderson, I hope I am not breaching some terrible constitutional convention in starting early but the clerk has not yet had apoplexy, so I assume we are all right! We wanted to talk to you basically about the process rather than about substance of the issue, although that is bound to come up because you cannot separate the two entirely, but essentially it is the decision-making processes which caught our attention. First, could you identify yourselves?

(*Baroness Hayman*) I am Minister for State at MAFF, with responsibility for veterinary medicines.

(*Professor Aitken*) I am Chairman of the independent Veterinary Products Committee.

(*Mr Anderson*) I am Director of Policy at the Veterinary Medicines Directorate.

2. Thank you very much indeed. As you know, there has been a lot of research conducted into the impact of OP sheep dips especially on human health but even on the day of recall MAFF itself issued a press release saying, "any ill effects from prolonged low-level exposure to OPs remain unproven", and the same document said that the government's "regulatory committees advise against any general withdrawal of OPs from the market". The obvious question occurs why was the risk from OPs deemed so great when the recall was decided upon and why the did Veterinary Products Committee think this urgency was there in November 1999 but not in the previous July when it was issued. Was it a panic measure? Was it a proportionate action? That is the key opening question.

(*Baroness Hayman*) I will start and then Professor Aitken can talk about the decision-making within the committee. I think the theme, as you say, throughout many years of debate about the effects on human health of organophosphate has more and more concentrated on the effects of the concentrate itself. The IOM report which sparked off the response by my predecessor, Jeff Rooker, in July went to the VPC, the ACP and the Committee on Toxicity, for urgent consideration. The interim advice from the VPC then in July focused very much on container design of the concentrate for OP sheep dips and it was at that point that they first asked the manufacturers for plans to minimise the risk to operators from the concentrate. So the later finding from the COT report that the effects of long term exposure at low levels were still not certain, did not justify complete withdrawal of the product, and needed more research to see if there was a sub-group that was susceptible, did not detract in any way from the concern that has always been there about exposure to the concentrate and concern to improve container design which goes back to 1994 when the first work was done with the manufacturers about trying to improve container design for the concentrate.

3. So how was it being delivered? Talking hypothetically, if it had been delivered in bulk tankers in its dilute form, would you not have been so concerned? Was it the containers of concentrate which marked the difference between the concerns expressed in July and the decision taken in December?

(*Baroness Hayman*) I do not think there was a difference at all. I see this very much as part of the continuum. It was about container design—I am not sure whether large scale bulk containers of dilute have ever been suggested as the way.

4. I was seeking to crystallise the nature of the concern.

(*Baroness Hayman*) It is much more about the valves, the prevention of accidental spillage, the possibility of delivering dip in containers. Water solubility, for example, has been one suggestion that has been put forward and work has been done on pesticides on container design. That was what was focused on in July. Plans were submitted by the companies in November as the VPC had asked them to do and those were plans for both interim and long term solutions to the risks of concentrate, so it very much was a continuum. But in looking at the advice of the Committee on Toxicity, which we had asked to bring together all the strands, the VPC were then, as I understand it, given the choice of whether they allowed product to remain on the market with the added concerns that have been expressed while containers were changed or whether, while containers were being changed, product should come off the market. That was the advice I then received unequivocally that products should come off the market, and I accepted that advice.

(*Professor Aitken*) If I may, the Minister has summed it up very succinctly and very correctly. There were two areas of concern which focused immediately in July when the meeting was rather hastily convened at short notice, one of which the Minister has identified: the risk of contamination from use of the concentrate and the disregard which operators had for the recommendations for the wearing of protective clothing, and these at the time identified the interim recommendation that there should be plans for containers which would not expose operators to the risk of contamination.

Mr Jack

5. For the record, could I ask if Mr Rooker or you yourself, Minister, have watched sheep dipping operations and the use of the existing containers and the proposed new ones?

(*Baroness Hayman*) I cannot answer for Mr Rooker; I have not seen sheep dipping in operation.

6. And you have seen both the new and the old ways of doing it?

(*Baroness Hayman*) I have not, I said.

[**Mr Jack** *Cont*]

7. You have not?

(*Baroness Hayman*) No.

8. Is there any reason on a practical matter like this that would stop you from going and looking at it to assess whether the advice actually worked in reality?

(*Baroness Hayman*) There is nothing that would stop me doing that and I would be happy to do that. Equally I would not take my own judgment from one or two visits in contradistinction to the advice of the committee of experts set up to advise ministers under the Medicines Act about appropriate action in these circumstances.

9. I understand the point that you make, but this is a practical matter and all the evidence we have had is from practical people involved in having to dip sheep and use these materials. We shall probe what they have to say later on but I would like to know, if you have not seen the operation yourself, whether you could find out for us whether Mr Rooker went to see this operation so that he too might have some practical insight into what was involved?

(*Baroness Hayman*) If you think it is the appropriate mechanism for me to act on behalf of the Committee to ask him, I am very happy to do so and will pass back as a postman that information.

Mr Mitchell

10. And do not omit to talk to the sheep while you are on the job! I am a bit mystified by this because there has been a groundswell of concern for quite sometime about OPs; the Countess of Mar, Booker—not Rooker—in *The Sunday Telegraph* and I myself have been concerned and have written from time to time and we always get the bland assurance that nothing is wrong. Are you now telling us concerning the press release regarding prolonged low level exposure to OPs that the ill-health effects remain unproven—so much for all those people who have been complaining about health effects—but that there is an effect on people who have splashed the concentrate all over themselves? Is that the distinction you are making?

(*Baroness Hayman*) I think the weight of scientific evidence is that there is no doubt that exposure to the concentrate can be dangerous to human health and have very bad effects on human health. I do not think there is dispute about that. The scientific dispute or the evidence that has been accruing over the years which has not come to a fixed point in terms of anybody's certainty is whether low levels of exposure to OPs over a period of time cause ill health or indeed—and this is one of the issues that was raised in the IOM report and the COT report in particular—whether there is a sub-group of the population particularly at risk from this. I do not think, however, that any of the bodies, whether it is the Health and Safety Commission, the VPC or any of the committees that have looked into this, have doubted that concentrate, if mis-used accidentally or deliberately, is a dangerous substance—and that makes sense really. We are dealing with a chemical designed to kill some living organisms and it would be unlikely to be something you would want to use carelessly or recklessly.

11. But you know from the research, and there have been cases in the paper, and the OP Information Network in Scotland have written to us and said, "We estimate that approximately 500 people in Scotland have had their health affected by such exposure". Are you saying that those effects come not from splashing around with the dilution, wrestling with the sheep in it, but from being splashed by or making contact with the concentrate? Have you made a distinction in the research?

(*Baroness Hayman*) I think the researchers find it easier to establish cause and effect of harm between the concentrate and exposure to it. The difficulty in assessing some of these registers of potential sufferers is that it is a mixture of people some of whom think that they have been exposed over long periods of time to small amounts who may, in fact, have been exposed to accidental spillage of concentrate: it is periods of time, these people have never been very well investigated in terms of their own symptoms and one of the pieces of research we are setting up in response as part of the four-point plan that I announced in December is actually to look at those sufferers and see whether we can learn from them. Now that is a piece of research that there has been a lot of criticism in the past has not been done - looking at the self-reported people who feel they have suffered that damage. We had a seminar on 28 March that I went to where scientists working in the field on the effects of OPs on human health came and debated. I cannot give you definitive answers because, if you listened to the breadth of scientific advice there, there are differences of view. This is a moving field.

12. But this is extraordinary. After all the groundswell of problems arising over a number of years, all that is ignored and then suddenly, wham bam, last year, we get this ban.

(*Baroness Hayman*) I do not think you could say it was wham bam, honestly.

13. Well, the industry was taken by surprise, none was prepared for it, this is alternative packaging, quite out of the blue?

(*Baroness Hayman*) Can we take that bit by bit and start in 1994 with the concern over packaging and container design that was discussed between the industry and the Veterinary Medicines Directorate and the action that was then taken to improve container design because in 1994 concern over spillage and the need to improve the design was first being discussed and acted on. So we are not talking out of the blue in 1999. Then we go to July 1999, when the IOM report was published focusing concern on container design. Jeff Rooker met the manufacturers then to talk through his concerns about container design: it could not have been a total shock to them because the Veterinary Products Committee looked at the issue and communicated with them in July and asked for, within three months, proposals for alternative container design and made clear that regulatory action would be taken if suitable alternatives were not found. So I do not think it is fair to suggest that it is out of the blue. We are talking about a transparent process, reported to Parliament that had been going on for some time and of which the industry was aware. As far as alternatives are concerned, I absolutely recognise—and Mr Jack will

[**Mr Mitchell** *Cont*]
be glad to know that I did at least talk to a lot of people who dip sheep—their concerns about the lack of what is considered to be a satisfactory alternative at the same price as OP sheep dip but there are a range of other products, whether they are SP dips, injectables or pour-ons, that are available for use, so we are not talking about an absolute gap of alternatives, although I would not under-estimate the fact that these are not considered satisfactory by many farmers and sheep farmers.

14. I am not complaining about the final action. I am pleased that a new government and new ministers have produced action in an area where a number of us have been ferreting around for years with no effect, and nothing has been done. What I want to know is why so suddenly? Let me ask how many suspected adverse reactions have occurred as a result of contamination while dispensing concentrated sheep dip from these containers? How many can you pin it down as?

(*Baroness Hayman*) Could I ask Mr Anderson to answer that?

(*Mr Anderson*) Under the suspected adverse reactions surveillance scheme which was set up in 1985, since then 751 reports of human reactions which the reporters attribute to contact with organophosphate sheep dips have been received by the Veterinary Medicines Directorate.

15. How many are from the concentrate, and how many from the dilution?

(*Mr Anderson*) It is very difficult to say. Part of the problem is that a lot of these reports are historical and to some extent they might have been triggered by expressions of concern about the safety of OPs. Certainly in terms of dates of reporting, the peak was in the period 1991/1993 when concerns were first raised, but in terms of the exposure to OPs, many of those reports are historical going back with a history of sheep dipping over many years, so it is quite difficult to disentangle, so many years after the event, just how many were definitely attributed to exposure to concentrate and how many were attributed to long term low level exposure.

16. But you will be aware that again, the OP information unit from Scotland tells us that the Committee on Toxicity working party report was highly critical of the lack of substantive data on OP patients submitted by the various adverse reaction schemes. Here you have a chorus of complaint, claims in the newspaper that people are having their health affected adversely, and we have not got an adequate adverse reaction scheme functioning. Then, suddenly, you pin the blame on the concentrate and that goes.

(*Professor Aitken*) May I just say in response to the line of questioning that Mr Anderson has pointed out the number of reports that have been received and has emphasised that many of these are historical; people casting their minds back over several years to try to recollect whether they were dipping with a particular product and very often they have forgotten the days they were doing it and over what period of time. It is just a factual record of a report being received that adds up to the 750. The number that can be ascribed sufficiently to ascribe a probable or possible cause is much smaller than that—I do not have the figures with me but I would suspect it is of the order of 20 per cent at the outside of that total and it is a subject which the appraisal panel of the suspect adverse reaction scheme, a subcommittee of the VPC, is looking at actively at the moment.

(*Baroness Hayman*) But I think the area of dispute, if I may say so, is around the issue about low level exposure. I do not think there is an issue of dispute amongst doctors or amongst scientists that the concentrate can cause immediate obvious and attributable harm. The dispute is over the longer term and that is why I have taken forward the work on the investigation of the patients who are self-reported, on the networks, to see if, in these much more intangible, more difficult to pin down cases, we can get better information. But that does not detract from what I think is commonly agreed ground which is the potential danger from exposure to the concentrate and therefore, in my mind, the responsibility on government to ensure that we minimise risk if that product is, we are told, to remain available.

17. Does that not bring up the question of whether the Veterinary Products Committee, which seems to rely largely or even solely on information from the product manufacturers when it is assessing a product, should be responsible in licensing the product for assessing the health implications as well on a continuing basis, which does not seem to have been adequately done in this instance?

(*Professor Aitken*) The Veterinary Products Committee does, in the process of authorising any application that comes before it, go through a very rigorous exercise of judging its quality, safety and efficacy and it takes into account in that process the issues concerning possible harm to human health.

18. But on information supplied by the manufacturers of the product primarily?

(*Professor Aitken*) That constitutes a considerable part of the information presented but it has available to it a much wider range of information deriving not only from the knowledge of its individual members and, therefore, through its corporate expression, but also by access to other reports dealing with the chemical concerns that might be related to that particular incident. I would have to say that much of the questioning that is addressed to applications that come before both the Veterinary Medicines Directorate assessors and to the VPC is based upon testing information that is not presented within the documents that we are provided with. So I would not accept your comment that it is exclusively concerned with information derived from the manufacturers.

19. Not exclusively but it still has the responsibility for assessing the health consequences which is an on-going process, which does not seem to have been adequately done in this particular instance.

(*Professor Aitken*) Absolutely.

Mr Drew

20. We are talking about the process of the decision but I think this is very pertinent and I think Austin's line of question is very important. I would like to follow up with this. We are talking here about the cautionary principle, not the precautionary

[**Mr Drew** *Cont*]
principle because the problem has already happened. I just wonder how much you have dwelt upon, for those people who have been medically diagnosed or possibly will be, how much impact that will have in terms of trying to bring forward the explanations and obviously, in due course, possible litigation.

(*Professor Aitken*) It is difficult to be definitive about the actual causes of the illnesses which have been reported through the reporting system because, as I have indicated previously, there very often is only limited information and very often unsupported by any medical history or diagnosis, so I think it is difficult. The appraisal panel's function is not to ascribe causality to individual cases but to try to identify trends in the emergence of adverse report incidents that are drawn to it. Those adverse reports come in two ways: one is mandatory requirements upon the manufacturing company to report to the Veterinary Medicines Directorate as the regulatory body anything that becomes known to them about adverse reactions from the use of their products—and that includes human adverse reactions as well as animal—and the other is a form of reporting which is totally voluntary by individual people or by their veterinary surgeons, again to the Veterinary Medicines Directorate. As I have said, many of these reports are of limited content and do not give sufficient information to enable backtrack to be made to determine with certainty whether there is a causal link and it is not part of the purpose of the SARSS (Suspected Adverse Reaction Surveillance Scheme) team to ascribe individual causality but individual trends. There is an Appraisal Panel which deals specifically with these relating to human adverse reactions as opposed to animal adverse reactions.

21. But in terms of people who may not have been diagnosed but who suspect they are suffering from OP poisoning this will justify their stance; clearly I imagine they are talking to people at this time, the OP networks which have already been referred to, and they will be taking advice. How will you respond if and when people do come to you and say, "You have taken the decision, I suffer now because of what happened in the past"? How will you cope with that and will you deal with that evidence, because that will impact upon the individuals?

(*Baroness Hayman*) The licensing authority will have to answer for its judgments about the licensing of product and the licensing authority is ministers. We have to take account of the advice of the VPC under the Medicines Act but responsibility is with us and judgments will be made, if you talk about potential litigation, as I think you were suggesting, about the appropriateness of the judgments made on the evidence that was available. I have tried to give the committee some sense of the growing scientific work that has been done in this field and the reaction through the regulatory process to that. Mr Mitchell was talking about whether the committee only looked at what came in from manufacturers. Of course, this particular piece of regulatory action is taken very clearly on the result not of something that came from manufacturers but first the Institute of Occupational Medicine report published in July that ministers then asked the VPC for advice on, and that led to asking for the manufacturers to submit new designs, and then the Committee on Toxicity report that was published at the end of November, and again we asked all the advisory committees—

Mr Mitchell

22. But your argument is particularly dangerous here in that there is a recommendation from Lord Zuckerman in 1951 and from the Health and Safety Executive in 1980 that workers exposed to OPs on a regular basis should have their blood cholinesterase levels measured pre and post exposure. Now that recommendation was never enforced. Why?

(*Baroness Hayman*) That is asking me to answer far further back than Mr Rooker.

23. Yes, but you are saying the committee was doing its job and then other concerns arose and you took action but here was a concern expressed before that and which should have been on-going.

(*Baroness Hayman*) The VPC was not in existence—am I right or wrong?

(*Mr Anderson*) Certainly not in 1951.

24. But it was aware of these recommendations and it did not take any steps to say, "If we are going to license this and it is going to be used, these precautionary steps should be taken".

(*Professor Aitken*) I think you should take into account all the recommendations that were drawn to the users' attention on the means to use dips safely. It has always been the Veterinary Products recommendation that these particular products should be used with care and caution and very clear guidelines have been given what that means in practice, both through the design of the dip and the engineering controls that are involved when sheep are put through dips and also the particular type of protective clothing that individuals should wear to protect themselves from the hazards of exposure, and exposure in real terms is contact with the skin. That is the main route, and it is the concentrate which is the principal culpable agent. So there are requirements dating back a long time—I cannot give you specifics but they are very clearly there—as guidance to users as to how they can minimise or avoid contact with the dip, whether it be in concentrate or dilute form.

Mr Mitchell: It is right to make those warnings but, human nature being what it is, there will be mistakes and it says here in this HSE recommendation of 1980 that there should be regular blood checks on those exposed to it.

Chairman: Can I remind members of the Committee that we are basically dealing with the process over the last few months. I realise it is relevant but at the same time what is particularly relevant is the decision-making process and I am anxious to remain on track. I am going to be tolerant but not permissive.

Mr Mitchell: There should be an answer to the question—

Chairman: We will do a wind-up and perhaps you can have one then.

Mr Jack

25. Chairman, I hope my line of questioning will not deviate too much from your most recent stricture. Following on from the comments that were made earlier and bearing in mind we are not dealing with a brand new risk, as we have just heard outlined, in paragraph 3.1 of the Ministry's own evidence you comment on the Institute of Occupational Medicines' report which we have just heard mention of, published in July where, it "identified the handling of concentrated OP dip as the main source of potential exposure". Now that is rather soggy language. They had three years to study this and it is this evidence which triggers the events which we are exploring and it says "potential exposure". Could you tell me a little bit more about what the "potential" means? Can we put any kind of risk factors, numerically on this? What made the bells ring when you read this word "potential" after three years of intense study?

(*Professor Aitken*) I cannot do other than reiterate what I have said previously—that the potential for harm is there but the way of avoiding that risk is to wear proper protective clothing and to exercise care in the handling of the product. It is when that care breaks down that the potential can be expressed as reality.

26. Yet in paragraph 3.3 of the same evidence, referring to the Committee of Toxicity's report published in November, according to MAFF, that "concluded that the balance of evidence did not support the hypothesis that prolonged or repeated low-level exposure to OPs caused peripheral neuropathy or clinically significant neuropsychological effects. It indicated that, if such effects did occur, they must be relatively uncommon. There remained a question, however, over whether there might be a small group of individuals particularly susceptible to OPs". Now the language there suggests a lot of unknowns. "There remained a question"—this is after all this work has been done—"however, over whether"—we are not quite certain—"might"—still not certain—"be a small group"—unspecified—"particularly susceptible to OPs". We have known that since the 1950s and yet, on the basis of this rather soggily worded finding, we now find actions which have affected the practical availability of this product. Are you content that this is robust science?

(*Baroness Hayman*) If I can speak practically, I do not think that that was the basis for taking regulatory action against the concentrate and trying to minimise the risk of exposure to concentrate. That was the basis for having more research to find out whether even low levels of exposure, even according to all the advice and using substance safely, according to HSE accounts, could still cause harm. That is the nub of the debate about whether, in any form, OPs should be allowed to be used as veterinary medicines. What we are talking about is something much more practical: how we minimise the exposure and the risk of someone having concentrate coming on to their skin when they are undertaking that which you rightly point out to me a difficult task of sheep dipping. I do not think you can base on 3.3 the regulatory action that we took about in terms of the concentrate.

27. I am glad you clarify that. It is difficult to map my way through because in justification it says "Research and Committees' advice" in paragraph 3 of your own evidence.

(*Baroness Hayman*) But that is the research that suggested to the VPC that they should not recommend to the regulatory authorities that they refuse to license OP sheep dips. That is not what we have had recommended to us and that is not the regulatory action—

28. And yet the practical implications of the action you have taken appears to have minimised the ability of sheep farmers to get the preparation in time for sheep dipping?

(*Baroness Hayman*) Well, certainly this year there is a problem on availability of OP sheep dips and I would not suggest otherwise. I think the question that I had to wrestle with was whether the risk was such to justify the potential taking off the market of a product that many farmers wanted to have available to them and whether the action that was taken was proportionate to the risk. In doing that, I take very much the advice, as I have a responsibility to do, of the Veterinary Products Committee, which does have amongst its membership people who are far more experienced than me in these areas.

29. Finally, is there any way you can quantify these risks for us, because the language here in scientific terms is soggy, as a layman, and I have not had the benefit of reading all the full report so all the points I am asking about may have been comprehensively dealt with, but can the experts give me some kind of risk analysis in numbers I might understand as to what happens in the light of your recommendations or what does not happen?

(*Baroness Hayman*) If that could have been it probably would have been done in 1951 after Lord Zuckerman and we would not have been having these arguments for the last 50 years!

30. We have had four or five years' work on the job so we should be nearer getting some of these answers, should we not?

(*Baroness Hayman*) I think we are and it is because we have been honing down on issues like exposure to concentrate and engineering solutions to make sure people are not exposed to concentrate that we have got to the point where we have—but I am not the expert.

(*Professor Aitken*) I will just add to what the Minister has said. The remit of the Veterinary Products Committee is to evaluate matters of product safety and efficacy of products that go on to the open market. Were the current OP concentrate forms to come as a totally novel presentation to the committee, they would not pass because the containers in which the concentrate is supplied does not meet the best standards that are required at the present day and we know from all the medical evidence and all the scientific evidence that the risk factor lies in the concentrate—not in the dilution—and, therefore, it is necessary to take steps which justifiably would require the manufacturers to produce the product in a form which is as safe as it can be, and that is what we have asked for. Not to revoke the authorisation of OPs for ever but simply

[**Mr Jack** *Cont*]
until there is an improvement in the design of the containers of concentrate that satisfies the need to minimise the risk to the user.

Mr Paterson

31. Could I begin by stating that I am a member of the Council of British Leather Confederation and Vice President of the European Confederation of Tanners and Leather Dressers.

(*Baroness Hayman*) You have interests in this area, as I know.

32. I have interests but I am not paid—which is sad. I would like to pick up on Mr Mitchell's earlier line of questioning and just ask in simple terms that for some years this scandal has been brewing and now action has been taken. Can you give the committee three reasons to show that, first of all, the relevant authorities would pick up on such a case quicker in future and that human health would not be damaged in the way it has been? What have you actually changed?

(*Baroness Hayman*) Three reasons to suggest that—

33. —you would pick up on the problems quicker and to reassure us and the public. We have a submission here that 500 people have been affected, for instance?

(*Baroness Hayman*) The Royal College of Physicians' report on OPs I think was a major factor in ensuring that general practitioners, in particular in areas that were not perhaps those where sheep farming was concentrated and therefore issues about exposures to OPs were best known, were spreading the awareness and the Department of Health has taken action since then, and Mr Anderson will remind me about setting up some reference centres that GPs who are concerned about patients can go to and publicising those.

(*Mr Anderson*) Through the national poisons information centres to which GPs are directed for further information on the symptoms of OP poisoning.

(*Baroness Hayman*) Secondly, the piece of research we are funding is just about to start on the patients who have self-reported as having effects from OPs because that will be very important again in seeing whether there is a pattern of symptoms or exposure which then we can pick up on through advice, through farming unions, through people who use or come into contact with the product afterwards so that we have a set of potential symptoms or effects that ought to be sending warning bells to people. I suppose, thirdly, I would mention the action that we took in December, the four-point plan we put forward on the advice of the Committee on Toxicity, the whole work that has been done over time including the Institute of Occupational medicine, and the government's work to bring together the official group which published its report in 1998 on OPs, the increased advice available. We sent out, for example, to every registered sheep owner in the country a booklet of advice that was brought up jointly between the HSE and the Veterinary Medicines Directorate so people are alerted both to the potential risks and what can be done to avoid the risks but equally to know that they ought to pick up on things afterwards.

Dr Turner

34. Professor Aitken, you said that the containers in use would not be allowed nowadays but it is often the nature of science and progress that new build is often built to higher standards than old and in recalling old or insisting that all buildings are brought up to today's standards we have to balance risk against cost and disruption. I would like to ask some questions about the scale of risk that you saw in not taking fairly dramatic action. I could not find in the report from the ministry words which summarised that for me so I wondered if I could ask for a summary of what you saw the risk was in allowing the concentrate to be used in its present containers?

(*Professor Aitken*) Yes, I will try to do that for you. I will start by reminding you of the some of the points that the Minister has made. This was not a sudden decision but one progressing over a number of years with recommendations to the manufacturers to improve container design, going back to about 1993/94. They have progressed and improved the designs of their containers—some individual manufacturers more enthusiastically than others—

35. Can I interrupt you there. Were you happy with those modifications at that time, in 1994/95?

(*Professor Aitken*) At the time they were progressing they were meeting the requirements that were there then. There were better things that could have been done but at that time there was no urgent reason to get them to move further forward. However, there has been a recommendation on the part of the committee going back to about 1997 that technology has now progressed to the point where those totally closed systems for dispensing concentrates should be attainable. One alternative is the use of water soluble sachets. These systems have been adopted by chemical laboratories and have quite considerably reduced the hazard of contamination by chemical workers because of these systems. The comment that we made in July reinforced that message and the report which accompanied the press release and which was made publicly available, without prescribing what manufacturers should do, certainly mentioned both the opportunities for closed systems and water soluble sachets. What brought matters more closely to our attention was the Institute of Occupational Medicine's report which demonstrated clearly and unequivocally that the existing containers were a source of potential contamination, potential because if people were not taking the right precautions potential could become real, that the use of containers designed then were short of standards that ought to be expected. In looking at any form of critical path analysis for hazard, that very clearly was signalled and there was a requirement, therefore, on manufacturers to bring forward plans to improve.

[Dr Turner *Cont*]

36. But you have not told me what the words were that made you think the risk to human health was suddenly seen as large. Is there any word you can quote from a report? I could not find any in the summary.

(*Professor Aitken*) It is a well-established fact that exposure to concentrates is the greatest hazard to human health.

Mr Jack

37. If a dipper of sheep is properly dressed in the approved special clothing—gloves, boots, everything else—what is the risk then?

(*Professor Aitken*) It is reduced if the correct clothing is worn all the time and is not clothing which has deteriorated.

38. Reduced to what level?

(*Professor Aitken*) It is extremely difficult to quantify because one cannot be absolute but it is very substantially reduced. I think that is the best I can offer you.

