

MAVIS

MEDICINES ACT VETERINARY INFORMATION SERVICE

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■ DEFRA AGENCY REVIEW

The report of the review of Defra's science-based executive agencies was published following a Ministerial statement on 17 December 2002.

The review, which was announced on 26 March 2002, had the following terms of reference:

"To evaluate the effectiveness of the operation of Defra Agencies, with regard to the Departmental aim and objectives and their relationship with the Department and the sectors they serve."

In making his statement Lord Whitty strongly endorsed the review's recommendations. He said that:

"Defra should fully recognise and acknowledge the unique scientific contribution which the laboratory agencies make to our work and I hope that implementation of the review will firmly establish their position as world class suppliers of scientific services to government in their respective fields."

"The regulatory agencies have a different but equally important role in applying science in their licensing and policy work and I welcome the review's recommendations which confirm their status and suggest ways of strengthening their role and links with Defra."

A copy of the report "Defra Agency Review Science for Sustainability" is available on the VMD website www.vmd.gov.uk under Publications.

Further information: Chris Bean, Director of Corporate Business, VMD (01932 338331, e-mail: c.bean@vmd.defra.gsi.gov.uk).



CONTENTS

News	2
Licensing	5
EU	7
Suspected Adverse Reaction Surveillance Scheme	8
Veterinary Products Committee	9
Residues Controls and Monitoring	13
Marketing Authorisations	27

The best available information on the work of the VMD can be found on our on-line MAVIS service www.vmd.gov.uk



INVESTOR IN PEOPLE

The Veterinary Medicines Directorate
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
Tel: (01932) 336911 Fax: (01932) 336618
web: www.vmd.gov.uk
e-mail: postmaster@vmd.defra.gsi.gov.uk



ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

■ FEES FOR THE LICENSING OF VETERINARY MEDICINAL PRODUCTS IN 2002/2003

Some 700 interested parties were consulted on the proposal to increase fees for 2002/2003 by 2.5% in line with inflation.

Copies of the letters received in response to the consultation can be obtained from the main Defra library at Nobel House, 17 Smith Square, London, SW1P 3JR (telephone 020 7238 6573).

Following the end of the consultation period on 25 September 2002 Ministers were informed of the comments received. After due consideration Ministers agreed that the revised fees should be introduced. The Medicines (Products for Animal Use-Fees) (Amendment) Regulations 2002 came into force on 1 November 2002.

A copy of the VMD's letter of 1 November announcing the new fees has been placed on the VMD's website. A summary of the comments to the public consultation, is included in the letter. A copy of the Regulatory Impact Assessment relating to these Regulations is available from the VMD.

Further information: Veronica Vanstone (VMD, 01932 338372, e-mail: v.vanstone@vmd.defra.gsi.gov.uk).

■ MANUFACTURERS AND DISTRIBUTOR'S FEES

On 30 January 2003, a consultation document was published on proposals to amend the fees payable under the Feedingstuffs (Zootechnical Products) Regulations 1999 (the ZP Regulations) and The Medicated Feedingstuffs Regulations 1998 (the MFS Regulations). The consultation document is published on the VMD website and copies can be obtained from:

Further information: Martin Tustin (VMD, 01932 338312, e-mail: m.tustin@vmd.defra.gsi.gov.uk).

■ PROSECUTIONS

- At Shrewsbury Magistrates Court on 28 October Mr Herbert John Michael Batkin pleaded guilty to Offences under Regulations 32(1)(a), 23(1)(a) and 32(1)(d) of the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997, relating to the keeping of records of veterinary medicinal products administered to animals under his care. He was fined £2,000 and ordered to pay costs of £350 for each of the two offences to which he had pleaded guilty. Two further charges under the above Regulations were withdrawn on the basis of his guilty plea to the first two charges (see also the sulphonamides entry on page 14).
- At South East Suffolk Magistrates Court on 25 November 2002, Mr Keith Foster of Gayne Prospero Ltd pleaded guilty to 11 counts of placing unauthorised veterinary medicinal products on the market under Regulations 3 and 16 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994 (as amended). Mr Foster was ordered to pay costs of £250 and was given a one-year conditional discharge.

■ THE GOVERNMENT'S RESPONSE TO THE RECOMMENDATIONS OF THE INDEPENDENT REVIEW OF DISPENSING BY VETERINARY SURGEONS OF PRESCRIPTION ONLY MEDICINES (THE MARSH REPORT)

The Government's formal response to the Marsh Report was published on 10 December 2002. If you are interested in reading a copy of the response, we have made it available on the VMD website www.vmd.gov.uk under 'Independent Review of Dispensing' 'Formal Government Response'.

Further information: Mandy Jones (VMD, 01932 338320, e-mail: m.jones@vmd.defra.gsi.gov.uk).

■ MALACHITE GREEN

Following the item on the Farming Today programme of 23 November 2002 in respect of malachite green the VMD wishes to reinforce some of the points made by John FitzGerald during the interview and add some further information. Several of these points were contained in the Defra Press Release on malachite green issued on 11 June 2002. This can be found at www.defra.gov.uk/news/2002/020611c.htm (SEERAD and DARD also issued press releases.) This note also explains the results of further testing undertaken on samples of home produced and imported farmed fish in recent months.