Dr Turner

39. I was interested in the word you used that you were advised to withdraw it from the market and one of the distinctions being made here is in fact the order to withdraw it from use which is a very different thing from withdrawing it from sale. Was that distinction discussed and were alternatives discussed, such as has been suggested might have been available, including, for example, limiting it to trained people or people who have received some extra warning. Were those alternatives actually discussed and was the distinction between market and farm made?

(*Mr Anderson*) On the technical issue, when marketing authorisations are suspended, what is forbidden is both placing on the market and administration of the product. Because, of course, we were taking urgent action of this sort, we took legal advice and it was established that our interpretation was correct; that, in suspending a marketing authorisation, it became illegal both to sell and to administer the product and, because of issues raised with us by the industry, we took that concern to the European Commission, because the action that we were taking was under UK law implementing community directives and we received confirmation from the officials within the Commission that, because the action was taken on safety concerns, we were correct in suspending the marketing authorisations to require withdrawal not just from the supply chain but from the end users.

40. Did you consider any alternatives?

(*Baroness Hayman*) Yes. As I understand my responsibilities as part of the licensing authority, which is a collection of ministers, the responsibility is to take account of the advice of the VPC but equally the responsibility is with ministers and one does not have to accept that advice. The advice I received was unequivocal. The VPC stated, "We consider that the hazard of exposure to concentrated dip is sufficient to warrant recall of its existing containers". Together with colleagues I had to consider whether to take that advice: whether to do something less onerous—and one of those possibilities would have been to allow product to remain in use or on the market while parallel activity was going on to improve container design. Equally I could have done something more draconian, not accepted the advice that OP sheep dip should be available in any way and have permanently revoked licences. Together with colleagues, a range of options were considered and obviously there were all sorts of factors ranging from whether one should take an extreme precautionary approach, given 50 years of concern about the danger of OPs, or whether one should take a more pragmatic approach given the concerns that would obviously be amongst the farming community and those concerned with animal welfare, if OP sheep dips were not available. In the end, my decision which was taken together with other ministers responsible for regulatory action in this area, was to follow very closely the advice of the VPC.

Chairman: We are going to focus a little bit now on that decision.

Mr Mitchell

41. You did not ask for a second opinion at all?

(*Baroness Hayman*) I am not sure I would settle for second opinions from other ministers!

42. But you did not consult with the Committee or any other body to give you an opinion on the issue?

(*Baroness Hayman*) We received advice from the three regulatory committees that Jeff Rooker announced in July we would ask for advice from on the COT report and that was the Advisory Committee on Pesticides because there is pesticide use of OPs, the Committee on Safety of Medicines because there are human health applications of OPs, for example, for head lice, and the Veterinary Products Committee but I certainly did not go to anyone else to second-guess the statutory adviser, and I do not think that would have been appropriate.

43. Were other alternatives considered like detailed labelling on the concentrates?

(*Baroness Hayman*) The labelling issue is one that is on-going—I do not think it was considered as an alternative—and the compulsory certification issue was one I received advice on from the Health and Safety Commission but it was not seen as an alternative to container design improvements.

44. And there is no air of panic about this decision-making process?

(*Baroness Hayman*) No.

45. It is not the culmination of a long period of doubt which suddenly makes you decide, "Wham, bang we must do something about it"?

(*Baroness Hayman*) Unfortunately there is not a lot of "wham bang" in this; there is a lot of detailed accumulation of evidence. But when I came to this job in July it was set out for me very clearly that the IOM report had then been received, the government had undertaken to ask the Committee on Toxicity to review it and review policy on OPs, we would then consult the regulatory committees and as a group of ministers we would then have to take a government review before the end of the year and that was made clear, so there was no sense of panic, as far as I was concerned. It was a process which was laid out and

[**Mr Mitchell** *Cont*]
I was involved with. I am not saying it was an easy decision because there are not such clear-cut areas to allow you to say simply, "I know I am right and no one could possibly dispute it". Whether one was right or not has been disputed from both sides of the argument if I can put it that way.

46. I see that from the evidence we have. I say an air of panic because the Environment Agency seems not to have been consulted. Should it have been consulted under normal procedures?
(*Baroness Hayman*) Not as a regulatory progress. The environment agency through DETR were involved.

47. The Environment Agency says, "Given our statutory responsibilities to protect the environment, it is imperative we are fully consulted in future." That would indicate a bit of sulking to me.
(*Mr Anderson*) If I can help, the Environment Agency does, where appropriate, act as adviser to the VPC, as officials, but that is done through the Department of Environment, Transport and the Regions and their officials were in attendance throughout the process of the VPC's deliberations.

48. One final question on the VPC, it seems unrepentant after all this time on the OP issue. You said you were not going on revoke it for ever. That means that, as soon as new containers come out, you would continue as before, does it?
(*Professor Aitken*) If containers of a satisfactory design are brought forward, and we still have to get that information which I hope will happen in the course of the next ten months, then there is no scientific justification for not having them back on the market place provided they are used with all the safety measures that have been identified and are strongly recommended to users.

Chairman

49. What is the time for the approval of a new container?
(*Professor Aitken*) That is not something you can identify with any certainty. We still have not seen the new proposals but it depends upon the actual substance of the container and the methodology by which the concentrate will be delivered. The main concern would be to ensure that the product, in any new container, remains stable over the period for which it will be used. If there were something which was up and running and ready to go, then stability data should be generated within a matter of months but it would mean that the shelf-life of that product was limited to months. As time progresses, so stability data would generate additional information and extend the shelf life. At a practical level it would perhaps be over-optimistic to suggest that they might be back in the autumn of this year and more realistic to anticipate it will be about this time next year, but I cannot predict it because we have not seen the plans from the companies on the revisions.

Mr Drew

50. On the process of the implementation of the decision, could you take me initially through the lead up to 21 December when the decision was actually announced and who was consulted and how they were consulted?
(*Baroness Hayman*) You have to start the process with the announcement in July of the interim advice from the Veterinary Products Committee on the IOM report and manufacturers being told that they should submit plans to improve container design within three months. Those proposals went forward in November. At the same time it would have been made clear that the Committee on Toxicity report would be sent to the government's statutory advisers when it was received. It was received in November: it was made public, and the chairman of that committee gave a press conference quite clearly stating what their conclusions were. Then the process of receiving advice from the Veterinary Products Committee and the Advisory Committee on Pesticides and the Committee on Safety of Medicines took place over the next two or three weeks: it depended when their meetings were which ones came in when. When we had those pieces of advice all together I consulted with other ministers; we met on I think two occasions and there was a fair amount of correspondence. There was also advice from the Health and Safety Commission. This was, however, regulatory action: I was being advised and we were being advised about regulatory action. It was not, therefore, an appropriate situation in which to start consulting with people as to the way forward. Having received the advice, ministers had to decide what to do about that advice and take it forward. I was conscious that a lot of people wanted to know what the response would be: that we had received everything we said we needed to receive and that ministers had reached conclusions about what should be done which was the four-point action plan and I announced that as soon as possible, which I wanted to do while Parliament was still sitting—obviously—and it was announced on 20 December.

51. How many meetings took place at that period of time with representatives of the industry?
(*Baroness Hayman*) None with me.
(*Mr Anderson*) No meetings took place between the industry and ministers or the Veterinary Products Committee after the meeting which Mr Rooker had with the industry on 7 July. However, in developing their plans, manufacturers were allowed the facility of coming to see officials of the Veterinary Medicines Directorate in particular to establish what data they might have to produce to demonstrate the continued stability of their products in any new planned containers. There were two meetings which took place about August and following that, of course, the plans were submitted and went to the Veterinary Products Committee but those were purely technical meetings to assist the manufacturers in planning what data they might need to produce to support plans for new containers.

52. So you are asking the industry to come up with new containers and yet, effectively—it depends how you define a technical meeting but effectively—because this is the accusation, as you know, of the

[**Mr Drew** *Cont*]
industry—the 21 December decision was a shock: they did not know it was coming. I see you smiling. I think it is important that we know and we tease out what was expected of the industry in that period up until the revocation and, if it was not happening, what messages were going backwards so we can get some certainty that the right process was being pursued.

(*Baroness Hayman*) The meetings that took place in the interim were based on the fact that the manufacturers knew from July that we had asked for plans to improve container design, and I think appropriately we were working with the manufacturers through the Veterinary Medicines Directorate to help them come up with appropriate solutions. Equally it was absolutely explicit that the Committee on Toxicity was considering this subject: that ministers were committed to acting on the recommendations that we got from our statutory advisers, including the Veterinary Products Committee on that report and, as I said, that report was made public in November. I honestly do not believe that we can be accused of not informing the manufacturers of what was going on but the withdrawal of a marketing authorisation, even temporarily, is a formal regulatory action and it would not be appropriate for ministers to announce that or to try and negotiate that with the manufacturers affected in advance. After the decision, which we took on the advice of the committee, I certainly did respond to a request from manufacturers to meet them, together with representatives of farming and other interests, and there have been on-going meetings since then. The point was put to me clearly at that meeting that they were concerned that the working group of the Veterinary Products Committee did not perhaps appreciate the effects on animal welfare and I arranged for a meeting between the subcommittee and those groups so there has been plenty of contact since then. On the point of pre-warning what the regulatory decision would be, no, there was no pre-warning of that and I think that was correct.

53. Were you expecting the industry to work to a timescale? Obviously the industry were not working to that timescale because, unless somebody has got this completely wrong, the industry are shocked on 21 December. They just do not see this coming.

(*Baroness Hayman*) Well, they were working to a timescale and they met it in terms of submitting plans in November.

54. They did that but obviously the timescale was insufficient for them to get this right?

(*Baroness Hayman*) Well, they were working to submit plans by the middle of November and they did that so they knew what that timeframe was; they knew very well that ministers had committed to making decisions on the basis of the COT report and the advice on that before the end of the year and there were six weeks between that and that so there is not a lot of doubt about the timeframe.

(*Professor Aitken*) When the industry representatives presented their plans for new containers in November, at least two of the plans—both for the shorter and the longer term—were very promising and very likely to progress to satisfactory outcomes. The others had defects and deficiencies which I am sure have now been relayed or were relayed in November to the companies. Because of other events, those promising lines of development have not been able to progress. Had they been, then I suspect or believe that there might well have been OP dips available from this summer but other circumstances dictated that that could not happen.

(*Baroness Hayman*) And those are circumstances unrelated to regulatory action.

55. Can you take me through December 21 when the announcement was made? How was it made? Who was informed? Without going into the practicalities of removing the materials, were how were people supposed to know, down to the level of the farm that OPs, were being revoked?

Chairman

56. For example, advice to regional service centres?

(*Baroness Hayman*) Shall I start with the Parliamentary? It was announced in terms of a Parliamentary answer in both Houses. There was equally a press release that went out and I think that it went on to the MAFF website immediately which then takes you into the regional service centres, and individual manufacturers were informed on the same day and informed of responsibilities in terms of withdrawal on the farm. Equally, obviously, the farming press immediately covered the issue—I seem to recall doing an interview for *Farming Today*—so there was coverage of it. Again I would not pretend to the Committee that doing this in the week before Christmas would have been the time I would have chosen to do it if I had had complete control over the timetable, but there were certain decisions to be made about when Parliament was sitting, the fact that we had the advice available and that decisions had been reached that I felt it inappropriate, having been advised to take regulatory action to protect human health, to delay so doing.

57. Did you send a note to the Regional Service Centres, saying, "This is how you answer farmers' queries if they question you", "These are the sort of answers to give"? On the 21st, I guess the Regional Service Centres were probably lightly manned over the holiday period, as most offices would be, so if farmers did ring up and say, "When would be the earliest, say, that we can use them again", and those sorts of practical questions, how available was that sort of advice, do you think, for people just seeking to know, "What does it mean for us"?

(*Baroness Hayman*) Well, I suspect that the factors you have identified meant that over the Christmas period that was not easily available and we can possibly learn from that and make sure that regional service centres are more specifically informed on such issues.

Mr Jack

58. Just following that line of questioning, in the evidence to the Committee the National Office of Animal Health Limited referred to a fax of the 24th December which they sent to you which said that no company heard the VPC's judgment until the 20th

[**Mr Jack** *Cont*]
December. What did you reply to that fax? How did you rebut this allegation that nobody really knew what was happening until the 20th December?

(*Baroness Hayman*) Well, that was absolutely true. Nobody knew. Parliament did not know what the regulatory action was until the 20th December.

59. I am quoting from NOAH's evidence to this Committee: "As explained in my fax of the 24th December, no company heard the VPC's judgment until the 20th December", and I can only quote what they tell us.

(*Baroness Hayman*) That is absolutely true, and, as I say, nor did you as a parliamentarian hear until the 20th December. They heard on the same day as Parliament.

60. Sorry, but I got the impression that people were slightly in the know from earlier exchanges. Are you saying that nobody had got a clue?

(*Baroness Hayman*) I am saying that there is a difference between knowing what regulatory action the licensing authority took on the advice of the VPC that was received a matter of days before the 20th December, and knowing that the VPC were asking for improved container design and that announcements would be made by the end of the year, which had been explicit, on the record and known since the 15th July. Does that help?

61. We are talking about practicalities and timing here. I just want to wind the clock back before I get into some detailed requests for your comments about how the industry, which is farmers, saw this. Mr Paul Tyler, a Member of Parliament with a long record of campaigning on this particular area, put out a press release dated 8th February of this year, 2000, pointing out that in his judgment the case about timing and not knowing what was happening and the need to take action in this area was something of long standing and he pointed out in his press release that people were warned by the Veterinary Medicines Directorate in 1994/95 to improve the safety of their OP containers. Now, I think there has been a flavour of that through some of the things we have heard. I would like to know whether Ministers, upon taking office after the last election, in MAFF were briefed on this particular subject and, if they were briefed on it, what action did they take because the impression I get is that all of a sudden we move with lightning speed with practical difficulties to address a possible problem which, as Mr Tyler points out to us, has been around for a long time, so were Ministers advised of this in 1997?

(*Baroness Hayman*) Well, I was not a MAFF Minister in 1997.

62. But you are answering on behalf of the Department.

(*Baroness Hayman*) In order to make sure that my answers are absolutely accurate, although I never had any impression that Jeff Rooker was badly briefed on this issue, I think he was extremely well briefed on it, but if the Committee does not mind, I would rather that Mr Anderson, who I think was there at the time, could say what briefing was given in 1997.

(*Mr Anderson*) On taking office, the Minister and his associates were briefed on all the safety issues which concerned OPs, both that there had been doubts about container design in the past, that a certain degree of improvements had been made, but that to go further at that point in time was not a live issue. It became a live issue again on the basis of findings by the Institute of Occupational Medicine which reported on the 30th June 1999.

63. Can you refresh my memory—when did they start their work?

(*Mr Anderson*) They started their work three and a half years before that.

(*Baroness Hayman*) I think it was Mr Gummer who first asked the VPC to look at issues relating to OP sheep dip in 1993.

64. Let's have a look at some of the practical commentary which has come from the industry about this because, as colleagues have pointed out, people were taken by surprise by this. The Tenant Farmers' Association, in their evidence, say, "In the immediate aftermath of the announcement there was much confusion within the industry over what was expected and what was planned. There appeared to be no coherent thinking on a plan for withdrawal of product now declared illegal". In their evidence to us, the National Farmers' Union say, "On a practical level, the announcement just before Christmas and the Millennium break left very little time for stocks to be recalled, and a great deal of confusion as to who was responsible for what", and it goes on and says, "This is not a criticism of either the manufacturers or the suppliers, but an instruction to call in organophosphate dips from farms within a period of 20 working days gives an impression of a panic measure, something we would all want to avoid in this context". Likewise, the National Office of Animal Health again expressed concern and surprise which I read to you before. Therefore, on the basis of this, it seems that all of a sudden you decide at the most impractical time in the year, ahead of the millennium, to make an announcement of practical implication, but with absolutely no guidance, no plans, no nothing, no consideration, according to what the trade tell us, as to how this was all going to work. Why did you do it this way?

(*Baroness Hayman*) I think that is a caricature of what happened.

65. It is a summary of the comments which have been put before this Committee. These are the people who are having to deal in practical terms with this announcement, and we will come on to the implications of this for sheep-dipping in a moment because I have some compelling quotes from the National Sheep Association to which I would like you to respond.

(*Baroness Hayman*) This was not a panic measure. This was a matter of trying to implement the advice that had been received and the decision which had been taken as to appropriate action effectively. I have already said that if I had had complete freedom of action in this area, I would have preferred not to be doing this the week before Christmas, but, compared with the alternatives of delay until afterwards and the timetable of getting in the advice from the advisory committees and getting ministerial agreement and informing Parliament, I decided that this was the best in the circumstances to do. There was a period until the 31st January given for the withdrawal, so it was

[**Mr Jack** *Cont*]
not a matter of people having to do things over Christmas. In these circumstances, the responsibility for withdrawal lies with the licence holder whose licence is temporarily being suspended. That is the legal position. The manufacturers, therefore, had a responsibility through the chain to ensure successful withdrawal and that is, as I understand it, common practice on product recall on issues of safety across a variety of sectors.

66. How many farms had OP dips, in your judgment, at the time of the announcement?
(*Baroness Hayman*) I am not sure that I ever saw an estimate.

67. So you have no idea of the totality of the universe of the distribution that this recall exercise was going to have to affect?
(*Baroness Hayman*) No, but recall exercises have been conducted in the past and there is some experience about this.

68. When was this?
(*Baroness Hayman*) Mr Anderson, can you give me some examples? I know we had one for companion animals when we had to take off some medicines for dogs some time ago.
(*Mr Anderson*) A recent example was a product called "Droplix" where certain batches of the product, not the whole product itself, but in the manufacturing process something went wrong with certain batches and recall was effected by the marketing authorisation holder from veterinary practices and from pet owners.

69. But, in planning this, did you have any consultation quietly with industry, farming representatives, even your own MAFF officers who know the intimate details of running farms about whether all of this was going to be able to be done within a period where effectively Britain closed down for two weeks?
(*Baroness Hayman*) I think at the end of the day it was effectively done within that period. Certainly I was advised that it could be effectively done. I took that advice, the manufacturers in the end behaved absolutely appropriately and the withdrawal was completed.

70. So you can say now without peradventure that all of the material, either opened or not opened, was collected within the timetable that you set?
(*Baroness Hayman*) From the evidence that we have received which includes on-farm visits, from regional service centres, the veterinary service, we believe that all product was successfully withdrawn.

71. How much was the cost of this exercise?
(*Baroness Hayman*) You will have to ask the manufacturers that because they had to take the cost of it as the licence holder.

Mr Drew

72. Michael Jack has just referred to the TFA who said that the problem was not so much getting advice, but getting consistent advice. I wonder, with the benefit of hindsight, would you now have called the representatives of the regional offices in so that they knew exactly what the message was and, likewise, the industry? There must have been a lot of farmers out there thinking, "My God, what's going on here? I've got to ring someone and find out what they expect me to do".
(*Baroness Hayman*) Absolutely and I would not suggest that one can ever learn from doing these things and that there are not ways in which you can improve. I shall certainly take any lessons about improvement, and I have suggested that to the Chairman already, in terms of communication systems and we can always do things better and try to do things better.

Mr Öpik

73. I mainly want to ask about packaging, but just one thought has come up from what you were saying before. Do you actually have a timetable for when you will know whether contact with dilute OP is dangerous or not? I recognise the difficulties from what you said before.
(*Baroness Hayman*) I do not have a firm timetable. I think we have moved further ahead from the seminar on the 28th March because that will help us in terms of setting out the research requirements across government to get further information that will hopefully provide a little more clarity, and I would not suggest absolute clarity given the history of this subject, but I think we are moving forward. The time-frame within which absolute clarity of scientific advice will be received is not certain. I think people were hopeful that the COT Committee would give more clarity than in the end it did, so I think one would be foolhardy to give a firm timetable.

74. I do see the difficulties, but I must say it strikes me as a very important piece of research.
(*Baroness Hayman*) Yes, absolutely and we are getting on with it.

75. Can I move on to talking about packaging since really OPs were effectively withdrawn because of the concerns about packaging. Now, we have been talking about timing and so forth. I understand that the Veterinary Products Committee advised the manufacturers that they had to find a way of packaging more safely the concentrate and gave them a three-month time-frame before they would start revoking the marketing authorisation. That is right, is it not?
(*Professor Aitken*) That is correct.

76. What guidance did the VPC actually give marketing authorisation holders on the improvements required or was that left open?
(*Professor Aitken*) It was left open. It was not the role of the Committee to be in any way prescriptive, but simply to identify that there was a need to improve container design to a point where it would minimise or avoid the risk of contamination by the operator, but in the report which we produced in July, within that report which was fairly brief, but, which was, nonetheless, publicly available, reference was made to examples of what might be done. Totally closed systems was one and water-soluble sachets was another. These were not meant to be prescriptive, but were floated as ideas because these were practicalities which are in operation already within a different industry, the chemical industry,

[**Mr Öpik** *Cont*]
and operate very successfully, so we were not prescriptive, but we pointed them in a direction which we thought they would find helpful.

77. Turning to the timing, the National Office of Animal Health told us that the EU guidelines require about twelve months' stability testing for new packaging and actually predicted that it could take up to 18 months for packaging to get approval. Now, was three months actually long enough to allow sheep dip containers to be redesigned in the context of that?

(*Professor Aitken*) Three months is a relatively brief period, but it was important that we did have some opportunity for the companies to come forward with their ideas about what they would do and, as I have indicated in earlier comments, one of the submissions we did receive had made very significant progress in the way to an interim solution and had already begun some stability testing which would have meant that dip might have been available in the early part of this season, which is, shall we say, from about May onwards.

78. That company was not allowed to carry on either. Why was that?

(*Professor Aitken*) Well, that is perhaps not easy for me to comment in that regard, but it was a commercial matter. I wonder if Mr Anderson might be able to say to what extent it is possible to comment on the circumstances which resulted in that concept not going further forward.

(*Mr Anderson*) I think the difficulty here is that if we explain the circumstances, we would be identifying the individual company, but it was for a purely commercial reason that a strategic decision was taken which has meant that the company in question does not have the facilities now to take forward the development of the planned containers.

79. It sounds intriguing.

(*Baroness Hayman*) I think what one is trying to give a flavour of is that this is nothing to do with regulatory action or turning down a plan which looked very promising, but it is about commercial decisions which have been taken outwith the regulatory framework. I am sure that the Committee would have received in earlier papers at some point the advice of the Veterinary Products Committee in July that was published which did give some advice about ways in which containers could conform to best design practice, which recognised that beyond the three months there would be issues of stability testing and which raised issues like water-soluble packaging, so again I do want to try and negate the impression that this was all out of the clear, blue sky and that these were issues that had never been discussed before in a time-frame which had never been discussed before.

80. What was wrong with some of the other manufacturers? Was it general problems or was it the challenge of making them secure?

(*Professor Aitken*) It was the latter and again I have to be very careful with what I say because I do not want to identify particular companies, but they produced ideas and designs which, whilst forward-looking, had still within them certain flaws which would not have removed the potential hazard to the user. In that I would mention, and perhaps you have not seen the letter, but the letter which the Committee received from the Chairman of the Health and Safety Commission in which he said that the Committee should be mindful of the conditions of use of sheep dip and a particular concentrate, and of course we were and always had been, and one has to recognise that sheep farmers, like everybody else, will do what they believe to be expedient if they are under pressure and it is important that that expediency should not result in their exposing themselves or members of their team to a hazard which could be dangerous to them.

81. I take it, incidentally, that splashing is one of the issues?

(*Professor Aitken*) Yes, and that was made clear in the IOM report, that the containers then in use and in use up until the decision was taken to recall were liable to result in splashing of concentrate on to the person handling the container.

Mr Jack

82. Are there any other agrochemicals which are used where splashing directly on to the skin can have an equivalent harmful effect to the one you have identified for OPs?

(*Professor Aitken*) I would imagine that pesticides, particularly OP pesticides, would fall into that category.

Mr Jack: But you have not decided to go down the route for pesticides?

Chairman

83. Please give a very crisp reply to that question; I do not want to get too diverted.

(*Mr Anderson*) At the same time that the Government received advice from the VPC, it received advice from the Advisory Committee on Pesticides which confirmed that all the OP products authorised as pesticides were in containers which minimised the risk of splashing. The small exception to that is a very small number of household products authorised by the Health and Safety Executive and those containers are currently also under review.

Mr Öpik

84. Do you have an idea of what warnings should be on the packaging?

(*Professor Aitken*) Yes. This issue of labelling and the content of the label has been under review for some time both to make sure that the appropriate warnings are there, clearly identified, given due prominence, but that the label information is in simple, easily-assimilated language, and we have taken advice from the Plain English Society. That has now all been done and Mr Anderson will correct me, but I think that the label is virtually ready to go out for final consultation.

(*Mr Anderson*) We have consulted industry on the content and design of the proposed new model labels. However, given the additional concern expressed in the IOM report, we are intending to have a final look to see whether the danger of handling concentrate

[**Mr Öpik** *Cont*]
should be further highlighted in the final label to go out and we will address that issue in the context of bringing OP sheep dips back on to the market.

85. I know rather rhetorically that people tend to read warnings after there is an accident.

(*Baroness Hayman*) I think that is an important point and it is the same point that applies to a bottle of bleach in your home, so it is important both to minimise the risk by having a container with a lid which is not easily knocked off and accidentally spilt as well as having advice about safe usage. Equally, bleach is available in different sorts of containers now and in a more restricted way than it was when I was a child, so things do move on and one finds ways of protecting people and that has to be a combination of information and design.

86. Clearly, Minister, you see this as an evolution to a form of long-term sustainable packaging. If or rather when we get there, can you actually guarantee that OPs will be allowed back on to the market?

(*Baroness Hayman*) At the moment my advice is that there is not sufficient scientific justification for withdrawing OPs from the market if they are packaged in a way that minimises risk and they have appropriate warnings and we have appropriate systems for training people to use them as safely as possible, and that combination of measures means that they are safe to be there and that is the combination of measures that meant that we did not take regulatory action on the pesticide front on OPs because the advice was that the issues on packaging, which are actually easier to address than pesticides and I think we should recognise that, had been addressed. Equally, I think I have made it clear that this is an evolving field, so if new evidence were to be compellingly presented that then gave the regulatory committees reasons for giving different advice to licensing authorities, I cannot prejudge that. At the moment we do not have that evidence and the clear advice is not for total withdrawal, so were the VPC to be satisfied about container design, yes, this product would be back on the market.