- Malachite green is not listed as a veterinary medicine under Annexes I, II or III of Council Regulation 2377/90/EC, and its administration for that purpose is therefore not permitted in aquaculture.
- Fish farmers cooperated fully with the Government early in the summer of 2002 to stop the use of the product.
- The Government has taken scientific advice from independent advisory committees over the past eight years on the use of this product to ensure that the interests and the health of consumers are protected.
- The Government recognises that there are continuing concerns about its potential effect on human health, and is closely monitoring the long-term toxicological studies of malachite green currently taking place in the USA.
- Malachite green has been used extensively by the aquaculture industries in Europe and throughout the world for many years in the absence of any authorised veterinary medicine alternative. It has proved particularly effective at protecting the welfare of farmed fish.
- A veterinary medicine alternative to malachite green called "Pyceze" has now been developed in the UK with the assistance of funding from the salmon and trout industries and Defra. The active ingredient of this new product, "bronopol" was permitted by the EU for use in the treatment of fish for the first time last year. This alternative to malachite green is now being used by the fish farming industry in the UK and in some other countries.
- The VMD has granted a provisional marketing authorisation for Pyceze and we are currently assessing additional efficacy data provided to support the application for a full marketing authorisation. In the meantime Pyceze is available for the treatment of fish and their ova under veterinary prescription.
- As indicated in Defra's Press Release of 11 June, the European Commission was kept fully informed of the arrangements for withdrawing use of malachite green in the UK. The Commission is also investigating the position in other Member States and in countries exporting farmed fish into the EU.
- The VMD is open and transparent in its operation of their residues surveillance programmes. Testing for malachite green in UK farmed fish is carried out in accordance with EU statutory requirements in terms of the number of samples taken and the targeting of those samples to detect abuse.
- Further sampling of home produced and imported farmed fish was carried out in the second half of 2002. Residues of leucomalachite green above the Limit of Detection of 2µg/kg were found in 4 out of 93 samples of Scottish salmon. These were at concentrations of 2.8µg/kg, 10µg/kg, 10µg/kg and 13µg/kg. These are consistent with the concentrations found in the UK's statutory surveillance programme in previous years and reported to the Commission on an annual basis. 24 samples of GB trout farmed tested negative. These concentrations of leucomalachite green are unlikely to pose a risk to human health.
- A total of 62 samples of imported farmed fish were tested. 2 samples from the Faroe Islands contained concentrations of leucomalachite green at 10µg/kg and 11µg/kg. One of those samples also contained malachite green at a concentration of 0.8µg/kg. Defra's Chief Veterinary Officer has written to his opposite number in the Faroes inviting him to investigate the matter. This concentration of malachite green is unlikely to pose a risk to human health.
- All results are reported in MAVIS on-line (www.vmd.gov.uk) and in annual reports on residues surveillance. In keeping with other Member States our statutory surveillance results are sent to the Commission on an annual basis, and has included farmed fish following their introduction to the statutory surveillance programme in 1999. The VMD's and FSA's surveillance work is overseen by the independent Veterinary Residues Committee.
- The FVO commented on the use of malachite green following their mission to the UK in April 2002. The UK's full response to the draft of the FVO report can be seen through: europa.eu.int/comm/food/fs/inspections/vi/reports/united_kingdom/vi_rep_unik_8626-2002cm_en.pdf

Further information: Eric Crutcher (VMD, 01932 338322, e-mail: e.crutcher@vmd.defra.gsi.gov.uk).

■ PROPOSAL FOR THE RETENTION/REPLACEMENT OR REPEAL OF SECTION 118 OF THE MEDICINES ACT (1968)

A consultation exercise on the repeal of Section 118 of the Medicines Act 1968 and Regulation 14 of the Marketing Authorisation Regulations 1994 began on 19 December 2002. This consultation is being carried out jointly by the VMD and the Medicines Control Agency as it relates to the same regulatory provision in both veterinary and human medicines. These provisions set strict controls on the release of information on products supplied to Government as part of the regulatory process. Comments on the possible repeal of this legislation should be sent to Jo Eldridge for veterinary medicines.

An open meeting to discuss issues relating to the options concerning section 118 of the Medicines Act will be held on 24 February 2003 at the VMD. The meeting will start at 2pm with coffee available from 1.30pm and it is expected that the meeting will end by 4pm.

If you would like to attend, please contact **Mandy Jones** (01932 338320, e-mail: m.jones@vmd.defra.gsi.gov.uk) or **Max Templeman** (01932 338321, e-mail: vmptemp@vmd.defra.gsi.gov.uk) to book a place. Places will be available on a first come first served basis.

If you have any questions on the consultation package or the purpose of the meeting, please contact **Jo Eldridge** (01932 338317, e-mail: j.eldridge@vmd.defra.gsi.gov.uk). Please also feel free to send in details of questions on specific areas which you would like to discuss during the meeting. Details of the consultation package can be found in General News on MAVIS on-line.

■ STAFF CHANGES

The following staff changes have taken place since the last issue of MAVIS.

- Phil Banks transferred on promotion to the Veterinary, Fisheries and Aquatic Science Division, Science Directorate on 18 November 2002.
- Paul van Putten left the VMD on 13 November to take up a position in industry.
- Justin Murphy joined the Finance team on 14 October and Caroline Watson joined the Finance team on 25 November.
- Joe Frempong will be joining the VMD as a Scientific Officer on 24 February.
- Colin Bennett was promoted to Senior Executive Officer and Caroline Povey was promoted to Executive Officer in the VPC Secretariat team on 9 December 2002.
- Jo Eldridge was promoted to Higher Executive Officer in the Policy branch on 13 January.
- Suzanne Pearce joined the VMD as an Executive Officer in the Information Management team on 17 February.
- Miguel Godfrey transferred to the Cabinet Office on secondment for two years on 31 January. Noel Joseph took over Miguel's post on temporary promotion to Senior Scientific Officer on 3 February.
- Paula Huckle joined the Pharmaceuticals and Feed Additives as a Scientific Officer on temporary promotion on 27 January.

Further information: Natalie Shilling (VMD, 01932 338335, e-mail: n.shilling@vmd.defra.gsi.gov.uk).

■ MERCHANTS AND SADDLERS FEES

The consultation to amend the fees for 2003/2004 for registration, retention and restoration of Agricultural Merchants and Saddlers with the Royal Pharmaceutical Society of Great Britain was recently completed. The Parliamentary Under Secretary, Mr Morley announced the changes in the House of Commons on 30 January 2003. The details of the new fees are:

FEES

Application in respect of each premises	PreviousNew	
	fee	fee
Agricultural Merchants		
1 For registration under Article 5	£ 232	£ 232
2 For retention of registration under Article 5	140	153
3 For restoration of registration under Article 5	197	197
Saddlers		
1 For registration under Article 5	127	127
2 For retention of registration under Article 5	76	83
3 For restoration of registration under Article 5	107	107

Further information: Martin Tustin (VMD, 01932 338312, e-mail: m.tustin@vmd.defra.gsi.gov.uk).

LICENSING

■ PROPOSALS FOR NEW CONTROLS ON CHEMICALS

Holders of marketing authorisations and manufacturer's licences will wish to be aware of developments in three areas concerning proposed controls on chemicals.

In 2001 the European Commission published a White Paper, *Strategy for a future Chemicals Policy* (COM(2001) 88 final), on the impact of chemicals on the environment and human health. It was considered that existing legislation on chemicals had not been effective and that more needed to be done. The Commission is currently developing proposals to establish a new scheme, called REACH (Registration, Evaluation and Authorisation of Chemicals), the aim of which is to protect the environment and human health, maintain competitiveness, avoid fragmentation and increase transparency and the amount of information available. The Commission is expected to publish their proposals in the first half of 2003.

The proposed scheme would apply to all substances produced in quantities of 1 tonne or more per producer per year. It would involve registration of individual substances including the provision of information relating to the substance. Substances of highest concern would require authorisation for specific uses, and others of concern would be subject to targeted risk management. Under the authorisation procedure the substance would be banned unless the companies could show that a chemical could be used safely in specific circumstances, and there would be consideration of socio-economic costs and benefits as part of this process. For targeted risk management the default position would be that all uses would be permitted unless ruled out by the risk management strategy. It is not proposed that the new legislation should replace existing sectoral authorisation processes, such as those applying to veterinary medicinal products. However, we are currently unsure of the potential impact on veterinary medicines of the above proposals.

In addition to the above, in line with the UK's 1999 Chemical Strategy to address concerns over delays in EU level action, the Government has accepted the advice of the UK Chemicals Stakeholder Forum that it should seek to establish a formal voluntary agreement with the chemical industry to reduce environmental risks arising from the use of nonylphenols, octylphenols and their ethoxylates. In parallel to the establishment of the voluntary agreement, negotiations are proceeding in the EU on the European Commission's proposal (published on the 16 August 2002) for the 26th Amendment to the Marketing and Use Directive (76/769/EEC) that will restrict the marketing and use for certain uses of nonylphenol and nonylphenol ethoxylates. There are a number of chemicals being

considered by the UK Chemicals Stakeholder Forum, so it is possible that voluntary action will also follow on these (see www.defra.gov.uk/environment/chemistrat/stakehol/index.htm)

It is currently proposed that both the voluntary agreement and the Marketing and Use legislation will cover the use of nonylphenol ethoxylates in veterinary medicinal products, specifically sheep dips and teat dips. This may result in companies re-formulating those products that currently contain these substances. In this case applications to vary the relevant marketing authorisations will be required.

The Defra website is currently being updated but you will be able to find information on EU Chemicals policy at www.defra.gov.uk/environment/chemistrat/index.htm

Further information on REACH may be obtained from Giulia Musto, Defra Chemicals Strategy Team, Tel: 020 7944 5267, e-mail: Giulia.Musto@defra.gsi.gov.uk

The contact point for the voluntary agreement on nonylphenols, octylphenols and their ethoxylates is Isabella Earle, Defra, Chemicals Strategy Team, Tel: 020 7944 5283, e-mail: Isabella.earle@defra.gsi.gov.uk

The contact point for further information on the EU Marketing and Use proposals is Roger Tregunno, Defra, OECD and Risk Management of Chemicals, Tel: 020 7944 5266, e-mail: Roger.tregunno@defra.gsi.gov.uk

■ NOTES FOR GUIDANCE

EMEA/CVMP/1090/02 of December 2002: Position paper on the maximum in-use shelf-life for medicated drinking water.

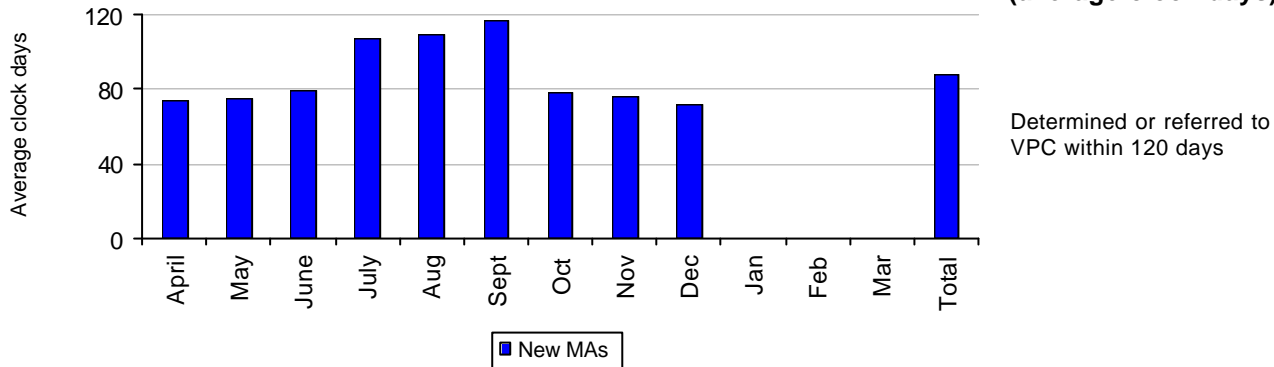
LICENSING BUSINESS PERFORMANCE AGAINST TARGETS

The Licensing Business is exploring ways to increase the transparency of our performance and to allow stakeholders to monitor our performance against targets throughout the year, rather than once a year in the VMD Annual Report. The attached charts represent our first attempt at achieving this aim and depict on a monthly basis the average number of days taken to complete the target defined in the legend to each figure. The last column on the right of each figure represents the overall average achieved during the financial year and the text to the right represents the average day target. We would be grateful for feedback from readers as to how easy they find these charts to understand and if they contain useful information. Suggestions on how they might be improved will be welcome and we will amend the charts in light of comments received.