87. So if by some miracle the packaging turned up tomorrow and passed all the tests, then yes—

(*Baroness Hayman*) And it is not just a miracle; it might be that there is a combination of an interim solution and a long-term solution and it might be that an interim solution could be provided more quickly because it did not need such long stability trials as a long-term solution, so this is not totally gloomy from the point of view of people who are interested in getting the product back on to the market, and this is not an un-doable thing, but it is possible to solve these issues.

88. Lastly, I think I know the answer to the question, but have you considered doing any health analysis of people who come into contact with sheep dip probably at a dilute level, vets, slaughterhouse staff, people like that? I recognise that that probably might be a difficult piece of research, but is that something you would consider doing?

(*Baroness Hayman*) Well, I think that we are asking for proposals for research across the board and obviously we will have to prioritise what the most important research is, and the further away you get from usage, I suspect the more difficult it will be to get a piece of research that actually delivers for you. I am most anxious that we get on with the analysis of the case history of the people who believe themselves to have been harmed and to look at genetic susceptibility and to me those at the moment are personal priorities in research.

Chairman: A one-sentence question from Mr Jack without subordinate clauses!

Mr Jack

89. Why was it not possible that the splash-proof technology from pesticide products containing OPs was not immediately transferred into the sheep area?

(*Mr Anderson*) The short answer is that stability studies would have been required. At present all containers of OP sheep dip concentrate are made of tin-plate. The pesticide containers are of a plastic material, polyethylene lined to avoid leeching of the product through the container, but the sheep-dip formulations have not been, as far as I am aware, tested in those containers and some stability trials would have been required if manufacturers had chosen that particular solution.

Mr Drew

90. Could I move us on to animal welfare and health. Is it fair to say that one of the reasons why it has been so difficult to take a decision on OPs is that OPs have always been accepted as the most effective way in which you can keep scab down on sheep?

(*Professor Aitken*) That is true. OP dips have the advantages of being broad-spectrum in their activities, so it is not just against scab, although that is a major problem and concern, but it is against all the other ectoparasites as well. They also do have a residual activity once a sheep has been through the dip. They are not totally infallible, however, because mistakes can occur and sheep may not be dipped or they may not be dipped adequately, or, in the case of scab, mites may get into positions or locations where the dip does not reach, but yes, they are very effective, and I would accept that.

91. So what advice are you now giving to farmers in terms of their ability to control scab in particular and, as you say, the other things where OPs are the most appropriate method of control?

(*Professor Aitken*) Well, there is an interesting comment which you may have had in your submission from NOAH which certainly was made to the working party of the VPC which met the industry representatives—that is, the farming industry and manufacturers—about five weeks ago and that was that their assessment—that is, NOAH's assessment—was that OP dips were used for about 50 per cent of the sheep in the country which indicates that 50 per cent were not using OPs, so they were using the alternatives which are and have been available for some time, and these are other dip formulations based upon synthetic pyrethroids and injectable preparations for the control of sheep scab. There are also pour-on preparations which are useful and effective for other forms of parasite, so there is an armamentarium of specific products which are available to treat ectoparasitic infestation of sheep. They do lack, let us say, the appeal of OPs in terms,

[**Mr Drew** *Cont*]
I think, of their ease of adminstration, their relatively lower cost and I know that there have been concerns expressed about the ecotoxicity effects of synthetic pyrethroid dips, but there is an armamentarium there to be used.

92. If sheep disease, particularly scab, grows exponentially, and I accept what you have just argued, that there are alternatives which may be not as good as OPs, is this an argument for fast-tracking the use of new containers with the OP at whatever level of concentration?

(*Professor Aitken*) Well, fast-tracking will, I think, depend upon the presentations that the Committee receives on the plans that the manufacturers have for improving container design and thereafter it is a matter of generating stability data. I think Mr Anderson might want to amplify the particular ways in which fast-tracking could be achieved, but once the Committee has been satisfied that their design is of the order of prevention that is acceptable, then the next question is that of stability and that might take, as has been indicated, a year or more, but could be done in the short term in three months.

(*Baroness Hayman*) Can I say that in the longer term there is obviously a need to tackle the disease and we are funding a programme of research of £1.6 million for alternative strategies to control sheep scab because there are disadvantages with everything that is available at the moment, so looking more fundamentally in areas of particularly prevention and alternative control mechanisms is, I think, an important long-term thing for MAFF to be doing as well as the short-term issues.

93. Is there a case where you do get extreme breakdowns of sheep through disease or some form of temporary derogation in the use of OPs inasmuch as these exceptional circumstances could be allowed under control and they help in terms of the ability to be able to carry out further scientific and medical examination because almost certainly, as you recognise, there are going to be cases where there are going to be increases in sheep disease?

(*Professor Aitken*) That is a regulatory matter, not a scientific one.

(*Baroness Hayman*) Well, I think the state veterinary service has set up a working group to look at welfare issues affecting the sheep sector and is meeting early next month to consider further ways of monitoring sheep scab and practical issues for control and I suppose that is one possibility. As I understand it, it is not that it is impossible to find an effective mechanism for dealing even with a large-scale outbreak, but it may be the use of an SP dip, and there are concerns about that, it may mean a combination of an injectable and a pour-on and it may have to be repeated, and it has additional costs, but it is not that there is unavailable treatment for disease across the board to say that the only thing you could do is OP dip. On the Veterinary Products Committee there are practising vets and a working farmer as well as academics and toxicologists, so these are areas that can be covered, but at the moment my view would be that I recognise that many people find the alternatives unattractive, not least on cost, but it is not that there is no alternative at all.

(*Professor Aitken*) I would just add, if I may, that each of these alternatives has been through the regulatory process of evaluation for its safety, its quality and its efficacy and they are only available if efficacy can be demonstrated, so they are available and they are efficacious.

94. But you would accept that there is an animal welfare implication naturally in this and it is how you get the balance right between the human health controls, which is why you have taken this action, and what one would hope would not happen, which is a greatly increased incidence of sheep problems?

(*Baroness Hayman*) And the cost and the burden to the industry and those are all issues that have to be considered in the round and which, as I think I said earlier, do not lead you to an unequivocal answer that everyone will agree is the right balance.

Mr Paterson

95. Do you know of any scientific developments either funded publicly or privately which will lead to the availability of a satisfactory alternative to OPs which works as well and is as cheap within the next five years?

(*Professor Aitken*) That is crystal ball gazing. There are a number of areas of research being carried out, as the Minister has mentioned earlier on. Some of these are looking at things like the basic biology of the mite to try to identify whether there are weak links in its metabolism which can be targeted specifically with modern drugs and modern technology. Another is to try to exploit the sheep's innate immunological ability to mount an immune response to the allergic reaction that the mite induces. You would be optimistic looking at five years; I think that is ten years. There are other similar approaches which are taking place. I would have thought five years is an optimistic estimate but one never knows, serendipity might change that view.

Mr Jack

96. I want to clarify a point in terms of the scope and scale and impact of what you have said. You said 50 per cent, and I was not quite certain whether it was 50 per cent of farmers or 50 per cent of the flock who were currently using OPs.

(*Professor Aitken*) It was a figure which I took from a presentation which was made by NOAH that in terms of the sale of the various medicines used to control ectoparasitic disease in sheep, 50 per cent of sheep in this country were probably going through OP dips for the control of sheep scab and other ectoparasites; by implication, the other 50 per cent are using something different.

97. Is that a United Kingdom figure?

(*Professor Aitken*) That is a figure from NOAH which would apply to the United Kingdom. You would have to ask them for the specifics.

98. I would personally find it quite useful, bearing in mind the high level of sheep breeding in places like Scotland and Wales, to know the total extent because the same piece of evidence from NOAH points out that farmers still choose OP dips, pointing out that 15,000 have chosen to undertake a certificate of

[**Mr Jack** *Cont*]
competence in spite of ten years of bad publicity. Moving to the environmental issues, Mr Mitchell referred to the Environment Agency and they certainly have alerted us to the potential impact on the environment of the synthetic pyrethroid dips, which I gather are the alternative, and the National Sheep Association in their evidence sent us a copy of a letter dated 6 January, Minister, which was addressed to you in which they point out that the alternative chemical used to control ectoparasites in sheep by the plunge dip method is synthetic pyrethroid where "it is common knowledge that SPs are far less friendly to the environment" and it goes on then to talk about this particular preparation, the OP preparation, as being the best in terms of the farmers' armoury in dealing with problems with sheep. What did you reply to the National Sheep Association to totally put their minds at rest that there was going to be no adverse impact on the environment of the decision that you took?

(*Baroness Hayman*) I do not think I replied in those precise terms but how I would reply to you is that I was concerned, as I said earlier, at the fact that SP dips have had concerns raised about them and provide greater challenges in terms of safe environmental disposal than OP dips. In order to be reused and disposed of on land the dip has to be approved under the Groundwater Regulations by the Environment Agency and, equally, the environmental impact is one of the issues that is assessed in terms of whether the product should be licensed in the first place. When I met the National Sheep Association I accepted that there were concerns on SP dips environmentally, not such as to suggest they should not be licensed but there were concerns about the environmental issues. Equally, they have raised with me issues about growing resistance. I do not think I have ever tried to suggest to the Committee that there are easy alternatives. There are down sides to all the alternatives.

99. Are you telling me that in the consideration of practicalities of this matter you did not do any kind of environmental impact study yourself before the announcement was made?

(*Baroness Hayman*) I relied on the environmental impact study that had been made to allow SP dips on the market and the work done every time the SP dip is used by the Environment Agency.

100. Evidence suggests that possibly larger numbers of farmers than we might have thought are moving in the direction of these alternatives and although you are quite right in saying that you had an environmental impact study done at the time to ask whether these are safe, the Environment Agency in their evidence said they concentrated on "raising awareness of the hundredfold greater environmental toxicity of SP as compared to OP dips." To a layman that sounds like a quantum increase in the environmental threat. Perhaps I am wrong. Put it into context for me.

(*Baroness Hayman*) I am sure as statutory advisers the Environment Agency are concerned about the growing use of SP dip and its effect on the environment and they will alert Ministers to that.

101. It says here in the Environment Agency's evidence, I repeat what Mr Mitchell drew attention to earlier, that the Agency is concerned about the lack of consultation that took place prior to the suspension of OP dip licences. You gave the impression earlier that you had a lot of these environmental persons sitting around in various committees listening to all this. Are the Agency employing mutes who have taken vows of Trappistry and therefore do not wish to contribute anything until suddenly they are freed from these chains of silence by an announcement? That is quite condemning evidence in an era of so-called joined-up government that this island of silence tells us that they are concerned about the lack of consultation.

(*Professor Aitken*) If I may, I would just make a few comments here. First of all, all of the licensed products of the synthetic pyrethroids have been through that rigorous process of assessment in relation to their eco-toxicity and the fact they are particularly toxic to aquatic environments and aquatic invertebrates is well-established and well-known.

102. If it is well-established why does the Agency say it does not think there is adequate consideration of the environmental risks posed by veterinary medicines under the current authorisation procedures. That is pretty damning evidence.

(*Professor Aitken*) I would suggest there is a need for dialogue between the Environment Agency and Veterinary Medicines Directorate about the severity of the review process that takes place.

103. So you have got no idea of the impact, according to this other piece of evidence, of pouring all this nasty OP stuff down the drains or into the streams? I am left with an environmental disaster looming in my mind.

(*Professor Aitken*) If I am allowed to continue my commentary, the certificate of competence which is now required of all purchasers of dips requires them also to be given training in the safe handling and disposal of dips, not just OPs but synthetic pyrethroids as well, and that includes reference to the environmental agencies over the appropriateness of disposal procedures. Investigation of some of the recent incidents that have been related to the use of the synthetic pyrethroid dips has identified not so much disposal as misuse during their use for the dipping process. The advisory leaflets that are available also give very clear indications about the need to consult environmental agencies about the correct approach towards disposal. So I think it is less than fair to say that there is no information; there is quite a lot of information and quite a lot of direction and encouragement to users to use products safely in relation to the environment.

104. Are you going to be talking to these silent environmentalists to get them up to speed on all of this as a result of what they have said here in their evidence.

(*Baroness Hayman*) Certainly on the issue of joined-up government, as I think I foreshadowed in what I said earlier, there were discussions across departments including DETR, to whom the Environment Agency are statutory advisers, about

[**Mr Jack** *Cont*]
these decisions in the round. On individual Groundwater Regulations permits, then the use of SP dips has to be individually assessed.

105. What detailed information at this stage do you have with reference to sheep dipping and the Groundwater Regulations bearing in mind that up until 20 December two formulations were useable? I do not know anything about this. Can you help me?
(*Baroness Hayman*) Not at this moment but if it would be helpful to the Committee I will certainly ask for whatever information there is at DETR and the Environment Agency about usage in the past, number of permits and any potential changes.
(*Mr Anderson*) One piece of information we do have, Chairman, because a representative from the Environment Agency briefed the Veterinary Products Committee Working Party at the same meeting in which the industry representatives briefed them on welfare issues, is that SP dips were implicated in 38 pollution incidents over the period 1997-98 when such incidents peaked but that the figure for 1999 of incidents requiring investigation (and the results are not yet known) was in single figures.

106. What was the comparative data for OPs?
(*Mr Anderson*) A combined total for OPs and SPs was 61. So 23.

107. So you got more SPs than OPs. It does not concern you?
(*Baroness Hayman*) It does concern me. This whole area concerns me. I worry about every aspect of it but I have to try and balance up what is the right thing to do given all of potential risks—and there are potential risks across a wide field here, they are not only in one direction—and I think my job is trying to get the most sensible assessment of the appropriate way forward given one's responsibilities as a licensing authority and the advice that one has a responsibility to consider. I do not take that over narrowly. I do think I have to look at wider considerations. Of course I am concerned about the potential environmental risk, as I am concerned about the potential cost to the industry, as I am concerned about animal health, but at the end of the day one has to make a judgment which boils down to do you temporarily suspend this product or do you not? Do you totally go beyond the advice and take a supremely precautionary approach? And I have tried to explain to the Committee some of the factors that went into how we came to this decision.

108. Just one final question. In terms of the effectiveness of dealing with the problems faced by sheep for which OP applications are used, how do SPs compare in effectiveness on a scale of 100 per cent knock-out of nasties to OPs?
(*Professor Aitken*) If you are looking at this in purely biological terms in relation to the product being properly utilised under the correct conditions you would not see a distinction except in the area of the greater persistence of OPs on the fleece of treated sheep than is the case with synthetic pyrethroids. The other area, was which is not a scientific one, is the question of cost.

Mr Paterson

109. Could we turn to the economic angle. The NOAH submission told us that "the ability of the farmer to choose the most appropriate product for his or her own particular circumstances is vital. At this critical time for sheep farming, OPs are perceived by many farmers as being the most cost-effective for them." Why should farmers not be presented with all the information and then decide for themselves on the basis of risks and costs to themselves?
(*Baroness Hayman*) Because in the licensing of medicines Ministers have a responsibility not simply to license any product that anyone wants to manufacture or anyone might want to buy, we have a responsibility to ensure that a product on the market is properly assessed for safety, for efficacy and for quality before anything is on the market and I believe that we have a responsibility to take the appropriate action to ensure that we minimise the risk that people then choose to take or not take. Some people would not use OP sheep dips at all whatever the packaging, and that is their choice. Some people would use them, equally, if they were no constraints on packaging at all. I do not think it would be appropriate to have no constraints at all and I do not think anybody would suggest putting the clock back that far. What one is trying to do is find the right level of universal protection beyond which people can make their own choices. My advice is that there is currently technology that is applicable here that could improve safety and minimise risk through container design. I therefore thought it appropriate to ask the manufacturers to use that technology.

110. It is interesting, despite all the appalling stories that come out in the press about this, that the actual proportion of OP dips in sheep ectoparasite cells was rising, according to NOAH, before the ban came in.
(*Professor Aitken*) It depends which document you are reading. I have already mentioned the figures from NOAH. If you go back to the Institute of Occupational Medicine Report, in their preamble they indicate they have difficulty identifying sufficient numbers of farmers using OPs to incorporate in their study because of the move away from OPs so fashions go up and down and different parts of the country will adopt different methods.

111. To get back to the economic impact, the Farmers' Union of Wales said they were deeply concerned at the potential economic impact. When you made this decision how high up the scale of priorities was the impact on farmers of a sudden withdrawal of OP dips?
(*Baroness Hayman*) It was certainly part of the context in which the decision was taken. In my responsibility for regulatory decisions about the protection of human health, I think that has to be part of the context, but I do not think that you can simply say that if something was very expensive or mediumly expensive or a little expensive then you would not take the appropriate action to protect human health.

112. I did not mean the cost of the product but the impact on the industry.

[Mr Paterson *Cont*]

(*Baroness Hayman*) But the impact on the industry is the increased cost of the product and maybe the increased cost of time and labour, as I am sure Mr Jack will remind me, of putting on two products, injectable and pour-on for example, rather than simply putting everything through a dip.

113. Their main concern is the potential for a major outbreak of scab this year.

(*Baroness Hayman*) Yes I know and I discussed that with them. I am concerned about that obviously and I am concerned to have better information because it is not a reportable disease and one does not know absolutely the levels of disease. There is certainly anecdotal evidence that it is increasing. Equally, there is some anecdotal evidence that there was less preventable dipping last autumn when there were OP dips on the market because of the economic state of the industry. That is another factor at work there.

114. I would have to take up with you the issue there is not the evidence because the British Leather Confederation wrote to you on 1st February and they have been saying for some time that since compulsory dipping was stopped in the early 1990s there has been a constant deterioration in the quality of British sheepskins. They can give you evidence.

(*Baroness Hayman*) I am not sure I can give the Committee the precise evidence of the number of cases of sheep scab this year and in the last ten years, which is what I would like to be able to give you.

115. I would submit they could give you that because the parasites damage skins.

(*Baroness Hayman*) I am sure they can and one could perhaps extrapolate out of that but it is not quite the same.

(*Mr Anderson*) A representative of the British Leather Confederation also met the Veterinary Products Committee Working Party and did present some statistics which unfortunately ended in 1995 but subsequently provided on a different basis more up-to-date information, all of which was presented to the Veterinary Products Committee at their meeting on 16th March.

116. We have got a very bad photocopy but it looks to me as though they have got figures going up to 1999. Perhaps you could take that up with them. On that question they estimate that the cost to Britain's agricultural industry is approximately a loss of £15 to £20 million in the devaluation of the skins. How closely did you take into consideration that industry's problems before you made this decision?

(*Baroness Hayman*) I could not say to you that I took that industry's particular circumstances individually as a major issue in decision-making. The decision-making was taken, as I say, in one's responsibilities as a licensing authority, but I would like to reassure you that the overall context on both sides of the argument, both in terms of the economic effects, the potential for increase in sheep scab and therefore the knock-on effects into other industries, was recognised as indeed was recognised the concerns of many people that one should take a more precautionary approach and a more broad brush approach and simply withdraw product whatever the consequences elsewhere because of the potential consequences for human health.

117. Given that there are real fears of a major sheep scab outbreak which will do real damage to the sheep industry and to the leather industry, what will you do if there is a major outbreak this year given that we are five years away from a satisfactory replacement for OP and given that we have heard the alternatives are not environmentally friendly and more costly? What will the Government do this year?

(*Baroness Hayman*) The best solution is to get appropriate packaging for OP sheep dips and get them back on to the market as soon as possible in a safe form. We will work with the manufacturers and give them any technical advice and support we can do to allow them to do that. Equally, we will monitor through the State Veterinary Service sheep welfare and incidence of scab and take advice whether it gets to the point where emergency measures are necessary. But, as I say, it is not that there are no alternatives at all available for dealing with the problem, although I recognise the down sides.

118. They are just not as good, they are not as effective.

(*Baroness Hayman*) I think Professor Aitken disputed that on SP dips.

(*Professor Aitken*) If they are properly used in the right circumstances following the recommendations on the label, they are effective. I would just remind you that on the basis of figures we have been given by NOAH 50 per cent of sheep in this country do not use OP dips and I am sure that the 50 per cent that do not use OP dips are not the full representatives of the ones with the damaged skins.

119. We will agree to differ. Those I know in the trade are convinced that the SP dips are not as effective. One last question, would you consider reimposing compulsory dipping?

(*Baroness Hayman*) I am reluctant to say never to any question because one has to take the appropriate measures in the case in point with the evidence. The advice that has been given to me is that compulsory dipping was not an effective mechanism—Mr Anderson has a longer memory than I do on these things—and that the suggestion that it should be reimposed in certain circumstances is not one that would be supported either within the industry or by the veterinary profession. I do not know, Ray, whether you want to say anything about that?

(*Mr Anderson*) Not really, Minister. Compulsory dipping was ended in 1992 and it was recognised that because of the changed economic circumstances of the sheep industry with a greater development, for example, of lowland flocks which were moved much more readily and rapidly, that the policy was not working in terms of having any success in eradicating scab.

120. Because it was difficult to implement?

(*Mr Anderson*) No, you could require compulsory dipping but there was a problem with tracking sheep. If you go back 30 or 40 years, the sheep did not move around the country so much between breeding and slaughter but with the development of the lowland finishing flocks, to some extent encouraged by the introduction of sheep quotas within the European Union, there was a great deal more movement of sheep about and the chances of a few infested sheep moving round the country and reintroducing scab

[**Mr Paterson** *Cont*]
were much greater than had been the case when a compulsory eradication policy had proved to be more effective.

(*Baroness Hayman*) There is also the issue of feral sheep and the possibility of them spreading disease. I know people have a view about how that can be dealt with as well and the Countess of Mar certainly has a scheme that involves compulsory sheep dipping but at the moment it is not being considered as a policy option.

Chairman: A very quick question from Mr Öpik and then the final question by Mr Drew.

Mr Öpik

121. It is a question about the environmental point that was being made before. It strikes me that 38 incidents with SP is equivalent to 3,800 with OP in an aquatic context. I worry that we are going to make things worse because it is a tactical solution not a strategic one.

(*Baroness Hayman*) The trend was down on the 1999 figures but I think you are right we have to monitor the 2000 figure. It is one of these aspects that we have to keep a handle on as we do have to keep a handle on the economic consequences.

(*Mr Anderson*) Can I clarify Mr Chairman, that is not a proper extrapolation.

122. I recognise that.

(*Mr Anderson*) What we are saying is that a smaller level of contamination by SPs could have the same effect on aquatic life but they do not kill fish, they kill the lower forms of aquatic life on which fish feed and the evidence is that in most pollution incidents that level of aquatic life will recover within a period of three months. It is not a permanent wipe out.

Chairman: As some of my fly fishermen colleagues have been discussing with me. David?

Mr Drew

123. Looking at government action after the recent announcement, the actual announcement had in addition to the ban three other elements to it, the revocation of the marketing consents for the three OP compounds, promotion of best practice and the development of a targeted research programme to be run by MAFF, the HSE and the Department of Health. We have talked about the third so I do not want to re-visit that. I just wondered what warning you gave to the manufacturers of the three OP compounds that revocation might occur and was it sensible to issue licences in the first place given the controversy in this area?

(*Professor Aitken*) As to warning, I can only refer back to the announcement in July of last year when it was indicated quite clearly that if there were no positive plans to improve container design and to uniform these that there was a risk that there would be a withdrawal of product. That was very clearly signalled at that time. On the issue should there be any licence at all, do you mean retrospectively some years ago?

124. I am really saying this is an area that is full of controversy. I did wonder whether it was wise to have a licence which people presumed would carry on regardless and whether there was another way of doing this.

(*Professor Aitken*) The authorisation very much depends upon continuing demonstration of quality, safety and efficacy and, as has been said several times in the course of these discussions, OP compounds are very effective anti-parasitic pesticides for particular ectoparasites of sheep. They are, however, toxic substances and they must handled with due care and precaution. If due care and precaution is adopted in their use then they are safe and should continue to have authorisation. It is the plugging of the loophole at the moment which is being sought.

125. If I can move on to an area we have not really talked about in any detail and that is the education and the training of those who dip. Is there an argument and one that is being pursued of extending the certification of those who are entitled to dip? I am a little unclear how you get that certification. You might want to say just a few words about that and the process of making sure that people do it properly.

(*Baroness Hayman*) Yes, the Veterinary Products Committee in July asked us to look at the issue of extending compulsory certification not only to those who purchase dip but to everyone who uses it and we asked for advice from the Health and Safety Commission on whether it was appropriate. I think everyone accepts that better training is important and that looking at the syllabus and encouraging people to undertake certificates of competence is an important way forward, and I am certain that practice has improved over the years. The advice of the Health and Safety Commission was quite clear, both in August and it was repeated in October, that they did not see compulsory certification as the way forward. To paraphrase—and it is my paraphrase—I think they were concerned that the responsibility was being shifted on to the individual operator and away from the responsibility of the manufacturer and, as I said earlier, it was important that we minimised risk through container design as well as encouraging safe usage by operators. They were not alternatives. But obviously that advice will be kept under review and if the Health and Safety Commission took a different view of that I would obviously have to take that very seriously.

126. The National Association of Agricultural Contractors has said in evidence to us that no NAAC members who dip or spray sheep have had any symptoms of OP poisoning. We have to take their word on this, but the corollary of what they are arguing is if you do not want to extend the certification because that may be adding to the problems if people do not do what they should do, is it possible you could do the reverse and limit the dipping to those who are expert in this area and have proven expertise and therefore if you do you can go as far as you can to eliminate the health risk?

(*Baroness Hayman*) I think we want to go as far as we can to eliminate the health risk. I think we have to recognise the practical realities of opportunities on farms and whether people can specialise and whether they have the numbers of workers to be able to do that, and I think the issue for me is whether we go

[**Mr Drew** *Cont*]
through the compulsory route or the supporting good practice route in terms of information and advice. I did have here the document that has been sent out I believe to every person registered as owning sheep. Equally that is advice—

Chairman

127. It has a black sheep on it.

(*Professor Aitken*) That is just in shadow.

(*Baroness Hayman*) It is not symbolic at all, I do not think! I think we have constantly to look at ways in which we can improve safety and safe usage on both sides of the equation and not simply concentrate on one at the expense of the other.

128. Minister, Professor Aitken and Mr Anderson, thank you very much indeed. It has been a lively session but I think we are all very interested if the subject and clearly we wished to go into an issue which has been around for a long time which has got a lot of emotional overtones as well as a lot of intellectual and scientific overtones. We are very grateful to you for coming and answering very frankly this morning. It has been extremely helpful to us. We hope we can send you on your way feeling you have discharged yourself and given us a great deal of information. Incidentally, if there is anything you wished you had said which you have not said or on reflection you feel you would like us to have something additional, let us have it quickly—

(*Baroness Hayman*) I will ring you at 2 o'clock tomorrow morning which is probably when I will think about it!

Chairman: The evidence will be on the internet tomorrow for those aficionados.