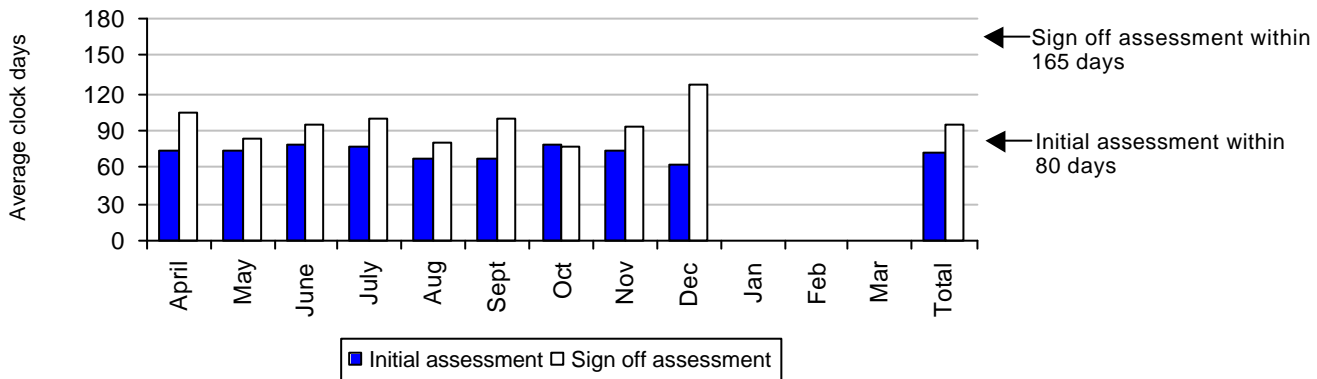
Further information on figures and charts: Lea Stott (VMD, 01932 338432, e-mail: l.stott@vmd.defra.gsi.gov.uk). For information in relation to licensing business performance contact David Mackay (VMD, 01932 338387, e-mail: d.mackay@vmd.defra.gsi.gov.uk).

New Marketing Authorisations*

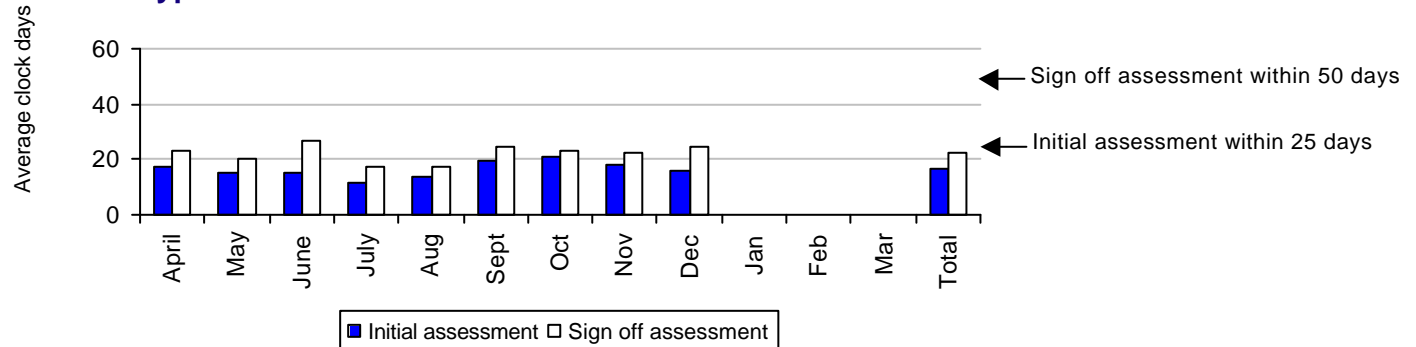
TARGETS
(average clock days)



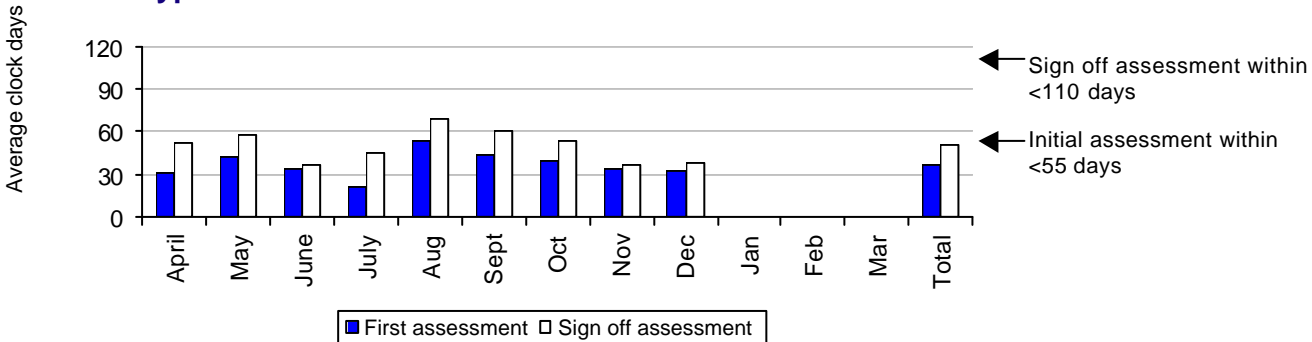
Renewals



National Type I Variations



National Type II Variations



*Figures for applications referred to the VPC are not included but are detailed in the separate table.

■ REVIEW OF EUROPEAN VETERINARY MEDICINES LEGISLATION (REVIEW 2001)

Meetings of the Council Working Group have been held on 11/12 November 2002, 12/13 December 2002, 7/8 and 31 January 2003 and 13/14 February. The next meeting is scheduled for 4/5 March.

Revised Commission Proposals

The European Commission has produced revised proposals for amendments to Regulation 2309/93 in the light of the European Parliament's Report of first reading which was adopted in October 2002. The revised proposals are available on the Commission website (pharmacos.eudra.org). The Commission is expected to produce revised proposals on the two Directives during March 2003.

The latest position on the issues of key importance to the UK is set out below.

Scope of the centralised procedure

The Danish Presidency had circulated a compromise that would limit the proposed extension to "innovative active substances" for human medicines and would only require centralised procedure to be used for growth promoting veterinary medicines. The current requirement for biotech products to be authorised centrally would cease. There was general agreement of the need for more flexibility for veterinary products. Concerns were raised about the change for biotech products. The Commission said it wanted to strengthen the centralised procedure and could not accept total optionality. It could not support the Presidency compromise.

In November, the Presidency withdrew its compromise for human medicines. Most MS retained previous positions. The UK said it could accept the status quo. The Commission said that the EP had supported its proposal and it will stick to it. However, in the 2nd reading it could accept different treatment for veterinary medicines provided this was supported by both scientific and political arguments.

EMA Management and Advisory Boards

The Danish Presidency explained its compromise proposal. For the Management Board, one representative/MS based on management expertise, with alternates permitted. A list of current MB competences had been included to improve the transparency of this provision. The Advisory Board would include EP, Commission and industry representatives. The Commission said it had proposed a small MB because of accession. It wanted Heads of Agency meetings to have an official role as the AB. It questioned the need for MS representation on both bodies. Most MS supported the inclusion of MS representatives on the MB. The UK said that it supported the Presidency proposal for the MB but would need to consult on the AB.