Letter to the Committee Chairman from Baroness Hayman, Minister of State, Ministry of Agriculture, Fisheries and Food (B 21)

Thank you for giving me the opportunity to give your Committee oral evidence in relation to its enquiry into the withdrawal of OP sheep dips. At the close of the session, you kindly offered me an opportunity to clarify or complete the evidence which I gave.

I recognised in evidence that we should have done better in giving MAFF's Regional Directors specific guidance on how to deal with enquiries from farmers about the implications of withdrawal of OP dips in the period immediately after the announcement on 20 December 1999. However, I would not wish to leave you with the impression that we did nothing subsequently. In fact VMD officials provided Regional Directors with question and answer material in January. They were also given oral briefing at their first regular meeting after the holiday period on 20 January.

Professor Aitken indicated that correspondence from NOAH had suggested that about half of the sheep in the UK would have been dipped in an OP sheep dip to prevent or treat ectoparasitic disease. We have since checked and I confirm that NOAH had indicated that about half of sheep treated to cure or prevent an ectoparasitic disease would have been dipped in an OP sheep dip.

I hope that these minor points of clarification will assist your Committee.

13 April 2000

Supplementary memorandum submitted by the Ministry of Agriculture, Fisheries and Food (B 23)

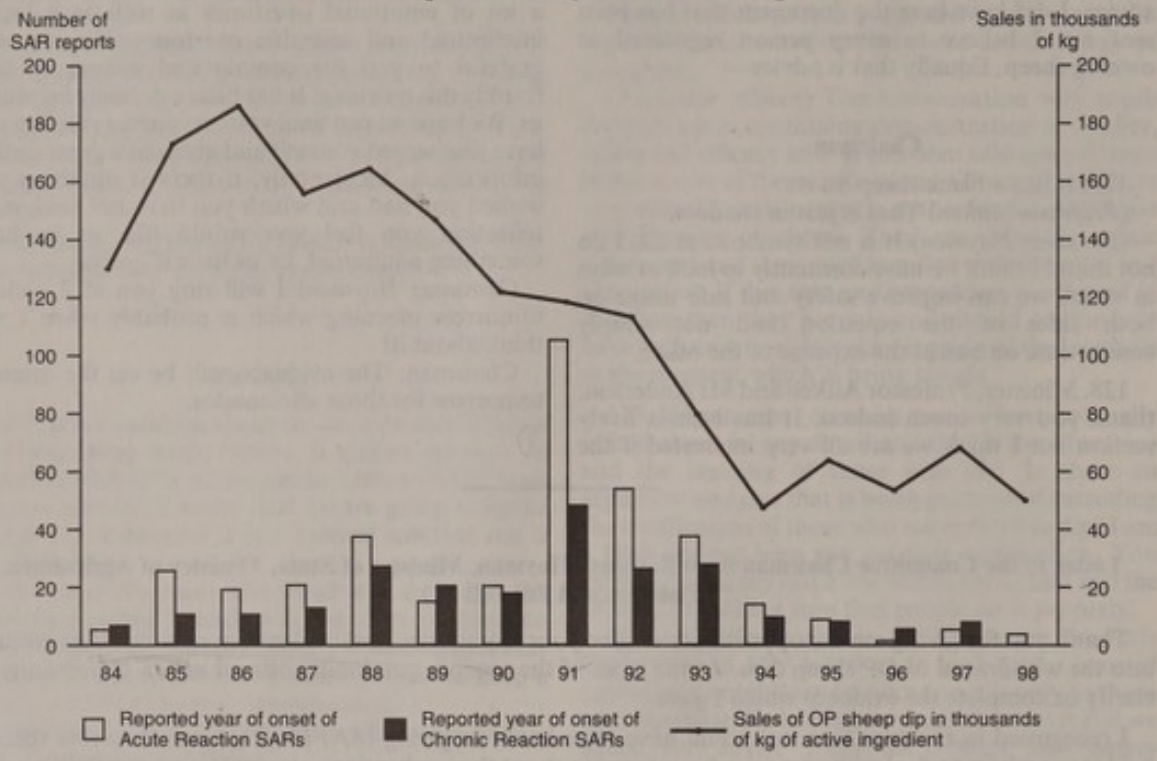
I refer to your letter of 12 April in which you ask for some further information following Baroness Hayman's evidence session on 11 April.

You requested information which concerns the impact of the Groundwater Regulations on sheep dipping. We do not have historical date on the usage of OP and SP sheep dips but the Veterinary Medicines Directorate has collated data on sales of OP sheep dips and I attach a copy of a table of sales (as well as cases of suspected adverse reactions broken down on the basis of the year of onset of symptoms) which is extracted from a report on the Suspected Adverse Reaction Surveillance Scheme to the Veterinary Products Committee which was published with the findings of the Appraisal Panel for Human Suspected Reactions from meetings in 1998. A copy of the full report is in the Library of the House.

As regards permits under the Groundwater Regulations, the Environment Agency estimate that approximately 13,000 (England 10,000 and Wales 3,000) applications for permits for the disposal of sheep dip under these regulations had been received as at 31 March 2000. It is not possible to break down this figure by sheep dip type.

I hope this provides the information the Committee requires. Please contact me if you need anything further.

Figure 6a: Comparison of sales of OP sheep dip with year of onset for acute and chronic SARs (excludes SAR reports where year of onset not provided)



* Acute reaction - Signs and/or symptoms which begin soon after exposure and cease shortly after exposure ends

** Chronic reaction - Signs and/or symptoms which persist after single, repeated or long exposure

25 April 2000

APPENDICES TO THE MINUTES OF EVIDENCE

APPENDIX 1

Memorandum submitted by the Secretary General, Animal Health Distributors Association (UK) Ltd (B 1)

Thank you for your letter of 3 March. I am pleased that the committee is going to look into the issue, however, in my view, this should be on a constructive basis, ie where do we go from here, and how do we get there. I would be totally opposed to a witch hunt in respect of the decision of 20 December and what went before, despite my belief that it could have been handled much more satisfactorily from all sides. However, it may be helpful if the Committee were to recommend that if a similar situation were to arise in future government should bring together manufacturers, distributors and users immediately before the announcement is made, to work out the least damaging and most effective means of recall and an appropriate and practical timetable.

Turning to the future, I can do no better than repeat extracts from my letter to the Minister, of 11 February, of which you have a copy—indeed whether because of the letter, or coincidentally with it, most of the suggestions contained in it seem to be happening—last week, this week and next week. Thus I hope this constructive phase is permanent.

As I said to the Minister on 11 February:

> "The first problem is that without OP dips the sheep industry faces an increasingly serious disease and animal welfare problem—alternative dips will be overused and as was said by their own manufacturer yesterday, may become ineffective in large parts of the UK by the end of this year. Injections of endecticide will not and cannot solve the problem on a nationwide basis. The second problem is that it is politically impossible, I fully recognise this, for you to reject advice received from a regulatory committee such as the VPC, or to have second thoughts after lobbying from industry and tell them to change their advice to you!"

I went on to emphasise the vital aspects of the VPC's advice on which the 20 December announcement was based:

> "Point 8.3.2.I is the key. VPC remind you that they requested urgent design changes in July 1999. They then go on to say that they have seen plans from manufacturers for changes, but that they 'advise that remaining marketing authorisations should be suspended until the design of containers is improved to minimise the risk of exposure to OP concentrate and/or clear plans are in place to effect the necessary improvements'. By using the 'and/or' this advice leaves it to you to decide whether to wait until changes are in place, or to end the suspension when the plans alone are in place—ie the suspensions could be ended from a specific future date on the basis that product is marketed in accordance with the plans submitted and agreed."

I went on to conclude:

> "Therefore the issue is for the VPC to be satisfied that the 'necessary improvements' have been 'effected'. Would it not be possible following yesterday's meeting, for you to write to the VPC, informing them of the extreme risk of an animal welfare crisis of which you have been advised, following your adoption of their advice on OPs, and asking them for a further report, by 31 March 2000, on the progress that is being made by marketing authorisation holders in developing plans, acceptable to them, the VPC, that would 'effect the necessary improvements', so that the suspension of market authorisations could be lifted on or before 31 May 2000. Such a request of VPC could encourage them to cut through some of the unnecessary traditional bureaucracy and formal appeal procedures associated with market authorisations, which would in this case waste time we do not have. It would persuade them to actually discuss with market authorisation holders what is possible in order to meet their requirements—which are, we must remember, to 'minimise' and not, however desirable to HSE, to 'eliminate' the risk, which is impossible."
>
> "I also suggest that as part of the package for ending the suspension of market authorisations, the idea which was put over at the meeting, that it be made a specific legal requirement that only the Certificate of Competence holder is allowed to handle concentrated OP dip—something that AHDA pressed for when the C of C was first introduced."

Finally, I mention to you the final point of my letter to the Minister—point 8.3.3.1 of the VPC's regulatory advice. This stated that "Ministers should re-emphasise to merchants the importance of ensuring that purchasers of sheep dips are fully aware of the potential hazard of exposure to sheep dip". It was not made clear earlier in the VPC advice (point 6.9) that it was AHDA, representing most of those supplying dips to farmers, who first proposed that this laminated A4 sheet should be produced and distributed. Indeed, the original AHDA proposal was that this A4 laminated sheet should be made legally part of the required labelling of each dip container, so that it was a legal requirement that one was handed over with every container of dip purchased. We proposed this so that it was not necessary for a farmer to lift a container of

dip (possibly open) to head height in order to be able to read the safety advice. Unfortunately this proposal, which would have been far more effective than that which was eventually adopted, was watered down as being impractical by others prior to the distribution route by AMTRA and NPTC being agreed. I return to this idea and suggest that when the suspensions are lifted, these A4 sheets are made a legal part of the labelling requirements to be handed over with each sale of dip.

6 March 2000

APPENDIX 2

Memorandum submitted by the National Farmers' Union of Scotland (B 2)

SUMMARY

The continued availability of organo-phosphorus (OP) sheep dips is absolutely essential to the health and welfare of the national flock.

They are the most cost effective treatment for sheep scab in terms of tackling infestation and providing protection against re-infestation.

The Government's concern about the safety of containers for the dip concentrate must not be used as an excuse for banning their use permanently.

Government Agencies—such as the Veterinary Products Committee—must work with the OP dip manufacturers to produce a satisfactory new container as soon as possible to ensure availability of the dip for the autumn of this year.

BACKGROUND

Scab infestation is a major problem for the British sheep industry. Its incidence has increased dramatically within the national flock since the termination of compulsory national dipping. The control of scab is essential to the health and welfare of our sheep. This will be considerably more difficult without the availability of OP dips.

The sudden withdrawal of OP dips—pending the development of new containers for the concentrate—has deprived the British sheep industry of its most cost effective treatment for scab infestation. The alternative treatments on the market are more expensive and do not provide either protection against re-infestation or the same coverage against other parasites as the OP dips. Also, the synthetic pyrethroid dips present a greatly increased environmental risk, and the injectables can give rise to problems with sheep marketing owing to their extremely long withdrawal periods.

It is essential therefore that OP dips are again made available to the sheep industry with the very minimum of delay.

Our determination to see OP dips reintroduced does not mean that we disregard the concerns for human safety that surrounds the use of these dips. We support the Certificate of Competence scheme aimed at ensuring that those who use OP dips know the safety precautions that must be followed.

The dips too must be made safe for those who use them. This means that if there is concern about the safety of the containers used for the dip concentrate, this must be addressed as a matter of priority. New and better designed containers must be developed. Government Agencies with concerns about the present containers—for example the Veterinary Products Committee—should work closely with the OP dip manufacturers to develop the necessary new containers.

Government concerns about the dip containers must not be used as an excuse to ban permanently the future use of OP dips.

The Union looks forward to the early development of satisfactory new dip concentrate containers and the renewed availability of OP dips in time for the main dipping season against scab this autumn.

14 March 2000

APPENDIX 3

Memorandum submitted by the Farmers' Union of Wales (B 3)

INTRODUCTION

1. The Farmers' Union of Wales welcomes the opportunity to comment on the Government's proposals for organophosphate sheep dips.

2. The Farmers' Union of Wales is an independent organisation for farmers and landowners, established with the aim of safeguarding and furthering the interests of its members and promoting a sympathetic understanding of their problems.

3. In Wales, the national flock of around 11 million sheep generates nearly 24 per cent of agricultural GDP, and the importance of sheep farming is further demonstrated by the fact that around 60 per cent of Welsh holdings carry sheep.

4. The control of ectoparasites is necessary to maintain the health of the national sheep flock. By far the most serious of these parasites is sheep scab, although blow-fly, keds, lice and ticks can also constitute serious health problems to the flock.

5. Whilst there is a variety of products available for the treatment of ectoparasites, the traditional method has been to dip the animals in a suitable insecticide.

6. Until 1992, sheep dipping was a compulsory exercise in the UK to control the incidence of sheep scab which caused major economic and welfare problems within the national flock. Unlike other European Member States, compulsory treatment was withdrawn before the eradication of the sheep scab mite, and so it remains endemic in the UK.

7. The FUW supports the points raised in a letter sent to Baroness Hayman by the National Office Animal Health Ltd (Appendix 1 [not printed]) and submits the following information in addition to these points.

The Government's Proposals

The Announcement

8. Whilst the FUW accepts the Government's rationale behind the withdrawal of OPs as a means of improving health and safety by removing the risk of contamination, the lack of a clear time-table for resumption of sales, coupled with the timing and lack of consultation on the possible impact of the withdrawal, has caused a great deal of confusion within the industry.

9. The Farmers' Union of Wales was also disappointed with the way in which the announcement to withdraw OP sheep dips from sale was made—by written Commons answer—immediately prior to the long Christmas break.

10. There is understandable apprehension over the Government's implementation of a deadline for withdrawal without any prior consultation with the agricultural industry on the least disruptive method of carrying out the Veterinary Products Committee's recommendations.

11. The FUW has consistently maintained that detailed research needs to be undertaken with regard to the serious incidences of ill-health reported by some farmers after using organophosphate dips. However, it is vital that farmers have a range of effective products to control sheep scab and the wider range of ectoparasites which pose a serious threat to animal welfare.

12. The Union welcomed the Government's acknowledgement of its calls to instigate a major research programme into alternative products for the effective control of parasites in sheep, although this announcement does little to address the short term demand for effective scab control products.

Implications for the Sheep Industry

13. During 1999, the Government introduced the Groundwater Regulations which transposed the requirements of the European Groundwater Directive 1980.

14. The provisions of the Directive called for a system of prior investigation authorisation and monitoring for the disposal of List i and ii products to land.

15. Sheep dip chemicals are classified as List i products and thus all disposals to land require authorisation by the Environment Agency.

16. The costs associated with obtaining authorisation, and annual monitoring charges coupled with low market realisations within the sheep sector, and the low level of applications for discharge authorisations received by the Environment Agency during 1999, suggest that many farmers withheld from dipping last year unless they perceived a specific problem.

17. Despsite concern regarding the human health effects of OPs on farmers, it remains true that organophosphate compounds provide the most effective insecticide for the treatment and prevention of the major ectoparasitic infections in sheep.

18. The FUW is concerned that the lack of dipping activity last year, coupled with the withdrawal of OPs from sale, could potentially result in an upsurge of sheep scab infection during 2000.

19. Anecdotal evidence suggests that the incidence of lice infestation is increasing, particularly in upland areas. Whilst clinical symptoms of scab and lice infestation are similar, OP compounds control both parasites, whilst louse resistance to synthetic pyrethroids and the unsuitability of many injectables to control lice means that there are important welfare implications which need urgent attention.

20. The Farmers' Union of Wales appreciates the reasoning behind the Government's decision to withdraw OP sheep dip containers from the market, given concerns over operator exposure to OP concentrates.

21. The FUW is also concerned that by withdrawing OPs from sale, the choice of products available for treating sheep for ectoparasites could have a major impact in Wales which has nearly three-quarters of its land mass designated as being of conservation or environmental importance.

22. Recent publicity given to the polluting effects of synthetic pyrethroids has invoked concern amongst conservation and other bodies about the possible upsurge in pollution problems associated with increased usage of SPs, due to their slower rate of breakdown within the soil.

23. Similarly, the FUW is aware of growing concern amongst conservation agencies that injectables such as Ivermectin can seriously damage the ecology of soil invertebrates.

24. Pharmaceutical companies have also expressed concern that the incidence of scab resistance to synthetic pyrethroids is likely to accelerate substantially if there is increased usage this year due to the absence of OPs.

25. Given that OP chemicals constitute around 50 per cent of ectoparasite control sales, there is also concern that an upsurge in sheep scab could result in a shortage of other products due to increased demand.

CONCLUSION

26. The FUW is deeply concerned at the potential economic and welfare implications of the Government's proposals if the forecasted upsurge in sheep scab breakouts is realised this year.

27. The Union believes that consideration must be given to allowing a dispensation for farmers suffering a scab outbreak to use organophosphates in the absence of practical alternatives.

28. Given the pharmaceutical companies' stated difficulties in producing the "new packaging" required by the Veterinary Products Committee (VPC) within a realistic time frame, consideration must be given to examining possible transitional arrangements which would allow OPs to be used in the interim.

29. The FUW believes that the VMD should reconsider the proposition put to them by the pharmaceutical companies, involving the use of "vented taps" which would reduce "glugging", thereby reducing the chances of user contamination.

30. In order to ensure that users are fully conversant with the safety procedures required to avoid contamination, the FUW supports the need for an urgent review of the anomalies of the Certificate of Competence for the Use of Sheep Dips which is required to purchase sheep dips but not for the actual dipping process.

31. The FUW is concerned at the way the decision was announced, the lack of a clear time-table for development of new containers, and the lack of consultation with the industry on the implications of such a decision.

32. The Union welcomes the Government's commitment to implement a targeted research programme into alternative products, although this has limited value for the short term need for a range of products which can be used in the most appropriate way.

16 March 2000

APPENDIX 4

Letter from the Director General of the Health and Safety Executive (B 4)

Thank you for your letter of 3 March, letting me know that the Agriculture Committee is to carry out formal inquiry into some aspects of the Government's recently announced proposals on organophosphate sheep dips. I understand that the inquiry is to be limited in scope and the HSE will not be called upon to give oral evidence.

Please do take our earlier submission as formal evidence to the inquiry. It may help the Committee to know in addition that the Health and Safety Commission has expressly endorsed the principle of reducing risk to concentrate handlers by improving container design, one of the items in the government's four-point plan and I believe likely to be one of the main points the inquiry will examine. It is an approach very much in line with the philosophy that underlies UK health and safety legislation: to engineer out the risks as far as we can before relying on systems of work and the personal protection of the individual worker. In parallel and as part of the review of anticholinesterase pesticides, also part of the plan, HSE is examining the design of containers used for concentrated non-agricultural products, and will make recommendations to the Advisory Committee on Pesticides for action on any found to be unsatisfactory by the standards now being applied to dips.

Much of the work done by HSE on enforcement, guidance and publicity, and referred to in our memorandum, is similarly focused on achieving risk control by engineering methods throughout the dipping operation. Our message is that much of the risk should be dealt with in this way, without having to depend heavily on the vagaries of operator behaviour. To the extent that there is residual risk that makes safe work methods and personal protection necessary our efforts are aimed at awareness raising and at making sure

that dippers are adequately equipped, trained, instructed and supervised. The targeted inspection programme being carried out by HSE inspectors is designed around these principles. We use publicity about actions taken to spread the messages beyond the farms actually visited.

16 March 2000

Memorandum submitted by the Health and Safety Executive

INTRODUCTION

1. On 20 December 1999 the Government announced its response to the advice from the Veterinary Products Committee (VPC), the Advisory Committee on Pesticides (ACP) and the Committee on Safety of Medicines (CSM) on the regulatory implications of the report on organophosphates (OPs) by the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT).

2. The action proposed by Ministers in their response takes the form of a four-point plan. This memorandum sets out for the Committee HSE's role in implementing the four-point plan; and provides general background information on HSE's role in relation to organophosphorus (OP) pesticides and veterinary medicines.

HSE'S ROLE IN RELATION TO ORGANOPHOSPHORUS (OP) PESTICIDES AND VETERINARY MEDICINES

3. The Health and Safety Commission (HSC) and the Health and Safety Executive (HSE) regulate virtually all risks arising from work activity in Great Britain. The HSC and HSE were established by the Health and Safety at Work etc. Act 1974 (HSWA), which lays general health and safety duties upon all who own, manage and work in economic undertakings. The HSC's main role is to propose health and safety law and standards to Ministers. HSE advises the Commission and enforces the legislation through health and safety inspectors. In certain premises, local authorities are allocated this enforcement role.

4. In general terms, HSE is responsible for ensuring that the risks to people arising from the use of chemicals at work—including OP sheep dips and pesticides—are properly controlled.

5. All pesticides and veterinary medicines must be approved by Ministers before they can be marketed in the UK. Applicants are required to submit substantial data dossiers for scrutiny to satisfy criteria of safety, quality, and efficacy. Dossiers are examined by scientists of the Pesticides Safety Directorate (PSD) and the Veterinary Medicines Directorate (VMD) and the advice of the independent ACP and VPC is sought. The Committees make recommendations as to whether the chemicals can be approved as a pesticide (ACP) or veterinary medicine (VPC) and, if so, under what conditions. Primary responsibility for the authorisation scheme for veterinary medicines (including OP sheep dips) rests with the VMD, an Executive Agency of MAFF. Once products are authorised for marketing and use, safe use at work is subject to the requirements of the Control of Substances Hazardous to Health Regulations (COSHH) 1999, made under HSWA. HSE and local authorities are responsible for enforcement of these requirements.

6. For pesticides, the Control of Pesticides Regulations, 1986 (COPR) require a thorough assessment of the risks such chemicals pose to both people and the environment. The PSD Executive Agency of MAFF administers approvals for agricultural pesticides; and HSE's Pesticides Registration Section deals with non-agricultural pesticides. HSE is responsible for enforcing controls on both agricultural and non-agricultural pesticides under the terms of an Agency Agreement made between MAFF Ministers and the HSC. This Agreement will shortly be replaced by new Agreements covering England, Scotland and Wales, following the introduction of Scottish pesticides legislation, but these are administrative changes and, in practice, HSE's role will remain essentially unchanged.

7. HSE liaises closely with MAFF (including its Executive Agencies, VMD and PSD), DH and other interested Government bodies in the formulation of policy and production of guidance relating to pesticides and veterinary medicines. For example, HSE is working with MAFF to revise the Code of Practice on Safe use of Pesticides on Farms and Holdings (the Green Code). One of the aspects of the code that will be looked at is the advice on OPs, in light of the COT findings. Advice and enforcement is based on COSHH, which place duties on employers to assess and adequately control risks to health and to train, instruct and ensure the competence of their employees.

8. HSE co-ordinates the Pesticide Incidents Appraisal Panel (PIAP) which reviews investigation reports concerning alleged ill health linked to pesticide exposure. HSE also co-operates with the VMD in the Suspected Adverse Reactions Surveillance Scheme (SARSS) which has a similar role for veterinary medicines. Both PIAP and the SARSS Appraisal Panel serve to inform the respective advisory committees about adverse reactions.

9. HSE is also represented on the interdepartmental Office Group on OPs (OGOP), which was established in 1997 to ensure effective co-ordination of policy and action on OPs by Government Departments and Agencies. OGOP is chaired by a senior official in MAFF.

The COT Working Group on OPs

10. The COT Working Group on OPs was set up in early 1998 in response to concerns about the human health implications of OPs. It was intended to be a fresh, thoroughgoing review of all the available scientific evidence. The Group's terms of reference were: "To advise on whether prolonged or repeated low-level exposure to OPs, or acute exposure to OPs at a lower dose than causing frank intoxication, can cause chronic ill health effects." For practical reasons, the Group concentrated upon class effects of OPs (ie they did not consider compound specific effects) and specifically neurotoxic effects. Although they were aware of concerns about other possible class effects of OPs (eg effects on the cardiovascular system, respiratory system and on bone density) they focused on neurotoxic effects because they were the types of illness most frequently attributed to OP exposure.

11. The COT report was published on 26 November 1999. Its central finding was that the available evidence did not support the hypothesis that prolonged, low-level exposure to OPs caused neurophysiological or psychiatric illness or significant harm to the peripheral nervous system, but the possibility that a small subgroup of exposed persons may be affected could not be excluded.

The Regulatory Committees' Advice

12. The regulatory committees unanimously agreed with the COT's conclusions that the conjectured ill-health effects resulting from prolonged low-level exposure to OPs remain unproven. They broadly endorse the report's recommendations for further research, especially to answer the question whether there is a small group of individuals particularly susceptible to OPs.

13. The regulatory committees advised against any general withdrawal of OPs from the market. However, in the light of the report published on 1 July 1999 by the Institute of Occupational Medicine on its epidemiological study into the effects of exposure to OP sheep dips, which confirmed that the main risk of exposure arose from handling the concentrate and highlighted deficient container designs, the VPC advised that all OP sheep dips should be withdrawn from the market pending the introduction of improved containers. This action was recommended after the manufacturers had been given the opportunity of a three month period to bring forward satisfactory plans for improved containers and delivery systems.

The Four-Point Plan

14. The four-point plan involves a number of Government Departments and Agencies and is being overseen by OGOP. HSE's main areas of involvement are highlighted in bold type below:

— Withdrawal of OP sheep dip products from the market until containers are introduced which will minimise operator exposure to the concentrate. The Veterinary Medicines Directorate (VMD) wrote on 20 December to all holders of marketing authorisations for OP dips requiring that sales be suspended, and recall by 31 January of product from distributors and farms. In line with the ACP advice, the Pesticides Safety Directorate (PSD) has taken urgent action to confirm that all containers of OP pesticide concentrates comply with modern standards, and has established that this is the case. Although it has no direct responsibility for these actions, **HSE has an input to them through its officials' attendance at, and advice to, the advisory committees**;

— An ongoing review of OP and carbamate anticholinesterase compounds (OPs and compounds with similar modes of action). **HSE's Pesticides Registration Section is responsible for the review of non-agricultural pesticides**, and PSD is carrying out a similar review of agricultural pesticides. As of 20 December 1999, approvals for 14 OP compounds had been revoked as a result of the review, in each case because the manufacturer had chosen not to submit the data packages required. The VPC is reviewing OP veterinary medicines other than sheep dips;

— implementation of a range of measures aimed at continuing to promote best practice in use of sheep dips, including:

(a) further improvements to labelling;

(b) **a continuing programme of targeted inspections of sheep dipping operations by HSE inspectors.** Part of HSE's Field Operations Directorate's preventive inspection programme, the visits target the use of OP and synthetic pyrethroid (SP) based sheep dips. The aim of the visits is to ensure compliance with COSHH including physical control measures; and that operators are properly trained and competent. Associated publicity is being used to maximise the impact of the inspection campaign in promoting compliance. Enforcement action (such as the use of notices and prosecution) is taken where appropriate. The targeted inspection programme is expected to run until the end of 2000;

(c) **a review of HSE guidance leaflets AS29 (rev2) "Sheep dipping", AS31 "Veterinary medicines—Safe use by farmers and other animal handlers", and AS27 (rev) "Agricultural pesticides", in the light of the latest scientific advice, including the COT report.** Where necessary, revised guidance will be published by March 2001;

(d) supply of protective gloves with sheep dip by the manufacturers;

(e) for sheep dip, licensing Ministers have accepted the HSC advice that users of OP sheep dips should not be compelled to hold certificates of competence. In 1999 the Commission twice reaffirmed its earlier view that while certification schemes had a place in the range of methods by which employers could satisfy their duties to train and ensure competence, there were major drawbacks to mandatory certification. Ministers have also decided not to extend mandatory certification for agricultural pesticide users, following a consultation exercise conducted earlier in 1999.

— A targeted research programme to take forward the research recommendations from COT and the regulatory committees. Ministers have now approved plans for a one day Workshop in March, involving scientists researching into the effects of OPs, in order to develop a research requirements document for topics recommended by COT. **HSE will consider (part) funding such research in due course with MAFF and DH.** The Workshop is intended to allow all participants to play a role in refining the questions to be addressed by the research programme. In addition, the Interdepartmental Network on OP Research (INOR—the research arm of OGOP) is currently discussing a proposal to investigate databases of people who believe they are suffering from the effects of OPs. INOR hopes that this latter project will start early this year. **HSE has been involved in the discussions, and may contribute towards the project costs.**

APPENDIX 5

Memorandum submitted by Mr B P Lugg (B 5)

I urge you in the strongest possible terms to get OP sheep dip back on the market for us to use as soon as possible.

The welfare issue is a very grave one, sheep will be at risk if we do not have this tried and tested product. It is also cost effective.

We should not be made to rely solely on the new Synthetic Pyrethroid types, quite simply they are more expensive and not as good.

No doubt you all have in the back of your minds the question of whether people have become ill as a result of using this chemical.

May I take this opportunity to test an opinion of mine on you.

When this Ministry of Agriculture's Sheep Scab dipping campaign was operating, not only did we have to dip all the sheep on the farm, which were perfectly healthy, we also had to dip any sheep which went to a live market in the previous 21 days. Often it was only done the day before market.

As a consequence, large numbers of farmers, dealers, drovers, lorry drivers etc, were constantly handling freshly dipped sheep.

It is my belief that if people contracted OP poisoning they did it at markets where little or no protective clothing was worn rather than on farms during the dipping procedure when protective clothing was always used.

MAFF's Sheep Scab campaign was in my opinion ill-conceived and you must not let this cloud your judgement in this matter.

Sheep farmers biggest problem is prevention of Blowfly Strike, which OP's do very effectively. Untreated sheep simply seek shade of trees and hedges in hot weather, then they stop thriving and gradually get eaten alive by maggots. (blowfly larvae).

However, once treated they continue to grow well and spend all day grazing out in the field even in hot weather because they are not being attacked by flies.

Please do everything in your power to get this product back on the market.

New containers which are easy to pour would be welcome, but above all we need it back on the shelves by the end of May at the latest.

16 March 2000

APPENDIX 6

Memorandum submitted by the National Farmers' Union (B 6)

Thank you for your letter of 19 January to Barney Holbeche inviting comments on the organophosphate dip proposals. I hope that the following summary of the NFU's position is helpful.

Before describing our concerns about the effects of withdrawing OP dip product licences, we must make it clear that the NFU fully supports the implementation of measures objectively identified as necessary to ensure the safety and efficacy of veterinary medicines. The authorisation of animal health products must rest on periodic review of that authorisation, and on re-assessment in response to new evidence. We accept that new evidence from the Committee on Toxicity is now to hand.

The extent of debate about these products in particular has focused attention on the way in which the withdrawal was handled, but this must not obscure the very real sheep welfare problems that could arise from the loss of the major agents in the control of ectoparasites. The majority of sheep farmers were using OPs up to last December (I believe that sales in proportion to the other options were gradually increasing), indicating that the product was working, and that it was effective against more than just the scab mite. In the short term at least this means a significantly reduced ability to control disease, leading us to consider whether some sort of derogation to use OP dips under supervision in exceptional circumstances might be workable.

The manufacturing companies are of course responsible for updating container technology to satisfy the new VPC requirements, and we need to urge those that elect to continue in this business to do so as a matter of urgency. We understand that some companies have fairly well advanced plans, and it would be consistent with good welfare practice for the licensing authorities to use the fast track system to deal with applications as rapidly as possible, and certainly in time for the main dipping season in the summer/autumn.

On a practical level, the announcement just before Christmas and the Millennium break left very little time for stocks to be recalled, and a great deal of confusion as to who was responsible for what. This is not a criticism of either the manufacturers or the suppliers, but an instruction to call in organophosphate dips from farms within a period of 20 working days gives an impression of a panic measure, something we would all want to avoid in this context. At a time when the whole "food chain" is co-operating by way of the Responsible Use of Medicines in Agriculture (RUMA) alliance to encourage best use practice on farm, the message emerging from this hurried exercise is a very negative one.

The burden of our message is therefore twofold. One, that the safety, quality and efficacy criteria circumscribing animal health product authorisation must be updated when necessary, to protect the animal, the operator, and the public. The act of doing so however must not unduly jeopardise any part of this protection. We feel that a proper consultation of all interested parties prior to (or immediately following) any announcement could have considerably reduced the potential impact on sheep welfare, and avoided the panic and confusion that has hit the sheep industry in the last four to five weeks.

Thank you again for the chance to comment. Please contact me if you need clarification, or any further information.

28 January 2000

APPENDIX 7

Memorandum submitted by the Tenant Farmers Association (B 7)

INTRODUCTION

The Tenant Farmers Association welcomes the opportunity of providing a Memorandum to the Agriculture Committee on the issues raised by the Government's proposals for organophosphate sheep dips as announced on 20 December 1999.

FEARS OF BACK DOOR BAN

The Association recognises the need for the Government to take a precautionary approach when it is presented with evidence which would suggest that public health, animal welfare and the environment may be at risk from contamination from OP concentrate due to inadequate container standards. However, the TFA was very concerned at the time of the announcement that it may be a "back door" route to the outright banning of the use of OP sheep dips. Our fears in this respect have been somewhat allayed by correspondence with Baroness Hayman (Minister of State in the Lords) who made it very clear that when "containers which meet the objective of minimising the risk of operator exposure to OP concentrate have been satisfactorily tested, there is nothing to prevent the renewed marketing of OP sheep dips".[1]

CONSULTATION WITH THE INDUSTRY

The TFA is critical of the Government for giving no prior warning to the industry about its plans. This put the TFA and other organisations in an extremely difficult position when attempting to advise members. The TFA recognises the right of Parliament to know the outcome of ministerial decisions prior to their wider dissemination but we feel that we could have been consulted on the Government's proposals prior to a final announcement which would have at least warned us to expect change in that direction.

ADVICE FROM GOVERNMENT FOLLOWING THE ANNOUNCEMENT

In the immediate aftermath of the announcement there was much confusion within the industry over what was expected and what was planned. There appeared to be no coherent thinking on a plan for withdrawal of product now declared illegal. Indeed the TFA found it difficult to get coherent and consistent advice from officials within the Veterinary Medicines Directorate and the Pesticides Safety Directorate on 21 December 1999.

It was also disappointing that the Government did not establish a helpline for farmers or give the already established MAFF helpline sufficient advice to provide callers with information on their position.

[1] Letter from Baroness Hayman to TFA Chief Executive, George Dunn, of 10 January 2000.

Alternatives

The TFA is also concerned that the Government's decision had little regard for alternative strategies for controlling scab during the period of product withdrawal. There are few viable alternatives to dipping using OPs that can be used on a wide spread basis and sheep health could suffer. It is alarming that the Government could take such action without thinking through the consequences.

Conclusion

The TFA understands the need to take a precautionary approach in situations like these. We would however wish to see a timetable from the Government as to when they might expect some manufacturers to meet the new standards on containers. We are however very critical of how the announcement was handled and the subsequent confusion surrounding the advice available.

10 March 2000

APPENDIX 8

Memorandum submitted by David St George and Dr Gillian S Wade C Psychol, Directors Celtic Dimensions (B 8)

Celtic Dimensions

Celtic Dimensions is a policy consultancy established in January 1999 to assist the newly devolving Celtic countries in, health, social, economic and political policy. Initially this has been restricted to Wales, Scotland and Northern Ireland but will be expanded to include The Isle of Man, Brittany and Cornwall. This will represent some 22 million people.

Initial projects are concentrating on Wales and specifically on health care matters. The main focus for 1999–2000 is improving quality of procurement of medicines and medical supplies and ensuring good Value for Money (VFM) for both public and private sectors.

Dr Gillian Wade has had public sector experience in University Research (culminating in a post as Honorary Research Fellow, University of Kent), NHS/Social Services, and the Audit Commission where she led the Welsh VFM studies' team as Senior Manager. During the last decade she has also been with private healthcare consultancies and latterly spent two years with a major pharmaceutical company as Director of NHS and Industry Affairs.

David St George has had 27 years experience within the Pharmaceutical, Diagnostic Agricultural and Veterinary industry in commercial roles with two major multi-national corporations. This has included strategic planning, healthcare policy research, public affairs and issue management. Latterly, this has included UK and EU responsibilities.

Background

An inquiry is being held by the Agricultural Committee around issues arising from the proposals to withdraw organophosphate (OP) sheep dips, pending the introduction of new containers [1]. This follows many years of concern around OP issues including Gulf War Syndrome, sheep dips, use of pesticides in humans and similar issues. Celtic Dimensions is able to offer some evidence and ideas around the general area of OPs which could be addressed within the overall inquiry.

Recommendations

1. Provide information on all packaged goods about the OPs used in their manufacture;
2. Establish residue levels and decay of residues for all OP products;
3. Create an awareness campaign of OP issues and not just sheep dip problems;
4. Ensure there are Devolved countries, UK,EU and World exchanges on the OP issues;
5. Co-ordinate activity across Food, Health and Agricultural agencies listed in Recommendation 4;
6. Check on multi-indication products which may be used in food, medicine and hygiene;
7. Develop simple tests for instant diagnosis of problems.

Situation Analysis

OPs are not confined to sheep dips. They are in general use within society for a range of applications (eg home use for insect control, medicines and public hygiene). Links have been established between the use of OPs and neuro-toxic effects. There is a body of literature to support this view and numerous enquiries have been conducted.

An emerging concern is not just the effect of one OP for one specific use but the general and aggregated use of many OPs in various applications. An illustrative example follows:

EXAMPLE: DICHLORVOS (DDVP)

Dichlorvos is an OP insecticide with contact, respiratory and stomach action. Like many OP insecticides it also inhibits the enzyme cholinesterase, which disrupts the nervous and muscular system. [2]

It has been widely available since 1955:

It has a variety of uses:

— Insecticide for agriculture, horticulture, aquaculture;

— Insecticide for home use (> 50 branded product available[3]);

— Drug treatment for WHO programme to treat schistosamiasis (river blindness) in developing countries as metrifonate. It converts to Dichlorvos once it has been metabolised in the liver;

— Possible drug treatment for Alzheimer's disease as metrifonate [4].

The efficacy of Dichlorvos is not in dispute.

The safety of Dichlorvos is problematical. Some of these concerns follow:

— The list of prescribed [sic] substances, derived from the "Red List" of substances most dangerous to the aquatic environment, included a number of pesticides approved under the FEPA [Food and Environment Protection Act]. These pesticides are Dichlorvos (12 others listed) [5];

— WHO Class 1 Pesticides list has classified circa 80 pesticides, including Dichlorvos, as "1b—Highly Hazardous". Many organisations, donor agencies and countries have taken steps to reduce or avoid altogether the use of pesticides in these categories [6];

— Carcinogenicity is seen as a potential problem.

Two major internationally recognised classifications of potential carcinogens are commonly referred to: IARC (The International Agency for Research on Cancer) and USEPA (the US Environmental Protection Agency)

IARC list Dichlorvos as a Group 2b—Possible carcinogenic to humans [7];

USEPA lists Dichlorvos as a Group C—Possible Human Carcinogen (limited evidence of carcinogenicity in animals in the absence of human data) [7];

— Dichlorvos was being tested on students as part of contract clinical trial work by a commercial laboratory. This started an investigative journalism campaign in the Guardian [8] [9] and was commented on in the medical press;

— Clinical trials in the treatment of Alzheimer's disease were halted by the FDA and the developer on the grounds of muscle weakness in a small number of patients. A few of these patients also needed respiratory support.

CONSEQUENCES

Following the example of Dichlorvos a number of consequences could follow for society.

— Exposure several times over in an uncontrolled manner;

— Identified potential risks of cancer, respiratory distress, muscle weakness and general neuro-toxic problems;

— Possible re-ingestion via food chain;

— Toxic overload by sheer amount of exposure. It is not implausible to think of an agricultural worker using a pesticide in their job, a medicine for their health, an insect spray for domestic hygiene and ingesting OPs via their food. Additionally they could be exposed to airborne droplets as a result of other farms spraying;

— If residues are not excreted they may be passed on via breast milk or reproduction.

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Reference	*Type*	*Details*
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	Publication	Farmers Guardian
	Issue	
	Date	10/03/00
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2	Title	Dichlorvos (DDVP)—A hazardous organophosphate
	Author(s)	Pesticides Trust
	Publication	Pesticides News—Fact Sheet (reprint)
	Issue	29
	Date	9/95 (still currently issued)
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3	Title	Dichlorvos & combinations—Insecticides
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4	Title	Drugs to treat Alzheimer's disease
	Author(s)	T Stone & G Darlington
	Publication	Pills, potions, poisons—How drugs work
	Issue	1st edition
	Date	2000
	Page(s)	145–6
5	Title	Guidance on safe disposal of waste pesticides used for non-agricultural purposes
	Author(s)	Health & Safety Commission
	Publication	The safe use of pesticides for non-agricultural purposes—COSHH 1994—Approved code of practice
	Issue	1st edition
	Date	1995
	Page(s)	41–2
6	Title	WHO Class 1 pesticides
	Author(s)	WHO
	Publication	Via The Pesticides Trust "List of Lists"
	Issue	Current
	Page(s)	9
7	Title	Carcinogens—IARC Evaluated Pesticides
	Author(s)	International Agency for Research on Cancer (IARC)
	Publication	Via The Pesticides Trust "List of Lists"
	Issue	Current
	Date	1999
	Page(s)	10
8	Title	Students are paid to eat pesticides
	Author(s)	John Vidal
	Publication	Guardian
	Issue	
	Date	30/07/98
	Page(s)	1
9	Title	More students are paid to eat pesticides
	Author(s)	John Vidal
	Publication	Guardian
	Issue	
	Date	4/08/98
	Page(s)	4
10	Title	Bayer halts trial on metrifonate Alzheimer drug
	Author(s)	Steve Stecklow
	Publication	Dow Jones News
	Issue	
	Date	23/09/98
	Page(s)	

APPENDIX 9

Memorandum submitted by Mr Evan Jones (B 9)

I was a sheep-farmer and used licensed sheep dips under the statutory dipping orders. Like hundreds of others, I have been diagnosed as having suffered a wide range of damage as a result of exposure to OP sheep dips. I stopped farming in 1992 and sold my farm in 1995. The prognosis is that I will not be able to work again.

The mass-poisoning of sheep farmers took place under the supervision of the manufacturers, MAFF, the HSE, The Veterinary Products Committee and the Veterinary Medicines Directorate. The Medicines Control Agency should also have been involved, but apparently it carried out no monitoring of the contents of sheep dip during most of the period that OP sheep dips have been used. The manufacturers and the Government agencies were well aware of the dangers of OP sheep dips and were well aware that people were suffering permanent damage but no action was taken. Not only were farmers not informed of HSE report Medical Series 17 but neither were their medical practitioners. This raises serious questions over the conduct of not just the manufacturers but also the HSE and MAFF.

The report of the Royal Colleges of Physicians and Psychiatrists on organophosphates concluded that the symptoms experienced by victims were real but the Government continues to try to deny this. Research by the Institutes of Occupational Health and Occupational Medicine came to similar conclusions and that the damage was measurable and was widespread but the Government has tried to deny this also, despite having funded the research, approved the protocols and the researchers.

There is no need for organophosphate sheep-dips. Sheep scab had been eliminated from Britain without the use of OPs. This is in stark contrast to the utter failure of the massive use of OPs under the Scab Elimination scheme from the 1970s until 1992. This points to OPs being inefficient sheep-dips under commercial farming conditions. There are sheep-dips which are licensed as being effective and which are based on less hazardous compounds. MAFF also licensed some farmers to use home-mixed dips that contained no dangerous compounds. MAFF must have satisfied itself that those mixtures were effective. So there is no need for OP dips.

OP sheep dips should not reappear on the market until all of the following conditions have been met:

1. That effective treatment is available to all of the individuals who have been damaged by OPs and those who might be damaged in future;
2. That the research currently underway at Porton Down into the effects of OPs on primates should be reported and the results subjected to public appraisal. That this research must involve the use of the unstable formulations that were in use until they were ordered off the market by the Government in 1993;
3. That the research currently being planned as a result of the Committee on Toxicity report on Organophosphates has been completed and the results subjected to public appraisal;
4. That there has been a full public inquiry into the entire issue of the licensing of OP sheep dips. The inquiry should consider why OP sheep dips were licensed despite the regulatory bodies' knowledge of the damage being done to sheep farmers and other workers. The inquiry should also consider why epichlorohydrin, a known carcinogen, was used to dip the British sheep flock and why HMG has not drawn this exposure to the notice of farmers and their doctors, and why epichlorohydrin was disposed of by pouring it into holes in the ground from which it would inevitably enter the water supply. Epichlorohydrin was eventually withdrawn from sheep dips and MAFF has stated that this was because of its carcinogenic qualities. The inquiry should consider why propylene oxide continues to be used in OP sheep dips despite being a known carcinogen;
5. That it is a legal requirement that OP sheep dips must carry a complete list of the ingredients;
6. That section 118 of the Medicines Act has been removed from the Statute book;
7. That responsibility for licensing veterinary medicines that involve human exposures should be the sole responsibility of the Secretary of State for Health in England.

21 March 2000

APPENDIX 10

Memorandum submitted by the OP Information Network (B 11)

In the report published in 1994 by the VMD Appraisal Panel for Human Suspected Adverse Reactions to Veterinary Medicines (SARs), under the heading "Conclusions and Recommendations", the report says:

> "The Panel noted that a number of SARs had occurred as a result of accidental contamination while dispensing the concentrated dip. As a result the Panel reviewed the containers of OP dip products currently on the market, and recommended to the VPC that companies should review the effectiveness of the container design. Discussions on the improvement of the container design are underway between the HSE and the companies concerned".

(As far as we can ascertain there is no report in existence on the outcome of such discussions).

In January 1995 the VPC reported to MAFF, it said:

> "The Appraisal Panel had considered a number of SAR reports where exposure resulted from handling a sheep dip container . . . and being splashed when dispensing the concentrate. Samples of sheep dip containers were obtained from license holders and examined."

(No report of the outcome of these examinations is available.)

Again, in the 1995 VMD SARs report, on p xiv it says:

> "The Panel were informed that all the companies/dip manufacturers had made progress in improving the design of sheep dip containers, to minimise the risk of spillage."

(There are no reports of improved dip can designs being accepted by HSE, VMD or VPC.)

In the 1999 report of the study carried out by the Institute of Occupational Medicine (Edinburgh) into sheep dipping it states that the main source of contamination and resulting ill-health comes from splashing of OP dip concentrate on the hands of dippers. It is clear that this is due to the dip can design.

When MAFF Minister, Jeff Rooker MP, responded to the IOM report, in July 1999, (see *Hansard*), he again recommended that manufacturers should be asked to submit improved designs of dip cans. This was five years after the original requests from the VMD and VPC.

By November 1999 Baroness Hayman had replaced Jeff Rooker, and she again asked for new designs to be submitted. As we now see, such requests had been made repeatedly with no apparent success, and for the manufacturers and other organisations to attempt to behave as if such requests come as a new and surprising request is less than honest.

It would be important to enquire into what discussions had actually gone on between the manufacturers and the HSE in 1994, and the VPC in 1995.

We are delighted to see that the Select Committee is at last looking into detailed questions of safety and protection for workers exposed to OP dips, and suggest that you might look into the Institute of Occupational Medicine reports of 1993 and 1994[2] into the effectiveness of recommended protective equipment. This was commissioned by the National Office of Animal Health, and has received no attention so far, although its conclusions are very important, and should be taken seriously.

14 March 2000

APPENDIX 11

Memorandum submitted by the Veterinary Laboratories Agency, Weybridge (B 12)

Research into perceptions of risk surrounding OP dips shows the importance of targeting risk communications to ensure their effectiveness.

An investigation into the perceptions of risk that different interest groups hold surrounding organophosphate (OP) sheep dips by Reading University, in conjunction with the Veterinary Laboratories Agency (VLA), Weybridge and the Institute of Food Research, Norwich has revealed shared as well as distinct concerns over the use of OP sheep dips. The findings demonstrate the importance of targeted risk communication relating to future policy decision making surrounding OP sheep dips.

The interview study, driven by a recognition of the importance of relevant and salient communication in determining effective policy outcomes, focused on an exploration of the differences in perceptions of risk surrounding OP sheep dips held by farmers, experts and the public.

Illustrative Results from the Main Study

Initial findings from the main study, included here for your interest, illustrate differences and similarities in the views expressed by farmers and members of the public.

Sheep farmers (n = 44) and members of the public (n = 39) were interviewed in three locations; Berkshire, Norfolk and Wales. The preliminary results described are for farmers (n = 15) and public (n = 15) in Berkshire, results for Norfolk, Wales and all experts (n = 33) are currently being analysed.

Views Expressed by Farmers*

Farmers interviewed described OP dips as more effective than available alternatives as they had a longer effect as well as being less expensive than other treatment options. Further they described them as the preferred choice in terms of animal welfare, as a way of controlling scab, which was "on the increase".

[2] (*Occupational Hygiene Assessment of Exposure to Insecticides and the Effectiveness of Protective Clothing during Sheep Dipping Operations*, Niven *et al*, February 1994, IOM Edinburgh, Report TM94/04).

Human health issues were also important to farmers, with two of the farmers interviewed expressing their view that there was a definite link between OP dip use and ill health effects to the user. Three people described effects, which they believed to be due to the use of OP dips, as sub-lethal or acute, using terms such as "dipper's flu".

Farmers expressed a lack of trust in the chemical companies producing OP dips saying that their motivation was profit. Also stated was the idea that farmers did not always follow dipping procedures and precautions and that regulations, such as the Certificate of Competence, were effective and necessary.

Views Expressed by Members of the Public*

Members of the public expressed concerns that OP dips may adversely affect sheep health. Whilst the view was expressed that the benefits may out weigh the risks surrounding its use, issues raised included the possibility of trauma for the sheep and the potential for residues of OPs in meat for consumption and/or wool products. In addition risks to both aquatic and terrestrial ecosystems were highlighted.

Members of the public were divided over a link between OP dips and ill health of user that effects to farmer health, in particular sub-lethal long term effects were described as well as uncertainty surrounding a potential link between OP dips and ill health which was hard to prove.

Use of the Preliminary Findings

The initial findings demonstrate clear differences in the perceptions of risk surrounding OP dips between farmers and members of the public.

Full analysis of the results of this study and a follow up quantitative study will examine what determines differences in perceptions of risk and how different groups balance concerns of human health and animal welfare. This information will then be used to examine determinants of difference in the perceptions of risk held and the need to account for such determinants in decision making.

Action Following the Temporary Withdrawal of OP Sheep Dips

In response to the temporary withdrawal of OP sheep dips on 20 December 1999 a telephone study has been initiated to investigate reactions of the farming community to the withdrawal. The results of this study are expected to be available within the next four or five weeks. If you are interested in seeing the results of this particular exercise please contact the author.

16 March 2000

*These findings are taken from full results held by the House of Commons Library and the Record Office in the House of Lords.

APPENDIX 12

Memorandum submitted by the Organophosphate Information Network (OPIN) (Scotland) (B 13)

Introduction

OPIN (Scotland) has been set up to look after the health interests of those individuals suffering ill health as a consequence of exposure to organophosphate chemicals. We estimate that approximately 500 people in Scotland have had their health affected by such exposure.

Regretfully at no stage of the time OPs have been under licence has there been available proper diagnosis or treatment of patient's symptoms. The symptoms listed in the Health and Safety Executive MS 17 are those common to OPIN (Scotland)'s Members.

It is quite grotesque that this neglect of farmer's ill health has been allowed for so long. The Royal Colleges of Physicians and Psychiatrists Report clearly identifies this problem and recommends the setting up of centres with experts in various medical disciplines to care for suspected OP patients.

I enclose a copy of OPIN (Scotland)'s recent Petition (Annex 2) to the Scottish Parliament for your information.

OPIN (Scotland), and its members, are concerned that OP Sheep Dip will be re-licensed before proper and acceptable diagnostic and treatment facilities are in place to deal with possible future victims of accidental or careless exposure.

Furthermore OPIN (Scotland) is concerned about the legal implications for litigation for any ill health caused by future exposure through spillage or inhalation from the re-designed containers. OPIN (Scotland) wishes to know who or what agency will be approving the re-designed container for use.

As the VPC, HSE and VMD failed to ensure a safer container was produced by the manufacturers in 1994 when the problem was first identified it will not be appropriate for them to be associated with the approval

procedure. It is not known how many workers have had their health damaged through exposure since the failure of these agencies to have a safer container produced.

However the threat of exposure lies beyond simply opening the container. OPIN (Scotland)'s members have revealed other areas of exposure not considered. Under new regulations regarding the preparation of animals for abattoirs lambs and sheep have to be cleaned. The area in question is the crotch high in lanolin. OPs by their very nature hold onto fat. Most lambs are dipped 14 days before going to the abattoir. The contact shearers have with OP residue in the wool is a constant threat to their health. No guidelines have been laid down for this exposure threat. In addition workers in the abattoir (including MAFF vets), when skinning the carcasses, handle the wool. Several OPIN (Scotland) members health is attributed to their contact with OPs in this way. There are no guidelines in effect for these workers. Until this is properly investigated it is important OP dips are not re-licensed. Unless this issue is resolved ignorant workers' health will be under threat. The re-designing of a container will not help them.