In November, there was agreement on 1 rep/MS. The Commission said it had accepted various EP amendments including one that allowed only one renewal of the three year membership. MS thought this was not acceptable as their representatives were likely to be their Chief Executives who may still be in post after 6 years. Two MS said their Parliaments may require consumer representation on the Management Board. There was no discussion on the membership of the Advisory Board which needs to be considered at the same time so that the Boards do not duplicate each other.

5yr Renewals

The Commission said it had accepted the EP amendment subject to the precise wording. This was along the same lines as the Presidency compromise i.e. one 5 year renewal then permanent validity subject to a sunset clause. Most MS could accept the Presidency compromise.

Sunset clause

Many MS remained unhappy with the sunset clause concept. This would mean that a product not marketed for a number of years (2 in Commission proposal or 3 in EP amendment) would lose its authorisation. The Commission said it wanted to increase the clarity of which medicines were actually on the market.

Most MS said that the clause should be for 3 rather than 5 years. The UK maintained its reservation on sunset clause as a whole.

Legal Base

A discussion took place on whether A 308 (unanimity) or 95 (QMV) should be the legal base for the Regulation. 152(4) was agreed for veterinary proposals.

Comitology

There was unanimous agreement that a single procedure should be used to decide on CP(V)MP advice on issuing MAs. It was generally agreed that this should be the management procedure as this was closest to current arrangements.

Pharmacovigilance

MS papers on detailed pharmacovigilance points have clarified many of the issues.

MS reservations to the Commission's original proposals to amend 2309/93

Discussion continued on the Presidency paper and areas of concern to MS were noted. The UK maintained its reserve on renewals, the sunset clause, scope, reducing the assessment time for fast track centralised applications and veterinary pharmacovigilance provisions.

Further information: Geoff Long (VMD, 01932 338319, e-mail: g.long@vmd.defra.gsi.gov.uk).

■ TESTING FOR SKIN SENSITISATION POTENTIAL OF VETERINARY MEDICINAL PRODUCTS: USE OF THE LOCAL LYMPH NODE ASSAY

Along with other UK Government regulatory authorities and agencies, the VMD has endorsed the statement of principles that, any suffering caused to animals and the number of animals used in a safety evaluation study conducted under the Animals (Scientific Procedures) Act 1986 should be the lowest necessary to achieve its identified objective.

The Local Lymph Node Assay (LLNA) has recently been validated by the European and US bodies for validation of alternative animal methods. An OECD guideline (No. 429) for conducting the LLNA was adopted in April 2002. The LLNA uses mice, causes less suffering and uses fewer animals than the current guinea pig maximisation test or the Buehler Assay.

Following communications with the Home Office, the VMD is informing applicants for authorisations for veterinary medicinal products and animal feed additives that the LLNA should be the test of first choice for new procedures conducted in the UK to investigate skin sensitisation potential under the 1986 Act. Such studies should be conducted in accordance with OECD guideline 429.

Existing studies conducted using other methodologies are still acceptable and we would not expect applicants to conduct an additional LLNA test where such data exist. However, the use of LLNA for European applications will be subject to the opinions of other regulatory authorities within the EU. We are taking steps to clarify the situation but, in the meantime, where data are likely to be submitted to other EU regulatory agencies, or non-EU bodies, applicants should enquire as to the acceptability of such data to avoid the need for unnecessary additional testing. If non-LLNA studies are to be conducted in the UK for such purposes, the Home Office would have to consider their licensing on a case-by-case basis.

On a general point regarding sensitisation testing, the LLNA, maximisation test and Buehler assay are intended to investigate skin sensitisation from topical exposure. Risks of sensitisation by other routes such as oral or inhalation may also need to be considered. Whereas these tests might give an indication of sensitisation risk from other routes of exposure, such risks might need further investigation. As no formal guidelines exist for such studies, these would need to be considered on a case-by-case basis.

Further information: Andy Browning (VMD, 01932 338395, e-mail: a.browning@vmd.defra.gsi.gov.uk), Stella Jones (VMD, 01932 338393, e-mail: s.jones@vmd.defra.gsi.gov.uk)

SUSPECTED ADVERSE REACTION SURVEILLANCE SCHEME

The definition of a Suspected Adverse Reaction (SAR) is taken from article 42b of the amended Directive 81/851/EEC: "adverse reaction means a reaction which is harmful and unintended and which occurs at doses normally used in animals for the prophylaxis, diagnosis or the modifications of physiological function". The definition of a human adverse reaction is taken from article 1 paragraph 2(b) of amended Directive 2000/37/EC "... means a reaction which is noxious and unintended and which occurs in a human being following exposure to a veterinary medicine." In addition to this the UK also include reports of suspected lack of expected efficacy, reports of off-label use of veterinary medicines, reports of environmental incidents and reported violations of approved maximum residue limits arising from the use of a veterinary medicinal product.

■ QUARTERLY REPORT

During the period 1 October to 31 December 2002, the VMD received 358 suspected adverse reaction reports involving animals. Of these 22 reports related to unauthorised use, 20 involved non-authorised or unidentified products and 11 reports were considered likely to be not product related. Two reports involved animal trials under Animal Test Certificate (ATCs) and 19 reports involved suspected lack of efficacy.

The remaining 284 suspected adverse reaction reports were associated with 119 licensed products.

The 284 reports were divided by marketing categories as follows:

- 262 Prescription Only Medicine (POM)
- 14 Pharmacists and Merchants List (PML)
- 0 Pharmacists List (P)
- 8 General Sales List (GSL)

During the quarter 11 reports of human suspected adverse reactions were received. All human incidents are considered by the Appraisal Panel for Human Suspected Adverse Reactions to Veterinary Medicines. The information thus accrued is analysed to identify any trends or signals that need attention.

One environmental incident was reported to the VMD in the quarter involving an unidentified sheep dip. A sheep dip bath drained to a slurry store via a drain hole and reception pit. The contents of the slurry store were spread onto land and this appears to have led to run-off of the sheep dip into a watercourse.

This Quarterly Report will be presented to The Veterinary Products Committee at their meeting in February 2002.

The Quarterly Report for the period 1 July – 30 September 2002 was presented to the VPC in November 2002.

Further information: Denise Burge (VMD, 01932 338427, e-mail: d.burge@vmd.defra.gsi.gov.uk).

VETERINARY PRODUCTS COMMITTEE

The Veterinary Products Committee (VPC) was set up in 1970 under Section 4 of the Medicines Act. Its terms of reference are:

- *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, or appliance) to which any provision of the Medicines Act is applicable; and*
- *to promote the collection of information relating to suspected adverse reactions for the purpose of enabling such advice to be given.*

Government scientists from the VMD, Department of Health, Health and Safety Executive, Department of Environment, Transport and the Regions and Food Standards Agency attend all meetings as advisers to the Committee.

The VPC held meetings on 17 October, 14 November and 12 December. It reviewed and confirmed the minutes of its previous meetings and considered the following matters relating to the authorisation of veterinary medicines. All conclusions reached are subject to review and confirmation at its next meeting.

■ OCTOBER MEETING

Applications

The Committee examined evidence relating to applications for:

- a renewal of a UK Provisional Marketing Authorisation for an anticoccidial product for use in chickens
- a variation to add an indication to a UK marketing authorisation for an anti-hyperthyroid product for use in cats

The Committee provisionally concluded (subject to confirmation at its next meeting) that of these 2 applications:

- 2 should be recommended for authorisation subject to certain conditions being met by the applicant;

General

The Committee considered and commented on the second UK SARSS Quarterly Report. Further details of this report can be found in MAVIS www.vmd.gov.uk.

The Committee considered the SARSS Review of adverse reactions reported - Non Steroidal Anti Inflammatory Drugs (NSAIDs). It noted that and commented on the report and agreed that a condensed report would be presented for discussion at a future meeting.

The Committee further considered the report of the VPC Working Group on SARSS. The report had been presented to the Committee at the July 2002 VPC meeting and Members had agreed to further consider the report at a future meeting. The Committee agreed to pass the report to the VMD for consideration and for the VMD to report back to the Committee in December 2002.

The Committee also considered a paper from a Working Group of CODEX on the Draft Code of Practice to Minimize

and Contain Antimicrobial Resistance. It noted and commented on the paper and agreed that the VMD will take forward its comments.

The Committee also considered an interim report on a project on the ecological effects of Sea Lice Products. It noted that information on this project is on the VMD website www.vmd.gov.uk.

Corrected VPC Summary Minutes for the meeting of September 2002 are available on the VPC website www.vpc.gov.uk or by request from **Caroline Povey (VMD, 01932 338491, e-mail: c.povey@vmd.defra.gsi.gov.uk)**.

Dates of VPC meetings in 2003 are available on the VPC website www.vpc.gov.uk or by request from **Caroline Povey VMD(01932 338491, e-mail: c.povey@vmd.defra.gsi.gov.uk)**.

It also received the following papers for information, which are publicly available:

- The Open Forum Report for the meeting last year, October 2001 www.vpc.gov.uk.
- Alliance for the Prudent Use of Antibiotics (APUA) Report on Clinical Infectious Diseases, 2002,34, S71-S144 (**copies available from [APUA apua@tufts.edu](mailto:APUA_apua@tufts.edu)**)
- The COT/COM/COC Annual Report 2001. (**Copies are available from COT Secretariat: Keith.Butler@foodstandards.gsi.gov.uk**)
- VPC Open Forum: List Of Attendees & Questions Received (available at the Open Forum 16 October 2002).
- Copies of The Veterinary Record Contents (front page) "This Week's Issue" for Vol 151, Nos 11-15 (further information www.vetrecord.co.uk).
- A Defra News Release announcing the appointment of Dr Susan Dawson to the VPC (www.defra.gov.uk)
- A Letter published in the Veterinary Record (12 Oct 2002) from Prof P Lees on "Antimicrobial Drug Resistance and Veterinary Therapeutics".

Additionally it received the following papers, which are not available for publication:

- Report from the Scientific Secretariat and the Biological Committee

- Report to the VPC on current ATC applications
- Quarterly report on Special Treatment Authorisations
- A report from the VPC Working Group on SARSS

■ NOVEMBER MEETING

Applications

The Committee examined evidence relating to applications for:

- a UK marketing authorisation for a line extension to a marketing authorisation for a product intended for the treatment and control of sea lice in salmonid species of fish;
- a variation to comply with Directive 1999/104/EC (TSE Directive) for a Marketing Authorisation for a hormone product for use in cattle.

The Committee provisionally concluded (subject to confirmation at its next meeting) that of these 2 applications:

- 1 should be recommended for authorisation subject to certain conditions being met by the applicant;
- 1 should be deferred to a future meeting.

The Committee also considered an application for the authorisation of a feed additive under the terms of European Community legislation for which the United Kingdom is a Concerned Member State. The Committee endorsed the assessment report and list of questions prepared by the VMD.

General

The Committee reviewed its Public and Special meetings and considered the format of the meetings and topics for discussion. Comments and proposals were noted by the VPC Secretariat and will be taken forward in the planning of meetings for next year.

The Committee considered and commented on the third UK SARSS Quarterly Report. Further details of this report can be found in MAVIS www.vmd.gov.uk.

The Committee considered and commented upon the report from the Appraisal Panel, a VPC Sub Committee, on "A Review of Container/Applicator Design for Synthetic Pyrethroid (SP) and Other non-Organophosphate (OP) Pour-On Products". It agreed with the recommendations of the Appraisal Panel to encourage improved container design.

The Committee also noted the first Annual Report on Surveillance for Veterinary Residues in 2001 from the Veterinary Residues Committee (VRC). Copies are available on the VMD website www.vmd.gov.uk or by request from **Isabel Sharma (VMD, 01932 338330, e-mail: i.sharma@vmd.defra.gsi.gov.uk)**.

Corrected VPC Summary Minutes for the meeting of 17 October 2002 are available on the VPC website www.vpc.gov.uk or by request from **Caroline Povey (VMD, 01932 338491, e-mail: c.povey@vmd.defra.gsi.gov.uk)**.

It also received the following papers for information, which are publicly available:

- Copies of The Veterinary Record Contents (front page) "This Week's Issue" for Vol 151, Nos 16-19. Further information www.vetrecord.co.uk.