OPIN (Scotland) is taking this matter up with the Trade Unions representing farm and abattoir workers.

Threat to Health

The Committee is no doubt aware of the recommendations of Lord Zuckerman in 1951 and HSE MS17 in 1980 that workers exposed to OPs on a regular basis should have their blood cholinesterase levels measured pre and post exposure. The Committee is also probably aware that these recommendations were never enforced. They must be before any re-licensing of Ops is even considered. Every worker coming into contact with OPs should have their cholinesterase levels tested prior to any re-licensing of OPs.

Licensing Procedures

It is also vital that the licensing procedure must be examined. It does not work towards assuring users that a product is safe to use. As previous Committee Reports state the aim of the licensing practice is to ensure the "safety, efficacy and quality of the product towards human beings and animals". No one, apart from producers, has faith in the present system.

We submit that a system that relies solely on the data of producers is unacceptable towards enforcing these aims of "safety, efficacy and quality".

The evidence is there for all to see:

1. it is alleged epichlorohydrin, a carcinogenic, was removed in 1981. No studies were carried out then or since on users to see if any individuals had been affected by exposure to the mixture. A system that allows companies to include such a toxic chemical and to withdraw it without any investigation is unscientific and unacceptable;
2. it is claimed phenols were withdrawn from the OP dips in 1993. The circumstances are incredible:
   (i) the VPC request data from the producers;
   (ii) the producers, en masse, withdraw phenols from the dips;
   (iii) the producers do not submit the data;
   (iv) the VPC does nothing, it does not:
      (a) ask the producers for data;
      (b) ask the producers why they all did this together;
      (c) ask why the phenols were removed;
      (d) research the effect phenols were having on the OP (diazinon); and
      (e) research the effects of phenols and OP as a mixture on users.

A licensing system which allows producers to dictate the rules is not a competent licensing system. A product cannot be safe because the producers claim it is. It can only attain the standards of "safety, efficacy and quality" if it has undergone rigorous safety checks by an effective licensing authority.

A persistent theme of all the reports of the nineties is the recommendation that additives in OP dips be researched to discover whether the toxicity of the OP product is increased. This recommendation by respected scientists and included in the recent COT Working Party Report has never been put into action. All kinds of chemical additives are used to ensure OP products are stabilised and yet are never researched to analyse their toxicity. This is unacceptable and must be rectified before any re-licensing of OP products takes place.

Adverse Reaction Reporting

The COT Working Party Report was highly critical of the lack of substantive data on OP patients submitted by the various Adverse Reaction Schemes. It was held to be of no value. Sufferers could have advised this. They have absolutely no faith in the various schemes and have no wish to co-operate with them.

A proper and independent adverse reaction scheme must be set up to competently, clinically investigate the reports. It cannot be right that the VPC are responsible for both the licensing and the assessing of ill health. On an ethical basis it is suspect that such a scheme is still in operation. Who on earth is going to find evidence that the product they have licensed is a threat to health of those using it?

Until a proper effective scheme is set up OPs should not be re-licensed. Furthermore representatives of sufferers should have a seat on the panel for sufferers to have faith in the operation of any scheme.

Alternatives to OPs

It is not imperative that OPs should be re-licensed. I enclose a letter (Annex 1) from an OPIN (Scotland) member who is a contract dipper and shearer as well as a substantial sheep farmer. His is the common sense approach which has been missing from the debate. The entirely safe alternatives should be used that are no threat to health. The submitting to the whinings of the chemical companies and various other bodies demanding the re-licensing of OP dips must be avoided.

Decisions taken by officials and scientists who have never witnessed sheep being dipped, never experienced the debilitating ill health as a result of exposure to OPs and never seen a loved one deteriorate physically, emotionally and intellectually are desperately suspect. It is time the defence of the OPs be looked at and sufferers listened to.

No one has ever proved OPs are safe to use or that they do not cause ill health. Until they do, which will be never, OPs should not be re-licensed until all the recommendations of various committees, groups and officials are properly assessed and put into practice to protect the health of future users.

Conclusion

The recommendations that have been avoided are:

1. the toxicity of additives and their influence on the toxicity of OPs should be researched;
2. a competent Adverse Reaction Reporting Scheme should be set up separate from the VPC/VMD;
3. an acceptable diagnostic and treatment arrangement should be set up separate from the NPIS;
4. the licensing system should be investigated and re-organised to ensure it is not the producers dictating the system;
5. a statutory testing system should be instituted for all workers using OPs as recommended by Lord Zuckerman and the H&SE; and
6. GPs should be given training in the diagnosis of OP related ill health.

These recommendations should be instituted prior to any re-licensing of OP dips to ensure farm workers and dippers are properly protected from exposure to OP dips. The health of workers is far more important than the health of sheep whose welfare can be efficiently managed with alternative methods.

However, the most important issue is the way in which the VPC licenses medicines such as OPs. It cannot be allowed to continue to base its decisions on the basis of data submitted by the producers. There has to be greater scientific analysis of the products by independent scientists prior to licences being granted. With the widespread availability of Gas Chronograph machines it would not be difficult or delay the decision on licensing.

I would like the opportunity to address the Committee on this issue.

Annex 1

Copy of letter to Aberdeen Press and Journal from Mr George Simpson

SHEEP DIPS

SIR,

I write regarding the story (the *Press and Journal,* 22 December) in which the chairman of the Scottish NFU's livestock committee, Malcolm Morrison said organophosphorous dip (OP dip) provided the most cost effective treatment for scab. He also said that its continued availability was absolutely essential for the health and welfare of our sheep. This is not the case; it is not absolutely essential for the health and welfare of our sheep, as there are other, safer products on the market which are said and proven, to do the job just as well—for example, non-organophosphorous dip and injectables.

As one of the 800 recorded sufferers of OP dip, I would like to ask Mr Morrison how much he is involved with the use of this substance, as it seems to have affected his judgement.

I am a contract shepherd working 365 days a year with sheep and am very much in favour of banning OP dips in favour of an alternative.

We may dress up like spacemen (or women) to dip our sheep, but as a sheep shearer, how do I and thousands like me protect ourselves from the residues of OP dip on sheep's wool, especially in a country where health and cleanliness is of the utmost importance.

For four or five days a week, during the winter months, I find myself shearing dirty lambs to present them clean for the abattoir. Many of these lambs reek from the smell of Op dip, and please don't suggest rubber boots, rubber trousers, rubber jacket, rubber gloves, rubber apron and face mask, as there is room for only one fairy on our Christmas tree.

George Simpson,
Kirkland, Forgue

Annex 2

Petition to the Scottish Parliament

DIAGNOSIS AND TREATMENT OF PATIENTS SUFFERING ILL HEALTH FROM EXPOSURE TO ORGANOPHOSPHATES

The Organophosphate Information Network (Scotland) submits this Petition calling on the Scottish Parliament to investigate why the Department of Health has made no effort, over the past 50 years, to provide appropriate specialist referral for effective clinical diagnosis and treatment for those patients suffering chronic ill health through exposure to organophosphate chemicals and furthermore failing to provide training and guidance for General Practitioners to assess and diagnose ill health caused by exposure to organophosphates.

I enclose evidence and opinion supporting the Petition and will be pleased to appear in person to answer any questions the Scottish Parliament may have.

9 March 2000

APPENDIX 13

Memorandum submitted by the British Leather Confederation (B 14)

WITHDRAWAL OF OP SHEEP DIPS—CONCERN OF THE UK TANNING INDUSTRY

We understand that you are inviting comments from interested parties on the issue of the withdrawal of organophosphate (OP) based sheep dips. While not directly involved in the issue, the UK tanning industry—from the point of view of processors of UK sheep skins—has a very strong interest. Not only is the declining quality of domestic raw material a major issue to our members, we also believe that the levels of parasite damage to skins is an indicator of the deteriorating health and welfare status of the national sheep flock.

We therefore thought it would be helpful to send you the enclosed documents which we hope explain and support our views.

(a) a copy of a recent letter sent to Baroness Hayman summarising our concern;

(b) a bar chart tracing the rapid and substantial increase in the level of parasite damage to sheep skins, over the period 1988–95, which covers the period of relaxation and abolition of compulsory sheep dipping in UK;

(c) a further bar chart plus base statistics demonstrating that the level of damage to skins has continued to increase since 1995 (these are from a separate source, using different grades of skins, because the source of the original figures went out of business—with declining skin quality a contributory factor;

(d) a supporting letter from one of the biggest sheep skin traders in UK—with more skins going abroad for processing, the views of the skin export trade are increasingly pertinent.

We hope that these comments are helpful, and if you or the Committee members would like any further explanation, please let me know.

17 March 2000

Letter to Baroness Hayman, Minister of State, MAFF from the British leather Confederation

WITHDRAWAL OF OP SHEEP DIPS—CONCERN OF THE UK TANNING INDUSTRY

I am writing on behalf of the British Leather Confederation to express our concerns at the recent Government decision to withdraw organophosphate (OP) sheep dips. The British Leather Confederation is the trade association for the UK tanning industry and in this role represents a range of sheep skin processors. Our prime concern in this matter is to protect the quality of UK domestic skins, but from a wider perspective we believe that skin quality—in terms of the level of parasite damage found on skins—is a helpful indicator of the health and welfare status of the national flock.

We already have evidence of dramatic increase (by around 60 per cent from 1991–95) in the number of skins damaged by parasites, following the progressive relaxation and abolition of compulsory sheep dipping in the late 1980s and early 1990s. Since then our members have reported that the level of skin damage has continued to increase. Two major sheep skin tanneries have closed in the last five years, and in each case the decline in the quality of raw material was a major contributory factor. Our overriding concern at present is that the withdrawal of OP dips could accelerate this decline and make a difficult situation even worse.

The hide skin and leather sector in the UK regularly makes a positive contribution to the country's balance of payments (between £140 million and £200 million over the last three years in a volatile market) and the sector plays an important role adding value to a by product of the farming and meat industry. The value of the skin is influenced by the final use of the leather, and this in turn is dictated by the original hide and skin quality. In a volatile market, the annual value of UK sheep skins at the abattoir over the last three years has been in the range of £45 million to £130 million. Although influenced by market conditions, the annual loss to the production chain, from farmer to tanner, currently arising from parasite damage, has been estimated at £15 million to £20 million.

Previous sheep dipping regimes and practices—based heavily on OPs—had the effect of controlling not only sheep scab, but also a wide range of other parasites such as blow fly, lice, ticks and keds. Some dips were also formulated to control mycotic dermatitis. Since then levels of parasite damage to skins have substantially increased, and although we are aware of alternative treatments, the OP products still have an important part in the farmer's armoury against parasites for a number of key reasons:

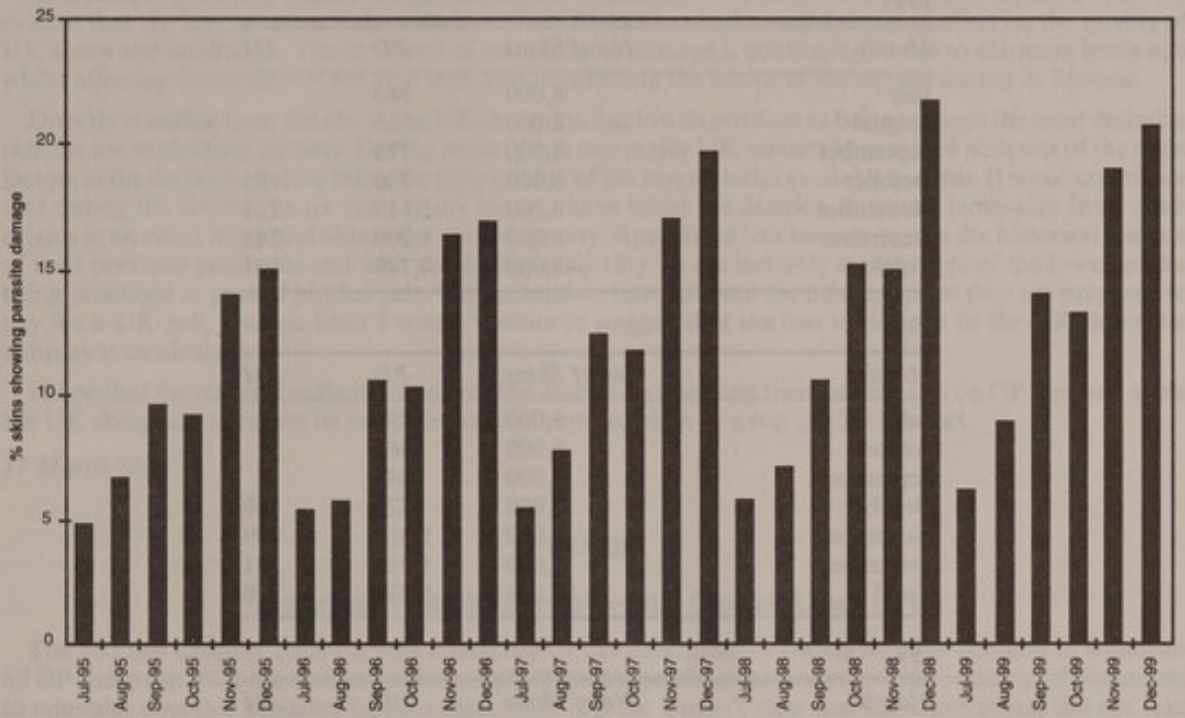
1. they are effective against a wide range of skin parasites, unlike the alternative products which have a more limited spectrum of effect. This also means that accurate veterinary diagnosis is advisable before using any of the alternatives;
2. the OP products can be used prophylactically, to treat and protect animals, whereas the alternatives are essentially treatments, with no significant protective effect, thus potentially allowing early re-infection with, for example, sheep scab;
3. there is more potential for misuse and/or underdosing with the alternative products, and, we understand, there are already instances of parasite resistance to a number of these products;
4. they represent the most economic treatment from the farmer's point of view;
5. while still representing an environmental challenge to sheep skin processors, in discharging their effluent, as well as to farmers, OP compounds are also considerably safer in environmental terms than the alternative synthetic pyrethroid dips which are estimated to be up to 100 times more toxic to aquatic life than the OPs.

While we are aware of certain health and safety issues regarding the OP products, there are well established procedures throughout industry for dealing with hazardous materials and we do not see the OP products as significantly different.

For all the reasons outlined above, we believe that the OP products still have a vital part to play in the control of skin parasites on sheep and that they should be allowed back into circulation as soon as practically possible.

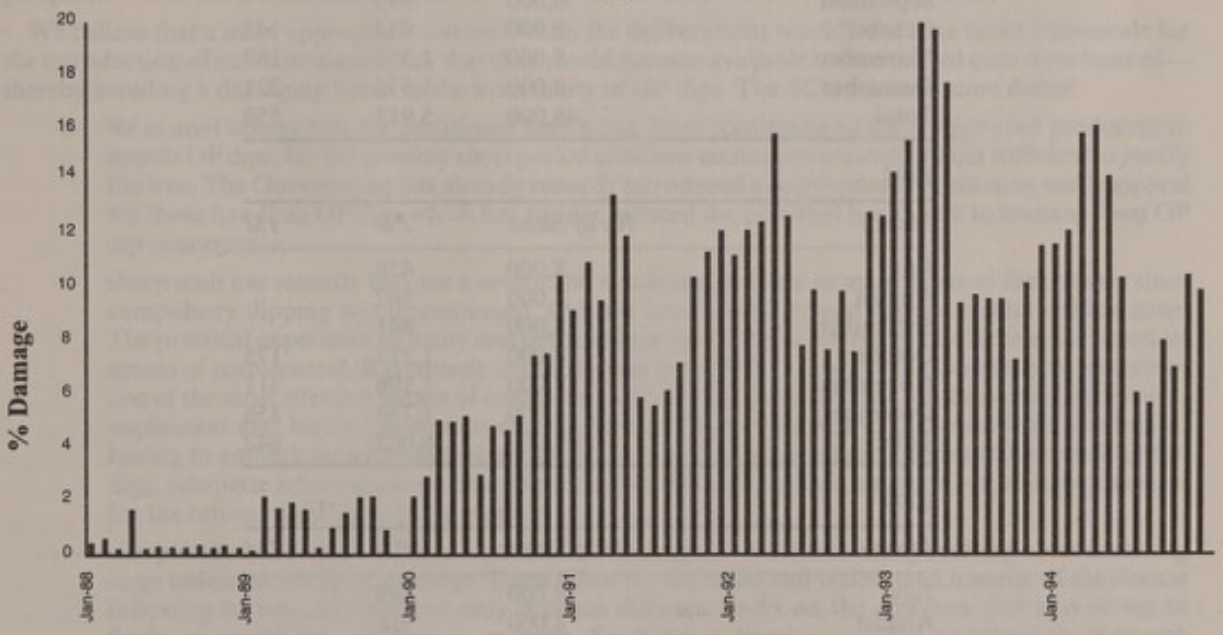
1 February 2000

Raw Materials scar damage found at the pickle inspection
UK Doubleface Crust Sort Fault Analysis
-Skins Showing Parasite Damage (%), n= 8000/month



UK doubleface crust sort fault analysis—skins showing parasite damage (%), n = 8000/month

Raw Materials Scar Damage Found At The Pickle Inspection



Parasitic Damage Stats

UK DOUBLEFACE CRUST SORT FAULT ANALYSIS

1995

Month	*No of Skins*	*PD*	*IM*
July	8,000	386	
August	8,000	535	
September	8,000	775	
October	8,000	736	135
November	8,000	1,117	221
December	8,000	1,200	245
Total	48,000	4,749	601

1996

Month	*No of Skins*	*PD*	*IM*
July	8,000	435	
August	8,000	461	
September	8,000	841	
October	8,000	825	160
November	8,000	1,314	299
December	8,000	1,358	311
Total	48,000	5,232	770

1997

Month	*No of Skins*	*PD*	*IM*
July	8,000	433	
August	8,000	620	
September	8,000	995	
October	8,000	934	142
November	8,000	1,356	187
December	8,000	1,575	221
Total	48,000	5,913	550

1998

Month	*No of Skins*	*PD*	*IM*
July	8,000	458	
August	8,000	562	
September	8,000	841	
October	8,000	1,213	175
November	8,000	1,196	311
December	8,000	1,734	356
Total	48,000	6,002	842

1999

Month	*No of Skins*	*PD*	*IM*
July	8,000	489	
August	8,000	711	
September	8,000	1,115	
October	8,000	1,058	112
November	8,000	1,517	98
December	8,000	1,654	178
Total	48,000	6,542	388

PD = Parasitic Damage
IM = Injection Marks

Letter to the British Leather Confederation from Rudston Products (Int) Ltd

WITHDRAWAL OF OP ORGANOPHOSPHATE DIPS

As a company trading United Kingdom origin Sheepskins both within the UK and wider afield it is very evident that the lack of use and the withdrawal of OP dips has had a very damaging affect on the quality of UK sheep and lambskins. The incidence of ectoparasitic damage is continuing to rise to alarming levels and whilst affecting the quality of the skin may also be affecting the health of the animal during its lifetime.

Directly resulting from the above the UK sheepskin has lost its position as being perhaps the most desirable skin for use in clothing leathers. During recent years two major UK tanners have closed with one of the main factors in the decision to close being the poor quality of the raw material available to them. It is our experience that during the last five to six years many tanners have taken the decision to source lambskins from other origins in an effort to try and obtain the desired quality. Apart from this tanners pay on the historical outturn of their previous purchases and with the decline in quality we are not only seeing more of the lower grades being produced as graded pickled pelts but the tanners have lowered the inherent price they are prepared to pay for a UK pelt. On this basis I would venture to suggest that the loss in revenue to the UK sheepskin industry is incalculable.

I hope that the relevant authorities will see the wisdom in reversing their current ban on OP dips and allow the UK sheepskin to regain its full potential and rightful place as a top quality product.

17 March 2000

APPENDIX 14

Memorandum submitted by the Scottish Crofters' Union[3] (B 15)

The Scottish Crofters Union is very concerned by the government's December 1999 decision to withdraw all OP sheep dip from the market, and to recall all stocks, pending the design and introduction of containers to minimise operator exposure to OP concentrate. It is the Union's view that the Government did not take sufficient account in its deliberations of the impact such immediate action would have on the industry or on sheep welfare, and that its decision is flawed as a result. This bias is not surprising given the expertise and perspective of all the parties involved in drawing up the advice (COT, VPC, ACP, CSM).

We believe that a more appropriate outcome from the deliberations would have been to set a timescale for the introduction of new containers such that they would become available before the old ones were banned—thereby avoiding a damaging break in the availability of OP dips. The SCU views in more detail:

- we cannot accept that the additional health risk from continuing to allow approved producers to handle OP dips, for the possibly short period until new containers are available, is sufficient to justify the ban. The Government has already recently introduced a requirement for training and approval for those handling OP dips which has further reduced the potential health risk to humans from OP dip concentrate;
- sheep scab has recently become a severe and escalating problem in many parts of the country since compulsory dipping was discontinued, and it is clearly a major and current animal welfare issue. The practical experience of many crofters to date is that OP dips are the most effective and practical means of scab control. It is entirely inappropriate in the SCU's view for the Government to remove one of the most effective means of controlling scab at such a critical time for the control of this very unpleasant and highly contagious disease. Crofters have been left in the unenviable position of having to embark on scab control initiatives on an unprecedented scale without the benefit of OP dips, adequate information on the efficacy of alternatives for their situation, or a likely timescale for the return of OP dips to the market;
- sheep scab, once introduced, is a particular challenge to control in many crofting areas featuring large unfenced common grazings. These allow for the rapid and widespread transfer of the disease following its introduction, not only between different flocks on the common, but also across to flocks on neighbouring common grazings. Eradication therefore requires an extremely thorough gathering of these vast areas, and exceptional levels of co-operation between the very many flock owners concerned;
- dipping sheep is no longer a statutory requirement, and there are several alternative treatments available. These facts, taken together with the ample advice available and the new requirements for the training and testing of operators, surely mean that Government need not be concerned about public liability in the event of the misuse of OP dip;

[3] The Scottish Crofters Union has a membership of c 3,300 located in the most peripheral parts of the Highlands and Islands of Scotland. The very poor agricultural quality of their land, the harshness of the climate and shortness of growing season means that hill livestock rearing is the only agricultural option open to the vast majority of crofters. Virtually all of the SCU's crofter members have sheep enterprises, and for most of them this will be their only agricultural enterprise. The viability of hill sheep enterprises is therefore critical to crofters' incomes and to the viability of the many peripheral and economically fragile crofting communities.

— there are already too many constraints on crofters' freedom to manage their sheep in the manner best suited to their own, and their flocks' particular circumstances. Crofters and farmers are now well informed of the risks of careless handling of OP dip concentrate, and of the safeguards required, and the decision on whether or not to use OP dip should be left to their balance of judgement. The Government's OP decision flies in the face of its claims to be doing everything it can to reduce the constraints and regulatory burden on producers;

— the Government's proposals are clearly unjust on producers who have already been forced by other recent legislation to incur substantial expenditure in order to continue to use OP dips. Producers have invested time and money in the training and certification required by recent Government legislation for the use of OP dips. Many producers have also spent money on the approval and registration (and possibly upgrading) of their spent dip disposal sites in response to the recent Groundwater Regulations;

— these costs are relatively higher for crofters with their small flocks, and the withdrawal of OP dips could mean that this expenditure has been effectively wasted—at a time of severe economic hardship in the sheep sector;

— there is a possibility that dip manufacturers and suppliers, themselves currently under severe financial pressure, may decide to pull out of OP dips altogether, rather than meet the cost of developing and introducing new containers for a possibly lower turnover of product. The temporary ban envisaged could therefore conceivably result in a permanent loss of the product.

The rushed process that led to the Government's decision on OP dips is of concern. At the very least there should have been a period of consultation with the industry to ensure a thorough discussion of all aspects to the debate before any decision was taken. Such a period of debate would also have allowed information on the true efficacy of the alternatives to OP dips to be collated, and an information programme prepared for implementation in the event of a ban.

We believe therefore that the Government should, as a priority:

1. review its decision to withdraw OP dips from use in light of advice from this Commons Agriculture Committee enquiry;
2. inform producers of the likely timescale for the re-appearance of OP dip on the market. There has been absolutely no indication of this, so producers do not know whether the required container improvements will be readily met this season or, at the opposite extreme, whether the specification is impossibly high for manufacturers to meet at a justifiable cost;
3. state clearly its views on the future use of OP sheep dips, and indicate the type of future research finding which might cause it to implement a general ban on OPs. Manufacturers, suppliers and producers are understandably suspicious that the current proposal is simply a stalling tactic prior to an ultimate banning of OP dips.

20 March 2000

APPENDIX 15

Memorandum submitted by the National Sheep Association (B 16)

BACKGROUND

The Association has been concerned for a number of years that the welfare of sheep has been compromised by the shortage of products available to the industry to control ectoparasites while causing little or no damage to the environment and to users.

OPs were introduced to sheep farmers as a far more environmentally friendly product than the organo-chlorines which had been in place for some years and which were far more persistent for sheep welfare purposes but because of their persistence were extremely damaging to the environment. The loss of OPs, even temporarily, is serious and in the absence of any other broad spectrum control with protective capability and low environmental impact, a serious hindrance to high welfare sheep keeping.

We wrote to Government on 6 and 10 January 2000 stating our concerns (see Annexes).

Specific reasons for wanting OPs back on the market as quickly as possible

1. There are more external parasite problems in sheep today than at any time since the 1939–45 war. Sheep scab is now endemic and widespread. Lice infestation is growing.

2. Situation has been brought about partly by the confused messages given to farmers by the authorities and the difficulty in developing new product which has low or no side effects.

3. Plunge dipping has long been recognised as the best method of effecting cure, control and protection of sheep from broad spectrum ectoparasite infestation and while this is possible by using formulation based upon synthetic pyrethroids (SPs) those products are far more damaging to the environment.

4. Other products such as endectocides (injections which contain chemical formulations which deal with both endo and ecto parasites) are available but none of these has the same broad spectrum activity on ecto parasites (do not kill all ectoparasites but work selectively) and have the downside effect of restricting marketability of sheep due to relatively long withdrawal periods (sheep keepers wish to sell lambs when they are in prime condition, this state can change dramatically even in 14 days, to have to wait 56 days for the best endectocide is clearly unacceptable). Endectocides do not have the same protective quality as the plunge dips and it is very easy to miss treatment of one or two sheep in a large flock, allowing a reservoir of infestation/infection to be maintained.