Additionally it received the following papers, which are not available for publication:

- Report from the Scientific Secretariat and the Biological Committee
- Report to the VPC on current ATC applications

■ DECEMBER MEETING

Applications

The Committee examined evidence relating to applications for:

- a UK marketing authorisation for an inactivated vaccine for use in rabbits.
- a renewal of an Exceptional Marketing Authorisation for use in poultry.
- 2 variations to change the legal category of products for use in cats and dogs from POM (Prescription Only Medicine) to General Sale List (GSL) category;

The Committee provisionally concluded (subject to confirmation at its next meeting) that of these 4 applications:

- 4 should be recommended for authorisation subject to certain conditions being met by the applicant;

General

The Committee considered and commented upon the report from the VPC Working Group on Hormones. It noted that the WG will meet early next year to produce a draft report for consultation, and that there will be further discussion of this topic at the VPC meeting in January 2003.

The Committee also considered the VMD paper on the draft report from the VPC Working Group on SARSS. It noted the comments of the VMD and agreed to conduct informal consultations before finalising the report.

The Committee noted the WiGRAMP Report and also noted that the FSA Action Plan was in progress.

The Committee took note of the annual return of Central Register of Members' Interests. Copies of the returns are available on the VPC website www.vpc.gov.uk or from **Caroline Povey (VMD, 01932 338491, e-mail: c.povey@vmd.defra.gsi.gov.uk)**.

Corrected VPC Summary Minutes for the meeting of 14 November 2002 are available on the VPC website www.vpc.gov.uk or by request from **Caroline Povey (VMD, 01932 338491, e-mail: c.povey@vmd.defra.gsi.gov.uk)**.

Dates of VPC meetings in 2003 are available on the VPC website www.vpc.gov.uk or by request from **Caroline Povey (VMD, 01932 338491, e-mail: c.povey@vmd.defra.gsi.gov.uk)**.

It also received the following papers for information, which are publicly available:

- Copies of The Veterinary Record Contents (front page) "This Week's Issue" for Vol 151 Nos 20-23 (further information www.vetrecord.co.uk).
- Copy of the Executive Summary "Pesticides 2001" from the Environment Agency. Full report available from the EA website www.environment-agency.gov.uk

Additionally it received the following papers, which are not available for publication:

- Report from the Biologicals Committee
- Report to the VPC on current ATC applications
- Correspondence relating to an application for a feed additive under the terms of European Community legislation for which the United Kingdom is a Concerned Member State.

■ INVITATION TO APPLY FOR MEMBERSHIP OF THE VETERINARY PRODUCTS COMMITTEE AND ITS SUB-COMMITTEES

EXTENSION TO THE DEADLINE FOR RECEIPT OF APPLICATIONS to 28 FEBRUARY 2003

The closing date for receipt of completed application forms for membership of the VPC and its Sub-Committees for terms of office from 1 January 2004 to 31 December 2007, announced in the last edition of MAVIS has been extended until 28 February 2003.

The terms of office of the Chairman and 11 members of the Veterinary Products Committee (VPC), 1 member of the Medical and Scientific Panel (MSP) and 4 members of the Appraisal Panel for Human Suspected Adverse Reactions to Veterinary Medicines (Appraisal Panel) come to an end on 31 December 2003. In addition, the VPC has considered the areas of expertise represented by the current

membership and recommends that this should be increased to include experts in Parasitology (food animal species) and Environmental Chemistry.

There are also two vacancies on the MSP, one for a Medical Epidemiologist, resulting from a resignation earlier in the year, and a Neurobehavioural Toxicologist/Clinical Psychologist, and 2 vacancies on the Appraisal Panel, for an expert in Accident and Emergency Medicine and a Veterinary Surgeon (general practitioner), which remain unfilled from the last round of appointments.

Applications, especially from women and members of ethnic minorities, are sought from those who are qualified and have current, relevant experience in:

- any of the specialisms represented by the current membership of the VPC – for appointment to the Chair of the VPC
- Clinical Toxicology, Ecotoxicology, Environmental Chemistry, Fish Medicine, Medical/Clinical Microbiology (antibiotic resistance), Occupational health/hygiene, Parasitology (food animal species), Residue Chemistry, Statistics (veterinary/biological), Toxicology, Veterinary Immunology, Veterinary Surgeon (mixed/small animal clinician), and a Working Farmer knowledgeable in the on farm use of veterinary medicines in a range of farm animals - for the VPC
- Toxicology, Medical Epidemiology, and Neurobehavioural Toxicology/Clinical Psychology – for the Medical and Scientific Panel
- Toxicology, Occupational Hygiene, Neurology, Clinical Toxicology, Accident and Emergency Medicine, and one for Veterinary Medicine (general practitioner) – for the Appraisal Panel.

Further information and application forms are available from:

Colin Bennett
VPC Secretary
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3LS

(Tel: 01932 338490, fax 01932 336618, e-mail: c.bennett@vmd.defra.gsi.gov.uk) and on the VPC website: www.vpc.gov.uk.

■ HORMONES IN MEAT

The Veterinary Products Committee (VPC), which gives independent advice in the UK on the safety, quality and efficacy of veterinary medicines, has set up a Working Group to review the latest evidence on the potential risk to human health from hormone residues in bovine meat and meat products. Stakeholders are invited to feed in to the process by submitting their views on the recent scientific evidence.

In April 2002, the European Commission published an Opinion of the Scientific Committee on Veterinary Measures Relating to Public Health following the completion of 17 scientific studies commissioned to provide additional information on the six hormonal substances. The committee also considered recent scientific literature. It has maintained its 1999 opinion that no threshold levels could be defined for any of the substances they examined. The new VPC Working Group has been asked to consider the Opinion and the new information on which it was based and to advise on whether the science justifies the current ban.

The initial stage of the process is now over. The Working Group met on 6 February 2003 to begin drafting their report. The draft report will be circulated to stakeholders to allow them to comment.

As background, you may be aware that the use of hormonal growth promoters in meat has been banned in the European Union in all food-producing animals since 1988. However, in 1998 the World Trade Organisation (WTO) ruled that the EU had not undertaken a proper risk assessment prior to imposing the ban and that the scientific reports referred to by the Commission did not support the EU position.