5. In order to respond to the danger of using Ops particularly, the only people allowed to use OPs and SPs are those who have demonstrated their ability to deal with these products by obtaining a Certificate of Competence (over 16,000 people so far). Removing OPs at extremely short notice is effectively breaking an act of faith between Government and those people with proven competence.

6. NSA takes the view that OPs, on balance, would seem to have at least as much benefit as any other product available for ectoparasite control in sheep with the least cumulative negative side effects on the environment. Its removal from the market provides no benefit to sheep farmers and is positively harmful. It provides a serious disbenefit to the welfare of sheep and the alternative which has similar properties (SPs) is far more damaging to the environment.

RECOMMENDATION

NSA strongly recommends that OPs are returned to the market as a matter of the utmost urgency and that the dialogue in which the industry is engaged to find safe delivery systems of the concentrate continues to a satisfactory conclusion.

March 2000

Annex 1

COMMENTS FROM NATIONAL SHEEP ASSOCIATION (MARCH 2000) TO GOVERNMENT ON ORGANOPHOSPHATE SHEEP DIPS

Copy of letter to Baroness Hayman dated 6 January 2000

GOVERNMENT ANNOUNCEMENT ON ORGANOPHOSPHATE DIPS

I am writing to inform you that the announcement made on 20 December concerning OP dips is considered by my organisation to be illogical, unreasonable, excessive and against environmental interests, sheep welfare and the peace of mind of producers. For these reasons we ask you to reconsider your decision as a matter of the utmost priority.

We will spell out our thinking as simply as possible.

1. *Against the environmental interests*

The alternative chemical used to control ectoparasites in sheep by the plunge dip method is synthetic pyrethroid. It is common knowledge that SPs are far less friendly to the environment. It is equally important to recognise that the general conclusion of sheep farming organisations* is that the best interests of sheep farmers are served by the maintenance of a wide armoury of products which can be deployed in the most appropriate way. For example, injecticides are suitable for breeding stock and animals kept for relatively long-term storage periods, but are not suitable for animals imminently destined for the food chain. The most effective injecticide having a withdrawal period of some 72 days.

Vitally important to recognise that at this time of year OPs are the favoured products for dealing with sporadic outbreaks of sheep scab and heavy lice infestation. Important also to understand that in disposal of spent dip terms the OP product is the safest option available especially when groundwater levels are at their highest.

2. *Against sheep welfare*

It is common knowledge that the sheep scab mite (psoroptes ovis) becomes most active during cold weather—ie this time of year. It is also well known in farming circles that since the removal of compulsory treatment period for scab that it has become endemic and even though it is unlikely to be recognised officially there is anecdotal evidence of quite massive, probably unprecedented numbers of sheep suffering from scab at the current time. As many of these animals are destined for relatively imminent slaughter it will not be suitable to inject them and as the Synthetic Pyrethroid is not considered by many to be effective the removal of OPs creates a void which is not filled by any other product and will result in a potentially serious welfare problem.

3. *The peace of mind producers*

Several years ago the Certificate of Competence was instituted with close industry co-operation at all levels. To date some 16,000 people have been approved which includes a great number of professional contract dippers. Since its inception the rules have been tightened and extended—again with the co-operation of the industry. An important part of the purpose of the Certificate of Competence was to ensure that people handling the chemical understood that they were dealing with a product which could be hazardous to their own health and to ensure they knew how to deal with it in the most suitable way. The test was taken by sheep farmers to ensure that they would be able to purchase and use the product which they considered to be the most suitable for the purpose of maintaining the welfare standards of the stock in their care. We take the view that the removal of OPs, even on a temporary basis, breaks an agreement of faith between users and Government without there being a suitable and acceptable replacement and this places enormous mental pressure on producers who consequently find difficulty in looking after their stock effectively. With this in mind and with the utmost respect for those who feel that users should be protected from possible exposure whilst opening the dip concentrate container we feel that to withdraw the product for this reason reflects unfairly on the competence of the users. We would also make the point that as it is impossible to remove all elements of risk in life that any assessment of risk analysis associated with container lids should bear this in mind.

4. *An illogical and unreasonable decision*

We would take the view that the best logical progression in this issue would have been to allow the process which had been started to get manufacturers to redesign containers to come to fruition. We understand that one company had provided a suitable system so it would have been far more reasonable in our view to have allowed that company to supply product in its new containers and give time for the other companies to come up to the same standard. The fact that in spite of this company having come up with a suitable design but was not given an immediate green light, smacks to us of a Government bent on imposing its will on an industry which has worked consistently and constructively to achieve an equitable result. Note must be taken of the fact that whichever way we look at it the product used to kill ectoparasites on sheep is likely to be a poison. It is equally a truism that all poisons will have a downside. We submit that OPs on balance would seem to have as much benefit as any other currently available and to have least cumulative, negative side effects.

We conclude that the removal of OPs from the market at this time provides no benefit to sheep farmers and is positively harmful, a serious disbenefit to the welfare of sheep and the potential for an added problem to be visited on the environment. We implore you therefore to reconsider this ill-thought decision, arrange an urgent meeting with the entire industry and re-establish a proper dialogue which takes us forward in a positive way.

*[NSA represents over 80 such incorporated groups throughout UK covering around 15,000 people as well as 11,000 individual farming families.]

Annex 2

Copy of letter to Baroness Hayman dated 10 January 2000

Further to my letter of 6 January on the above subject, I have been advised that I omitted two highly relevant factors concerning Synthetic Pyrethroids:

1. Synthetic Pyrethroids are not effective in controlling infestation of lice;
2. Where Synthetic Pyrethroids are used to control a scab outbreak most of the derivative products require sheep to be dipped twice in order to be effective.

These two issues alone mean that the situation is substantially worse than that portrayed in my letter of 6 January 2000. Effectively it means that the removal of OPs substantially and seriously reduces the ability of farmers to maintain the welfare standards of sheep. It also means that the risk of groundwater pollution by the need to dispose of increased amounts of spent Synthetic Pyrethroid based dips is considerably increased.

My organisation therefore requests an immediate moratorium on the 20 December announcement and also requests an urgent meeting of all parties, including suitable representation from the Environment Agency to find a more sensible resolution to this issue.

APPENDIX 16

Memorandum submitted by the National Office of Animal Health Limited (B 17)

On 20 December MAFF Ministers announced the immediate suspension of all OP sheep dips on the UK market, instructed companies to recover existing product from the market, including farms, by 31 January. The stated reason was a concern that current packaging could result in those opening and pouring from the can becoming contaminated with the concentrate—identified by an Institute of Occupational Medicine

report in July 1999 (on the basis of a 1996 survey) as being the most hazardous part of the sheep dipping process.

We believe that the Government's decision and action was seriously flawed on grounds of legality, timing, communication, justification and consequences and so welcome the Committee's announcement of an enquiry.

1. LEGALITY

There are three ways in which the Government's actions appear questionable:

(i) part of the Veterinary Products Committee's advice in July and November is said to be their desire to see closed transfer systems introduced, citing "Best Industry Practice". According to MAFF's 20 December Press Release, VPC's remit does not extend to the consideration or approval of "Instruments, apparatus or appliances". (There also seems to be some confusion about "industry practice", as closed transfer systems are not used in the Animal Health Industry and there is currently less than five per cent take-up in crop spraying);

(ii) we have challenged the Ministry's ability to instruct companies to recover product from farms. They have powers to instruct removal from "the market", but leading Counsel tells us that the end user is not part of "the market". Nevertheless, companies placed advertisements and sent letters to distributors and farmers during January 2000 and made arrangements to accept any product farmers wished to return to them;

(iii) most seriously, MAFF have not followed their own rules, as laid down by Parliament, in The Medicines Act 1968 Schedule 2 para 2, and the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, both of which state that companies must be informed of the VPC's decision, and given the opportunity to appeal, before the VPC's advice to suspend or revoke a product is sent to Ministers. In a further complication, some statutory letters from VMD to companies advising them of their right to appeal did not reach companies until early February, even through allegedly sent on 21 December.

2. TIMING

The announcement of MAFF's decision on 20 December created a number of needless problems, particularly as neither manufactures, distributors nor farmers had any prior knowledge of the detailed decision:

(i) the closure of Government Departments on 23 December and the subsequent Christmas and New Year holiday meant that great confusion was caused because manufacturers, distributors and farmers could not get urgently needed advice—as a consequence no real action was possible until 5 January;

(ii) for sheep and farmers, the timing was most inappropriate as it suddenly removed from the market an effective, and trusted emergency remedy for outbreaks of scab;

(iii) routine dipping does not occur until April or later, thus the requirement to remove product from farms by 31 January was unnecessarily hasty—a three month period could have been used to develop and implement an agreed, practical and understood process of product recall;

(iv) the choice of a late December announcement, followed by a short deadline, seems particularly unnecessary as the Minister first received advice from VPC in July. If the evidence was not sufficiently dramatic to stop sales or use during the second half of 1999 we have to question why it suddenly became necessary in December, particularly after the publication of the COT report, which was critical of the earlier IOM report on which their decision was apparently based;

(v) so the question is really of the VPC—why did they feel the need to recommend a suspension and recall in November but not in July? We would also note that the VPC report (received second hand by NOAH) makes little reference to the sheep health or environmental consequences of their recommendation. We understand that this is because the report is predominantly a response to specific questions set by the "Official Group" on OPs. However, it must be a matter of concern that the veterinary and environmental experts on VPC apparently failed in their duty to raise these important topics.

3. COMMUNICATION

Compared to previous MAFF practice a number of shortcomings and poor communication have added to the industry's difficulties.

(i) interested parties received no prior advice of the announcement, nor were they invited to the Press Conference and so were unable to use the opportunity to clarify points with Ministers;

(ii) the VPC report on which Ministers based their decision was not published openly, but instead was sent, in an apparently ad-hoc fashion, to some organisations but not others;

(iii) it subsequently emerged that even relevant Government departments were not informed of MAFF's decision (DETR/EA, Scottish Executive Animal Health & Environment sections etc). This added to the confusion as people tried to find out what it meant.

(iv) a particular problem was that it was initially unclear whether, following the suspension of the licences, product became classed as "special waste"—subject to quite different transport and storage rules. Because there did not appear to have been interdepartmental consultation there was no clear advice available for those trying to comply;

(v) normal practice would have been for MAFF to call a meeting to discuss and explain the implications with all affected parties. This did not happen and is the principal cause of much frustration, confusion, bitterness and extra cost;

(vi) according to the VPC report, a letter from the Chairman of the Health and Safety Commission was sent to MAFF during autumn 1999. Although requested, we have not been permitted to see this letter which appears to have been most influential. We understand that this letter resulted from a closed meeting of the Health and Safety Commission. There is no-one with farming or veterinary experience on the Commission, nor have we been able to identify anyone who gave evidence.

4. Justification

While accepting the theory that handling the concentrate is potentially the most hazardous aspect of dipping, we find the arguments for this urgent and drastic action unconvincing:

(i) Numbers of "Suspected Human Adverse Reactions" to OP sheep dips have reduced dramatically, (we have asked VMD to provide us with the latest figures, but have yet to receive them) proving the success of the programme of farmer education and the Certificate of Competence introduced in 1995;

(ii) In particular the number of reports linked to handling the concentrate are understood to be very low;

(iii) For more than 20 years OP dip labels carried special advice on handling the concentrate. This advice is also contained in the joint MAFF/EA/HSE leaflet AS29 (attached [not printed]). In the 1998 review of labelling, industry emphasised the need for the distinction between concentrate and dipwash to remain, pointing out the greater risks of handling the concentrate. We await revised proposals;

(iv) In autumn 1999, VMD called a positive and successful meeting of all interested organisations on how to improve advice to farmers—this resulted in production of 40,000 "plain language" plastic cards which were sent to farmers in November 1999 which again emphasised the need for care when handling the concentrate (see attached [not printed]). Very few farmers will yet have had the opportunity to put this reminder into practice;

(v) The requirement to introduce "Closed transfer systems" is not mentioned in the VPC report of November 1999.

While we accept VPC's advice to Ministers in November 1999 that "more caution" is needed in handling the concentrate, we believe MAFF's hasty action was disproportionate and has resulted in a number of negative consequences, mostly foreseeable.

The Consequences

Since 20 December, a number of concerns have emerged which extend beyond the simple question of operator safety:

1. *Animal health and welfare*

UK sheep are prey to a wide range of debilitating and potentially life threatening parasites which are killed by OPs. Following the decision to end compulsory treatment, sheep scab is now endemic throughout Great Britain. Afflicted sheep are so damaged by the irritation of the parasite that they can stop feeding, lose condition, fertility falls and in extreme cases animals may die or be destroyed.

Blowfly strike, where maggots literally eat the sheep alive, can take hold in a few days, animals die of toxic shock or have to be destroyed. Other parasites, once rare, such as lice and keds, have increased since the end of compulsory dipping.

OP insecticides have a very broad range of activity, thus their use reduces the incidence of many minor parasites as well as scab.

2. *Disease control*

The success of first HCH and then OP dips was not only to reduce the number of scab outbreaks to a minimum, they also reduced a number of minor parasites to the point where many veterinary surgeons only knew of them from text books. Since the end of compulsory dipping, not only scab but many other parasites are also on the increase.

The sudden and unplanned removal of OP dips from the market has left a significant void, with a reduced range from which farmers can choose the most appropriate product to treat their sheep.

3. Farm Costs and the Right to Choose

The ability of the farmer to choose the most appropriate product for his or her own particular circumstances is vital. At this critical time for sheep farming, OP dips are perceived by many farmers as being the most cost effective for them.

According to evidence given by the British Leather Federation to VPC on 7 March 2000, the products' broad spectrum can lead to "added value"; by also killing parasites of minor clinical importance, the sheep skins will be of better quality and increase the value of the animals. Since the end of compulsory dipping the fall in quality of British sheepskins has done serious damage, driving one processor out of business.

Farmers still choose OP dips—15,000 have chosen to undertake the certificate of competence to dip, and, despite 10 years of bad publicity about OPs the proportion of OP dips in all sheep ectoparasite sales is now rising, currently standing at 27 per cent by value, 50 per cent by usage. This rise in OP usage is significant as it demonstrates the continuing faith of farmers in the products to protect the health and welfare of their flocks.

No one has ever been forced to use OPs, and farmers, like all consumers, should have the right to make an informed choice of the right product for them and their animals.

4. Future Supplies of OP Sheep Dips

We were extremely pleased to note from MAFF's press release that it contained no criticism of the product itself, and noted Baroness Hayman's belief that OP dips in new packaging would be back on the market "in time for the next dipping season". While we welcome her confidence and support, it would seem that this is unlikely:

(i) No company heard the VPC's judgement until 20 December and it was not until 24 February that they were able to discuss with VMD/HSE what is expected of them or what "Best Industry Practice" means;

(ii) EU guidelines requires 12 months stability testing for new packaging—even if VMD bend these rules, six months seems likely to be the minimum accepted and then the VPC have to approve the companies' proposals. Once the new packaging is approved, packs will have to be manufactured, filling lines modified etc. A big investment in time and money which, it has been suggested, means that it would be prudent to assume 18 months without OP dips in new packs.

Early in January we wrote to Baroness Hayman urgently requesting a meeting (Annex). We hoped, in particular, for the product re-call to be deferred until proper discussions had been held. Unfortunately it was not possible for her to see us until 10 February—by which time the product had all been collected.

The team which met the minister on 10 February was impressive:

National Farmers Union of England and Wales;

Farmers Union of Wales;

National Farmers Union of Scotland;

National Sheep Association;

Animal Health Distributors Association;

Sheep Veterinary Specialist.

as well as NOAH and representatives of sheep dip manufacturers.

All impressed upon the Minister the desperate potential consequences for sheep health and welfare, potential increased risk to the environment and the likelihood of the licensing rules meaning that it could be 18 months before the new cans were likely to reach the market. All this during "the worst outbreak of scab for a decade" (B Jennings—Animal Health Chairman, NFU).

We are pleased to report that following that meeting there appears to have been a very positive shift in the attitude of officials and two further meetings have taken place:

Firstly, a "technical" meeting between company staff and VMD/HSE officials to "brainstorm" on various solutions to the packaging criticisms outlined by VPC last autumn.

Secondly, a meeting on 7 March between a sub group of VPC and the Farming and Veterinary experts who met the Minister, supplemented by British Leather Federation, to explain at first hand their welfare, environment and economic concerns.

Following these meetings it has been explained to us that VPC will need to review their advice to Ministers before Ministers are prepared to re-consider the 20 December suspension. The anticipated timetable is now an Appeal at the May VPC meeting to propose interim solutions to enable OP dips to return to the market for the autumn 2000 dipping season. During this time development work and testing will continue aimed at placing new packaging and transfer systems on the market for autumn 2001.

Upgrading the "Certificate of Competence"

While the details of improved mechanisms are still to be worked out, one important proposal is already tabled: At the meeting with Baroness Hayman on 10 February the organisation present unanimously proposed that the current requirement for a purchase of sheep dip to hold the official "Certificate of Competence" should be extended:

(a) so that the person in charge of every dipping gang should hold the certificate;

(b) that only certificate holders should be permitted to handle the concentrate when filling or replenishing the dip bath.

Proposal "(a)" was, in fact, the original industry recommendation when the certificate was introduced in 1995; The same concept is contained in the VPC's own report of November 1999 and in the recent report of MAFF's Salmon and Freshwater Fisheries Group, (for environmental reasons).

For reasons we do not understand this widely supported initiative is being blocked by HSE. We would welcome the Committee's support to solve this impasse.

Allegations of Industry Prevarication

In a press statement issued in February 2000 by the chairman of the all party organophosphate group, (attached) Mr Paul Tyler MP alleged that although concerns about sheep dip packaging were raised by VPC in 1994, manufacturers ignored those concerns.

The facts are, as I wrote to Baroness Hayman on 15 February:

> "Following VPC recommendations in October 1994 company representatives met with representatives of HSE and VMD at the NOAH offices on 23 January 1995. Following that meeting companies did make a number of changes to their packaging and I understand these changes were approved by VMD/VPC/HSE. Since then, and in spite of continued official scrutiny of OP dips, no further criticism of packaging has been made by VPC/VMD until summer 1999."

Furthermore (22 February 2000) *Hansard* reported Baroness Hayman, in response to the Countess of Mar, saying "changes in container design were made following the VPC's recommendations in 1994 and 1995"

The allegation that manufacturers ignored VPC advice is untrue, it also impugns not only VPC but also VMD and HSE, by implying that no action was taken to ensure compliance with VPC's requirements.

Conclusion

While we welcome the recent progress following our meeting with Baroness Hayman on 10 February, this episode raises a number of important concerns, many of which have wider relevance. In chronological order.

1. The Health and Safety Commission's decision to interfere in the licensing process by writing a letter to Ministers which has yet to be published and which was produced without affected parties (manufacturers, veterinarians or farmers) being invited to give evidence—a breach of natural justice if nothing more;
2. Veterinary Products Committee—deliberately structured to comprise a wide range of scientific disciplines—producing a report to Ministers which focused only on operator safety without advising Ministers of the consequences for animal health and welfare, or the environment;
3. Following the decision to suspend these products on 20 December:
   (i) The demand to withdraw product from the market, and from farms (questionable in law) within 20 working days;
   (ii) The failure of Ministers or officials to call, or agree to requests for an urgent meeting so that an agreed plan of action could be constructed and queries answered;
   (iii) The failure of officials to follow clear legal procedures by not advising Marketing Authorisation holder of VPC's decision and to give them the right to appeal before that advice was sent to Ministers.

In short, while we believe that a shift to new types of packaging which will reduce the risk of operator packaging is desirable, we believe the announcement and the transitions to new packaging could have been better handled and that the consequent confusion, costs and risks could have been avoided.

We welcome the Committee's decision to hold an enquiry and would be most pleased to provide further written or oral evidence.

23 March 2000

Letter to Baroness Hayman, Minister of State, MAFF, from the Director, National Office of Animal Health Ltd

OP SHEEP DIPS

Further to my fax of 24 December, I am now writing to express industry concerns over both the content and handling of the MAFF announcement on 20 December, to request an urgent meeting involving all those who will have to live with the consequences of the announcement and, pending that meeting to request that your announcement is itself suspended so that a proper dialogue can commence and a jointly agreed programme be put in place.

The MAFF decision could have serious consequences for animal health and welfare, disease control, environmental pollution and the economics of sheep farming in the UK, although we note that none of these points were referred to in MAFF's press release.

HISTORICAL BACKGROUND

May I remind you of two previous decisions taken by MAFF which also seemed to be taken without Ministers being advised of the wider consequences and which have undoubtedly laid the foundation for the mess we all find ourselves in today.

Prior to 1984 the dominant insecticide used in sheep dips was HCH (Lindane)—highly successful both in its control of sheep parasites and its persistence, giving long term protection to sheep, it also had low human toxicity. However in 1984 the French government were looking for excuses to block British sheep exports (plus ca change?) and latched on to the British use of HCH Dips. To appease the French, MAFF officials spoke individually to each sheep dip manufacturer, telling each that "everyone else" had agreed to a voluntary ban. This manoeuvre succeeded and HCH dips were withdrawn from the British market. (It subsequently emerged that the French had outsmarted our officials and that HCH dips continued to be used in France for many years!) This was also the first recorded case of British officials preferring to impose decisions on UK farmers without taking the trouble to find out what was really happening on the other side of the Channel. As a result of MAFF's appeasement of Paris, within 12 months 95 per cent of the UK market was taken by OP dips.

During the late 80's two themes emerged; campaigners started to focus on OP's, while the Conservative government was looking for things to de-regulate and money to save. In the late 80's it seems that officials advised Ministers that these two challenges could be solved at once; and end to compulsory dipping would disarm the critics of OPs while at the same time reducing bureaucracy and government costs. The officials counselled an approach of stealth—firstly the compulsory dipping regime was steadily slackened, then, when sheep scab numbers started to rise the regime could be scrapped altogether as being ineffective. Finally, to cover up the inevitable consequences, the notifiable status of scab was ended, so that there would be no official figures to embarrass MAFF by recording the massive explosion of disease which sheep vets rightly forecast.

MAFF's files will confirm the considerable protests which arose from all parts of the sheep community. Much as farmers and industry hate bureaucracy, this was one of the few pieces of red tape which had the support of many farmers, merchants, vets and manufacturers because of its success in keeping scab under control and the very great fear of this devastating disease. Nevertheless the official view prevailed, compulsory dipping was scrapped and not only is Scab now endemic throughout Great Britain, but many minor parasites which were virtually extinct have also re-emerged.

I apologise for the lengthy introduction, but it is important that you understand the background, both to the present situation on the farm and the reasons for the industry's widespread distrust of officials on the subject.

THE CONSEQUENCES

Returning to 20 December, a number of concerns have emerged which extend far beyond the simple question of operator safety:

1. *Animal Health and Welfare*

UK sheep are prey to a wide range of debilitating and potentially life threatening parasites. Following the previous government's disastrous decision to end compulsory treatment, sheep scab is now endemic throughout Great Britain. Afflicted sheep are so damaged by the irritation of the parasite that they can stop feeding, lose condition, fertility falls and in extreme cases animals may die or be destroyed.

Blowfly strike, where maggots literally eat the sheep alive, can take hold in a few days, animals die of toxic shock or have to be destroyed. Other parasites, once rare, such as lice and keds, have increased since the end of compulsory dipping.

OP sheep dips have the widest range of efficacy against ectoparasites affecting sheep.

While a wide range of alternative products have been developed by the industry in recent years, none have the breadth of activity of OP insecticides.

2. *Disease Control and Resistance*

The success of first HCH and then OP dips was not only to reduce the number of scab outbreaks to a minimum, they also reduced a number of minor parasites to the point where many veterinary surgeons only knew of them from text books. Since the end of compulsory dipping and the introduction of a wide range of highly effective, but more specific, alternatives not only scab but many other parasites are also on the increase.

According to the NFU (*Farming Today* 22 December) resistance to both synthetic pyrethroids and to the avermectin family of endectocides already seems to be emerging on British farms. Removal of the OP products, which currently serve 50 per cent of the British market, can only force a greater reliance on the remaining scab treatments and an inevitable acceleration in the spread of resistance. Was this pointed out to you by officials?

3. *Environmental Pollution*

It is important to remember why OP products came into use for dipping—they were seen as "kind" to the environment when HCH dips were withdrawn in the mid 1980's. Now there is more choice for farmers, but every product has its advantages and disadvantages and SP dips, for example, have been cited as being a potentially greater environmental hazard if disposal instructions are not followed properly.

We discovered on Tuesday 21 December that the relevant experts in the Environment Agency and the Scottish Environmental Protection Agency were totally unaware of MAFF's announcement and expressed to us their grave concern that the removal of OPs from the market would inevitably lead to farmers, who traditionally prefer dipping, switching to SP dips. Did your officials tell you of environmental concerns about SPs, and that the Environment agencies had not been party to their advice?

4. *Farm Costs and the Right to Choose*

The ability of the farmer to choose the most appropriate product for his or her own particular circumstances is vital. At this critical time for sheep farming, OP dips are perceived by many farmers as being the most cost effective for them. The products' broad spectrum can lead to "added value": by also killing parasites of minor clinical importance, the sheep skins will be of better quality and increase the value of the animals.

Farmers still choose OP dips—15,000 have chosen to undertake the certificate of competence to dip, and, despite 10 years of bad publicity about OPs, the proportion of OP dips in all sheep ectoparasite sales is now rising, currently standing at 27 per cent by value, 50 per cent by usage. This rise in OP usage is significant as it demonstrates the continuing faith of farmers in the products to protect the health and welfare of their flocks.

No one has ever been forced to use OPs, and, before this news, there was a very wide choice of products available. Farmers, like all consumers, should have the right to make an informed choice of the right product for them and their animals.

5. *Future Supplies of OP Sheep Dips*

We were extremely pleased to note from your press release that it contained no criticism of the product itself, and noted you belief that OP dips in new packaging would be back on the market in time for the next dipping season. While we welcome your confidence and support, it would seem that here too you have been very badly advised.

(i) As explained in my fax of 24 December, no company heard the VPC's judgement until 20 December and even now have not been permitted to discuss with VPC what is expected of them or what "Best Industry Practice" means;

(ii) I am told that VMD rules require 12 month stability testing for new packaging—even if VMD bend their own rules to extricate themselves, six months seems likely to be the minimum accepted and first the VPC have to approve the companies' outline proposals. Once the new packaging is approved packs will have to be manufactured, filling lines modified etc. A massive investment in time and money which, in my experience, means that it would be prudent to assume 12 months without OP dips in new packs.

It would also be prudent for you to check with each company whether they intend to proceed with the packaging project.

THE WAY FORWARD

Finally, may I turn to the announcement on 20 December to suspend licences and demand that companies withdraw all products from farms before 31 January 2000:

(i) We have Leading Counsel's opinion that VMD have no authority to require product to be withdrawn from farms;

(ii) We question the need for this to be done by 31 January. As the main dipping season will not commence until April, three months notice would have allowed all concerned proper time to discuss and agree a plan of action;

(iii) Companies have been reminded that they have three months in which to appeal—supposing their appeal is successful, will MAFF re-imburse companies for the needless expense involved in unnecessarily gathering up product from the market? (And farms).

Logic would indicate that the deadline for collection should be move to 31 March to allow proper time for dialogue and for those companies who wish to appeal.

We understand that the reasoning behind the decision to suspend licenses is because of fears that farmers using existing cans could become contaminated while filling or replenishing the dip bath.

(i) We agree that this is potentially the most hazardous task in the dipping operation. It has been known for decades that contact with the concentrate was the most likely cause of OP poisoning. For this reason dip labels have, for over 20 years, contained advice on the use of extra protective clothing "when handling the concentrate". In this respect the IoM report said nothing new;

Interestingly, following VPC advice in February 1997 that labelling should be reviewed, in August 1998 VMD put forward proposals which had been modified so that there was no longer any distinction between the warnings on handling of concentrate and diluted dip. NOAH urged them to revise this so that the warnings on concentrate were more prominent, reflecting the greater risks in handling concentrate (followed up in writing on 13 August 1998).

Sixteen months later there is still no news from VMD/VPC on revised labelling for sheep dips.

(ii) While agreeing with the theory, we note that in real life the number of adverse reactions reported to be linked to contact with the concentrate are very low. This would appear to indicate that farmers are conscious of the dangers and are taking precautions, thus demonstrating that the Certificate of Competence and other education methods are working;

(iii) In spite of this good record, in July, following IOM/VPC advice and a proposal from AMTRA, VMD called a meeting of all interested parties and proposed a "plain language" plastic card should be sent to all sheep farmers. The wording was agreed and 40,000 copies were sent out in November. Not only was this a great expense to VMD (and hence the tax payer) but there were also considerable costs to those organisations such as AMTRA and RSPGB who voluntarily assisted with the distribution (AMTRA alone spent over £1,000);

(iv) One peculiar aspect of this recent saga is that we understand that VPC are intent on requiring companies to introduce a "closed transfer system" ie some mechanisms which will link the can to the dip bath. We were interested to read in the MAFF press release that the remit of the VPC specifically excludes "instrument, apparatus or appliance". Thus it would appear that, in insisting on a closed transfer system and in ruling on the suitability of company proposals the VPC were acting without authority;

(v) This pressure on companies, as explained to them by officials, to introduce "closed transfer systems" is even more peculiar as the VPC report of November 1999 make no mention of "closed transfer systems".

The Report does recommend "more caution" in the handling of concentrated dip (5.3) and we would suggest that the laminated notice positively noted in the Report (6.9) goes a long way to achieve this.

Compared to the recommendation for withdrawing current packaging the VPC report is remarkably mild . . . "not because existing containers are inherently unsafe when used in accordance with instructions but

because we believe that using them presents difficulties in handling, particularly when wearing the recommended gloves . . ."

Logic would indicate that there is no specific need to suspend the current packaging on operator safety grounds. Operators are well trained, advice on handling concentrate has been issued for many years. New advice was issued in November and adverse reaction reports are very low.

As outlined above, the summary removal of products which currently supply 50 per cent of the market will have inevitable consequences for animal health and welfare, disease control and farm economies.

We do recognise the need to improve packaging but cannot comply until VMD/VPC have explained what is required of companies. In the meantime there is likely to be a period of up to 12 months before new packs emerge.

For all the above reasons we believe that the advice you have been given is seriously flawed. Therefore the suspension of licences should be lifted and these useful farming tools should be allowed to remain on the market for an agreed period so the transition to new packs can be conducted in an orderly and trouble free way.

Finally we request that you convene an urgent meeting involving the relevant farming, veterinary and distribution groups so the widespread concerns can be explained to you at first hand.

7 January 2000

APPENDIX 17

Letter to the Committee Chairman from the National Association of Agricultural Contractors (B 18)

I am writing to you as Chairman of the Agriculture Select Committee as I understand you are holding a short enquiry on the withdrawal by MAFF of OP sheep dips pending the introduction of new containers.

Our members dip or spray a large proportion of the sheep dipped or sprayed in the UK. Before the banning of OPs in their present containers virtually all our contractors used OP sheep dips as the most effective against scab. OPs also pose much lower levels of risk of water pollution compared with the synthetic pyrethroid alternative. No NAAC members that dip or spray sheep have had any symptoms of OP poisoning. Our experience suggests that OP sheep dip concentrates handled by trained operators are not a risk to the user.

There is now a potentially serious animal welfare problem until new containers are approved. In addition the risk of water pollution by the use of SPs is much increased.

Prior to effective banning of OPs only trained operators could purchase OP concentrate. There were no restrictions on who could use it and this may have contributed to MAFF's decision.

Since we can demonstrate that in the hands of trained operators there is little risk from using OPs in existing packaging, would it not be possible as an interim measure to allow the continued use of OPs in existing packaging, providing it was only used by trained operators.

17 March 2000

APPENDIX 18

Memorandum submitted by the Environment Agency (B 19)

1. Introduction

The Environment Agency's primary aim is to protect and improve the environment and to make a contribution towards the delivery of sustainable development through the integrated management of air, land and water. The Agency does this through regulation and enforcement but also by influencing and educating industry, landowners, farmers and others to reduce environmental impacts of their activities.

The Agency supports all necessary measures to protect farmers from harm arising from the use of sheep-dip chemicals. It also recognises the necessary use of veterinary medicines to maintain sheep health. However, these chemicals can also harm the environment and therefore the Agency is concerned to ensure that full account is taken of this, when policy decisions are being made on their availability and use. This memorandum provides a commentary on the actual and potential impact of sheep-dip chemicals on the environment, the work the Agency is doing to ensure that this is minimised and suggests how organophosphate (OP) sheep-dip use can be managed to protect the environment.

2. Availability and Toxicity of Sheep-Dip Compounds

At present the only cost effective substitutes for OP dips are synthetic pyrethroids (SP) dips. Whilst these are less toxic to humans, SP dip compounds are typically 100 times more toxic to many forms of aquatic life, than are OP dips.

3. Impact on the Water Environment from Sheep Dipping Activities

Prior to 1996, when SP dips were not used widely, the Agency recorded relatively low numbers of water pollution incidents (less than 15 per annum) and there was no apparent widespread damage to the water environment from sheep-dips. After 1996 and because of human health concerns, there was a switch to SP compounds. Following this switch there was an increase in the number and the severity of water pollution incidents and in 1996 about 200km of rivers, including very valuable salmonid fisheries, were damaged.

In 1997 and in 1998 this damage continued. Of the 61 sheep-dip related pollution incidents that occurred in these two years, 38 were confirmed as involving only SPs and a further 16 were due to a mix of OP and SP dips. Surveys in Wales suggested that at least 750km of watercourses were impacted in 1997 and 1,200km in 1998. In particular, impact was noted on invertebrates, which are a vital part of the food chain for salmonid fish, mammals and bird life. Similar findings on a smaller scale were recorded in North West England.

In 1999, there was a large reduction in the use of SP dips. The National Office of Animal Health and Entec UK (a consultancy) have estimated that in 1999 OP dips were used for about 50 per cent of treatments and SP dips for less than 10 per cent. Other treatment options, including injected compounds, made up the balance.

The Agency is completing the collation and analysis of the pollution incidents that occurred in 1999. Preliminary results indicate that there has been a marked reduction in pollution incidents from sheep dipping. Only six incidents were confirmed in 1999, and all of these were from the use of SP compounds. Monitoring in Wales during 1999 has shown that the environmental impact of sheep-dips on rivers was less than in previous years.

Thus there is clear evidence over a number of years that SP dips pose a significant risk to the environment and that the risk from other options, including OP dips, is much less.

4. Agency Actions

Although there is strong evidence that SPs present a high risk to the environment, the Agency has not sought the withdrawal of licenses for SP sheep dips, because of the human health concerns associated with OPs.

Instead, it has concentrated on:

- raising awareness of the hundred fold greater environmental toxicity of SP as compared to OP dips;
- improving guidance;
- investing how changes to flock and dipping management can reduce the need to dip sheep and, where this is still required, what practical steps can be taken to reduce the risks to the environment.

In 1998 the Agency developed a sheep-dip action plan and in 1999 it published a sheep-dip strategy that contains 29 recommendations and actions to minimise the environmental impacts of dipping sheep.

The Agency has also commissioned Entec UK Ltd to prepare a guide for farmers on better flock management, in liaison with a wide range of individuals and organisations involved in sheep dipping. This guidance could have wider benefits to sheep welfare (less sheep infested), farm business (reduced costs of treatments), benefits to the environment (less dipping and less used dip for disposal) and operators (less exposure to sheep dip compounds).

5. The Way Forward

The Agency understands the industry view that OP compounds have a role to play in the effective control of sheep ectoparasite infestation at the present time.

In the short term, the Agency considers that the continued availability of OP dips is required if damage to the environment from SP dips is to be contained. In the longer term, it is essential to develop alternatives to both OP and SP dips in order to reduce the risks to both human health and the environment.

The Agency supports and extension of the Certificate of Competence for sheep dipping to include proper disposal of used dips. However, this certificate relates to the purchase and not the use of sheep dip chemicals. There is no requirement for the holder of the certificate to be present during the dipping operations. The Agency will be discussing this issue further with the Veterinary Medicines Directorate with a view to ensuring that the competence requirements relate to those carrying out the dipping activities rather than to the purchasers of dip.

The Agency is concerned about the lack of consultation that took place prior to the suspension of OP dip licenses in December 1999. The Agency has statutory responsibilities for both environmental protection and waste handling and yet was not involved or consulted in anyway before the decision to suspend OP dips.

The Agency does not think that there is adequate consideration of the environmental risks posed by veterinary medicines under the current authorisation procedures. The membership of the Veterinary Products Committee (VPC) could be usefully extended to include a further environmental scientist.

The Agency believes that there is a requirement for further research into a number of issues relating to sheep dipping activities. It supports the proposals for a targeted research programme and will participate as appropriate. This should not delay implementation of current best practice wherever possible.

6. CONCLUSIONS

6.1 The Agency supports the Government's proposals to provide greater protection for sheep dip operators.

6.2 Agency investigations have confirmed sheep dipping to be a serious risk to water quality. Sheep dip chemicals can have a significant impact on the water environment.

6.3 Practices involving sheep dip compounds have been poor, but there is evidence they are improving. Nevertheless the Agency believes that dipping as currently practised is unsustainable and cost effective alternatives need to be developed in the medium to long term.

6.4 The number of recorded pollution incidents match the usage of SP dip compounds. There were 34 incidents in 1997 and six in 1999, and the quantity of SP's as a percentage of total sheep dip compounds for the relevant periods was 38 per cent and 10 per cent respectively.

6.5 This suggests that whilst improved management by farmers may be sufficient to deal with the risks to the environment from OP compounds, it is not sufficient when using SP compounds.

6.6 The Agency was not consulted over the OP dip suspension. Given our statutory responsibilities to protect the environment it is imperative that we are fully consulted in future.

6.7 The Agency thinks that the environmental risks posed by veterinary medicines are not adequately considered by the authorisation process. The membership of the Veterinary Products Committee (VPC) could be usefully extended to include a further environmental scientist.

6.8 The Agency supports the proposed targeted research programme and will participate as appropriate. This should not delay implementation of current best practice whenever possible.

23 March 2000

APPENDIX 19

Evidence submitted by English Nature (B 20)

INTRODUCTION

1. English Nature is the statutory body responsible for advising both central and local government on nature conservation and for promoting the wildlife and natural features of England. In fulfilling its duties, English Nature:

- advises Ministers on the development and implementation of policies for nature conservation;
- advises Ministers on other policies affecting nature conservation;
- identifies, notifies and safeguards Sites of Special Scientific Interest (SSSIs);
- establishes, maintains and manages National Nature Reserves;
- provides guidance and advice on the principles and practice of nature conservation to a wide constituency;
- commissions and supports research and other projects relevant to nature conservation.

2. Through the Joint Nature Conservation Committee, English Nature works with sister organisations in Scotland, Wales and Northern Ireland to advise Government on UK and international nature conservation issues. English Nature has a lead agency role on pesticides and toxic substances on behalf of the other conservation agencies. This response also represents the views of the Countryside Council for Wales.

BACKGROUND

3. An environmentally sustainable sheep farming industry is an important component of the maintenance of both upland and lowland habitats of importance for nature conservation. The safety and well-being of the sheep flock is a vital part of this, and the effective control of parasites is an essential component of good flock management. Serious environmental problems have arisen from current methods of parasite control. Any future proposals which lead to changes to the management of parasites in sheep flocks will need to take account of the consequential environmental risks, and must also consider the need to maintain the structure of sheep farming on which nature conservation depends.

4. English Nature wishes to stress the nature of the environmental risks associated with the sheep dipping, and particularly the implications for nature conservation. The environmental risks differ for

organophosphate (OP) dips and the synthetic pyrethroid (SP) dips which are used as alternatives, and in particular there is evidence that the aquatic risks are significantly greater where some of the SP dips are used.

Toxicity of Dip Active Ingredients

5. Cypermethrin, one of the widely used SP dips, has a toxicity to the freshwater crustacean *Daphnia magna* some 100 times greater than the OP diazinon at the concentrations used in dip solutions. The Environmental Quality Standard (that is the concentration in surface waters below which it is thought not to harm aquatic life) for cypermethrin is 100 times lower than that for diazinon. The toxicity of cypermethrin to other aquatic crustacea and insects can be several orders of magnitude greater than its toxicity to daphnia. Other SPs such as flumethrin are less toxic to daphnia than cypermethrin or diazinon, but aquatic insects may again be more sensitive, due to the general sensitivity of insects to the synthetic pyrethroid insecticides.

6. Dips may be disposed of onto land, where they can pose a risk to terrestrial invertebrates and to vertebrates, such as wildfowl, grazing on treated vegetation. Earlier work has shown the toxicity of the organophosphate dip propetamphos to some groups of terrestrial invertebrates when applied to land (Coulson and Goodyer 1990), whilst there have been poisoning incidents involving wildfowl grazing areas used for the disposal of OP dip. Unlike the OP dips, SP dips are less likely to cause avian wildlife incidents due to their lower avian toxicity. However, their likely effects on terrestrial invertebrate populations, and hence indirectly on bird populations through affecting their invertebrate food supply, are less well understood. English Nature is undertaking a joint research project with the Countryside Council for Wales and the Environment Agency to determine more accurately the risks to birds and invertebrates through disposal of both OP and SP dips to land.

7. In summary, due to their intrinsic toxicity to invertebrates, the SP dips pose serious risks to aquatic life. In the case of cypermethrin this risk is several orders of magnitude greater than the OPs. At present, the relative risks to terrestrial invertebrates are less clear cut, although the SPs are likely to present a lower risk to grazing birds.

Incidents of Damage to Aquatic Wildlife Due to Sheep Dip

8. Problems of aquatic pollution incidents involving sheep dip have been occurring for many years. An increase in the number of pollution incidents was recorded in 1997 (Environment Agency 1998), and there were then several serious incidents involving SP dips, although some incidents also involved OP dips. Typically, stretches of river 5-10 km long may be affected by declines in invertebrate populations following an incident, but much larger effects have been recorded and recovery, where it has been measured, has been variable. In Wales, it was estimated during the 1998 survey that up to 1,200 km of upland water courses could potentially be affected, and it was concluded that sheep dip is the largest single known cause of impoverishment of fauna in upland rivers due to pollution (Environment Agency 1999a). During that survey, all but one of the substantiated incidents confirmed as being due to sheep dip were due to synthetic pyrethroids.

9. The effects of dip incidents have been most marked on the highly sensitive groups of aquatic insects. However, there have also been serious incidents involving other invertebrates, such as white-clawed crayfish which is a species listed under Annex II of the Habitats Directive, and for which a recovery programme exists under the UK Biodiversity Action Plan. Such incidents have affected a number of Sites of Special Scientific Interest (SSSIs) such as the rivers Wye and Eden. These rivers have also been selected under the Habitats Directive as Special Areas of Conservation (SACs) for this species, as well as for Annex II fish such as salmon which depend on healthy invertebrate populations for their survival. Other rive SACs affected by incidents involving SP sheep dip include the River Ehen in Cumbria, which is the only SAC selected in England for the freshwater pearl mussel. There has been a severe impact on invertebrates in this river, and some impact on juvenile pearl mussels; the implications for recovery of populations of this very long-lived species are uncertain.

10. The increase in incidents involving SP sheep dip coincides with a major shift from the use of OP to SP based dips after the mid 1990s. One of the factors which may have contributed to this shift is the widespread concern over health risks to users of OP pesticides (Environment Agency 1999b). An earlier report (Environment Agency 1998) suggested that one of the major reasons for the environmental problems arising from sheep dipping arises from a lack of farmer awareness, and the need for improved standards of dip installation and sheep management. The implementation of the 1998 Groundwater Regulations, and the requirement for authorisation of dip disposal routes is likely to raise awareness of the environmental risks involved during dip disposal. However, incidents have been attributed to both disposal and use of dip, including dripping from sheep into watercourses after treatment. There is currently no legal requirement for all those involved in dipping to hold a certificate of competence.

CONCLUSIONS

11. The current restrictions on the use of OP sheep dip products, pending further action on container design, will clearly lead to greater use of alternatives including SP products. Rather less is known about the environmental risks associated with the widescale use of other treatments such as pour-on and injectable products, but some of these may also enter the environment and affect wildlife through residues in dung. It is very important that where action is taken on the grounds of protection of human health, users are not misled into a false appreciation of the relative environmental safety of alternative methods of parasite control. English Nature urges the Agriculture Committee to recommend wider user education and suitable training on the environmental risks associated with parasite control, and in particular with dipping practice, as a part of any recommendation it may make on human safety grounds.

REFERENCES

Coulson JC and Goodyer S (1990). The effects of the insecticide propetamphos on invertebrates of grassland. Report by Durham University to the Nature Conservancy Council.

Environment Agency (1998). A Strategic Review of Sheep Dipping. ADAS report to Environment Agency. R&D Technical Report P170.

Environment Agency (1999a). Welsh Sheep Dip Monitoring Programme, 1998. Report from the Environment Agency Wales and Midlands Regions.

Environment Agency (1999b). Sheep Dip Strategy. Environment Agency R&D technical report p237.

28 March 2000

APPENDIX 20

Letter to Committee Chairman from Mr Paul Tyler, MP, Chairman, All Party Organophosphate Group (B 22)

Thank you for the opportunity to submit a very brief note to your Committee for its current inquiry. As you know, our Group comprises some 75+ MPs and Peers, with officers from all sides, and we have worked together for nearly eight years. I have not been able to consult all my colleagues on the content of this note, in the short time available, but I am confident that they would broadly agree with its recommendations.

We understand that your present concern is with the temporary withdrawal of OPs, pending improvements to the design of containers, to minimise danger from concentrates. Our remit is much wider, of course, but we acknowledge the value of your inquiry since it raises very important issues.

In particular, the line of questioning of Austin Mitchell and Michael Jack (as one would expect from a former Agriculture Minister!) of Baroness Hayman on 11 April exposed the basic truth of this sad saga; for very many years the inherent dangers of exposure to OPs (especially but not exclusively in concentrate form) have been known; for almost as many years the necessary protective and preventative advice and action has not been forthcoming; and each time new constraints, restrictions or warnings have been introduced this has involved a tacit admission that these were not previously adequate.

Therefore, the action taken by the present Minister before Christmas 1999 could scarcely be considered precipitate. Not only had a series of negotiations over container design taken place in 1994–95, but also a Ministerial meeting in July 1999 specifically highlighted this issue. If the manufacturers were not aware of the urgent need to improve safety after all this, and the Institute of Occupational Medicine Report too, they must have been deliberately courting the current impasse.

This is the real issue. Many sheep farmers now suspect that the huge chemical companies who produce and sell OP products have little interest in their long-term future. The sheep dip market is relatively small. What they are clearly interested in is avoiding any legal or moral liability for past negligence. If they can *claim* that they have had to withdraw these products from use because of unreasonable Ministerial requirements for rapid changes to the containers, and their action is for *economic* and *practical* reasons, they might escape the consequences of their past failures.

Indeed, they could even blame the Government for any cost or animal health penalties that fall on the sheep sector.

In short, they may be trying to browbeat both Ministers and the industry *either* into accepting the continuation of OP use, with a continuation of easy profit margins on a long-established product, or moving smartly on to new, safer products when these industrial giants are ready to do so, at greatly increased unit cost, without admitting to any liability for past OP damage to users' health.

That is why your Committee's inquiry is so crucial. Any failure to appreciate its wider significance could postpone or undermine the whole investigation of the OP problem, the animal health, human safety and basic economics of the sheep sector and the legal liability of the various players in this sorry saga.

17 April 2000

APPENDIX 21

Supplementary Memorandum submitted by the National Office of Animal Health Ltd (B 24)

On 11 April the Committee interviewed Baroness Hayman, Professor Aitken and Mr Anderson of MAFF. The internet transcript raises a number of points which we believe require further clarification or comment and, as we understand the Committee will not be asking us to give oral evidence, we set them out below using the paragraph numbers of the transcript for reference.

(A) Handling the Concentrate—the Need for Urgency?

In paragraphs 2-13 there are a number of references to the need for additional care when handling the concentrate. However, neither Committee members nor MAFF make the point, emphasised in our earlier document, that the need for this extra care is not a new revelation, but has been included in the advice on levels of OP sheep dip and MAFF/HSE leaflets since the mid '80s.

This is highly relevant to Mr Austin Mitchell's very pertinent question in Paragraph 14: "What I want to know is why so suddenly?". A question at the core of the whole issue.

Members will recall, for example, that the concerns over *current* containers and the risk of contamination when handling them to dispense concentrate was first highlighted by IOM in their *1996* on-farm survey—IOM did not, apparently, think it of urgent importance, but simply included it in their 1999 report to MAFF (a two and a half year delay). MAFF in turn did not take immediate action on receipt of that report, but allowed those containers to remain in use throughout the second half of 1999—even though, it will be remembered, Mr Jeff Rooker, MP, summoned sheep dip companies to MAFF to express concern in July 1999.

A further complication arising from the IOM report is that, with their farm enquiries taking place in 1996, it is unclear whether the containers they criticised were those updated by companies in 1995 following VPC discussions, or whether some of them were old stock, pre-dating those changes.

All subsequent comments by VPC, CoT etc, on pack design are based on IOM's 1996 survey.

(B) Alternative Formulations

In paragraph 35 Professor Aitken comments on the possibility of using new developments in crop spraying technology, such as water soluble sachets. Without wishing to go into great technical detail, it should be recognised that there is a considerable difference between the relatively simple task of formulating a weed-killer or insecticide for application to leaves or soil, and the great challenge of formulating an ectoparasiticide so it can penetrate several inches of greasy wool to reach the parasites living at skin level. (The sheep's coat has evolved to very effectively repel water—which is why they can survive in the British climate). To achieve this task requires the inclusion of solvents and emulsifiers in the dip formulation. Unfortunately these same chemicals have serious effects on conventional plastic containers, water soluble sachets etc. May we assure the Committee that sheep dip companies, many of which are also involved with crop spraying, would have switched to such packaging technology many years ago if it had been a practical proposition (not least because current sheep dip cans are more expensive than the plastic alternatives).

This explanation is also relevant to Mr Anderson's incorrect statement (paragraph 89) that sheep dip formulations have not been tested in polyethylene containers.

(C) Communication with Companies

In paragraphs 51 and 52 there is discussion on Mr Drew's enquiry about when companies knew of the suspension decision. While it is true that Mr Rooker warned companies in July of the potential for a suspension, as Baroness Hayman explained, this was dependent on their failure "to come up with alternative solutions". During summer and autumn 1999 companies developed alternative proposals which they believed met MAFF's requirements. These proposals were presented, in good faith, to VPC at their November meeting. However, it was not until 20 December that companies were told of VPC's rejection of those proposals.

Up until 20 December companies had every reason to believe that their proposals would be accepted. The "shock" on 20 December was thus in three parts:

- that the proposals had been rejected,
- that there was no offer of further discussions on how to improve the proposals,
- that instead an immediate suspension was introduced.

While Baroness Hayman is correct (paragraph 52) in stating that she met with industry representatives and subsequently arranged further meetings, her reply might have been more complete if she had explained that her meeting with industry was not until 10 February and followed a number of letters and faxes from NOAH and others requesting an *urgent* meeting.

(D) HSC Intervention

In paragraphs 80 and 125 there is reference to a letter to VPC from the Chairman of the Health and Safety Commission. As indicated in our earlier memorandum we had no prior knowledge of this letter, nor indeed, that HSC were discussing the topic. It must be a matter of great concern both to natural justice and the current drive for "transparency" that the HSC did not consult affected parties before formulating their advice to VPC, nor have we, even now, been allowed to see the full letter.

VMD did, on our behalf, ask HSC if we could be shown the letter, but were only permitted to release extracts.

(E) Market Share of OPs

In paragraph 91 and elsewhere Professor Aitken discusses NOAH's estimate that 50 per cent of sheep were treated with an OP dip. For clarification I should explain that our estimate is that of all UK sheep treated with some form of ectoparasiticide, 50 per cent were treated with an OP dip—the remaining 50 per cent being divided among a wide variety of treatments—SP and other dips, injectables, pour-ons etc. Most of these have a much narrower spectrum than OPs and most are ineffective against all three of the major parasites—scab, blowfly and (of growing importance) lice, unlike OPs. It would therefore be wrong to imply that the switch from OPs to products making up the other 50 per cent would be easy or without negative implications.

(F) Finally, may we welcome the news (paragraph 93) that the State Veterinary Service is to look at welfare issues affecting sheep in general and the monitoring of sheep scab in particular. This is very good news and I have written separately to the Chief Veterinary Officer offering our assistance.

We hope the Committee will find these additional comments of assistance and would be very pleased to provide further information if that would be of assistance.

3 May 2000

AGRICULTURE COMMITTEE REPORTS IN THE CURRENT PARLIAMENT

Session 1997-98

FIRST REPORT, MAFF/Intervention Board Departmental Report 1997, HC 310, published on 16 December 1997.

SECOND REPORT, CAP Reform: Agenda 2000, HC 311-I, published on 25 February 1998.

THIRD REPORT, The UK Beef Industry, HC 474, published on 3 March 1998.

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Printed in the United Kingdom by The Stationery Office Limited
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