The science underpinning the issue is not clear-cut and has led to differing Opinions from various Committees that have examined the evidence since the WTO ruling. In 1999 the European Commission published an Opinion of the Scientific Committee on Veterinary measures relating to Public Health (SCVPH) which stated that no threshold levels could be defined for any of the six hormonal substances they examined (17- β -oestradiol, progesterone, testosterone, zeranol, trenbolone acetate and melengestrol acetate).

The then Minister of Agriculture, Fisheries and Food asked the VPC to look at the SCVPH Opinion. The report of the VPC sub group was published in October 1999. The sub group concluded that the scientific evidence in the SCVPH report did not support the Community ban. Opinions were also issued by the Committee on Veterinary Medicinal Products (CVMP – part of the European Medicines Evaluation Agency), and the joint FAO/WHO Expert Committee on Food Additives (JECFA).

The SCVPH's Opinion on Review of previous SCVPH opinions of 30 April 1999 and 3 May 2000 on the potential risks to human health from hormone residues in bovine meat and meat products (adopted on 10 April 2002) is available from: europa.eu.int/comm/food/fs/sc/scv/out50_en.pdf

The VPC sub group report of October 1999 is available from www.vpc.gov.uk. The report can be found in the 'Reports' section as: Sub Group of the Veterinary Products Committee – Published October 1999.

If you wish to be added to the list of stakeholders for consultation on the Draft report, please contact **David Webb (VPC Working Group Secretariat) on 01932 338327, e-mail: d.webb@vmd.defra.gsi.gov.uk**.

RESIDUES CONTROLS & MONITORING

The VMD's veterinary residues surveillance programmes play a central role in ensuring that the consumer is protected against potentially harmful residues of veterinary medicines in food. The very low incidence of residues found indicates that the chances of an individual consumer being exposed in the long term to foods containing such high residues are extremely remote.

The VMD operates two complementary surveillance programmes, a statutory programme which implements EU legislation, the National Surveillance Scheme for residues in meat (NSS) and a non-statutory programme which supplements and expands the statutory programme. The costs of the statutory programme are met by charges levied on industry, while the non-statutory programme is funded by Defra.

There are powers under Residues Regulations and the Food Safety Act to remove from the food chain products containing residues at levels which represent a danger to human health. All samples above the Action Level are followed up and may result in a prosecution.

■ NATIONAL SURVEILLANCE SCHEME FOR RESIDUES OF VETERINARY MEDICINES IN ANIMALS AND ANIMAL PRODUCTS

Statutory Surveillance in 2002

The National Surveillance Scheme (NSS) operates in accordance with the requirements of Annexes I-IV of Directive 96/23/EC and Decision 97/747/EC. All countries in the European Union must carry out targeted surveillance for residues of veterinary medicines in a range of animals and animal products, including red meat, poultry, farmed fish (salmon and trout), milk, eggs, honey and wild and farmed game. The results of analyses completed between 1 January 2002 and 2 January 2003 are given in the accompanying tables. Details of the positive samples are given below.

Authorised officers collect samples from farms, slaughterhouses and egg packing stations. Where confirmed residues of authorised substances are found above the Maximum Residue Limit (MRL)*, a veterinary officer of the State Veterinary Service carries out an investigation at the farm of origin to establish the source of the residue.

Where unauthorised substances or high concentrations of authorised substances are detected, an Investigation Officer from the Department for Environment, Food and Rural Affairs (Defra) Legal Division will undertake an investigation.

■ RED MEAT

Up to 2 January 18,634 analyses had been completed on 20,252 samples. 44 samples were found to contain residues of veterinary medicines in excess of the Maximum Residue Limit/Action Level**.

Synthetic Steroids, Beta-Agonists and Natural Hormones

Zeranol is a semi-synthetic oestrogenic growth promoter. As noted in previous editions of MAVIS, research has shown that zeranol is readily formed from *Fusarium* spp.

toxins in cattle. Zeranol residues can therefore be present in animals that have not been treated with this illegal growth promoter. Up to 2 January 2003, one sample of cattle bile out of 113 tested contained a confirmed residue of zeranol. A veterinary officer of the SVS has carried out a follow-up investigation at the farm of origin of this sample. No evidence of the illegal use of growth implants or implanting equipment was found. Analysis of feed samples taken from the farm has confirmed the presence of the *Fusarium* spp. toxin zearalenone. Feed contamination is therefore the likely cause of this residue.

One sample of cattle liver out of 606 analysed has tested positive for the beta-agonist Salbutamol at a level of 0.05µg/kg. Further confirmatory analysis indicates that the residue is due to contamination rather than illegal use. Salbutamol is the active ingredient in a number of inhalers for human use. The VMD has informed the Meat Hygiene Service of the potential for contamination by sampling officers who use this type of medication. Toxicological advice is that this residue is not a risk to human health.

The SVS investigated residues of progesterone found in screening tests on two samples of cattle serum. Further samples were taken from animals at the farms as part of the follow-up visits. The result of one follow-up sample is still awaited. The sample taken on the other follow-up visit tested negative.

Nortestosterone residues have been detected in 6 samples of cattle bile and 4 of sheep urine. Alpha-nortestosterone occurs naturally in female sheep and cattle. Following liaison with the Department of Agriculture and Rural Development in Northern Ireland the SVS will carry out investigations where the residue is over 0.5µg/kg for male animals and 5µg/kg for female animals. They will therefore be following up on four of the cattle samples and

one sheep sample. The results will be reported in the next edition of MAVIS.

Antimicrobials

Kidney samples collected from 5,380 cattle, sheep and pigs have been screened for antimicrobial substances. Five pig kidney samples out of 964 analysed, tested positive for residues of antibiotics. Chlortetracycline was detected in four samples at concentrations between 670µg/kg and 860µg/kg (MRL 600µg/kg). Sulphadiazine was detected in 1 pig kidney at a concentration of 160µg/kg (MRL 100µg/kg). Although these residues are in excess of the MRLs, toxicological advice has confirmed that they are unlikely to be a risk to consumers. The SVS have completed their follow-up investigations into three of these samples. Feed contamination has been identified as the probable cause of one of these residues. In one case the veterinary officer was unable to identify the cause but felt contamination of the feed delivery wagon was a possible cause. In the third instance the finished pigs had had access to an area where there was medicated feed or faeces from animals being given medicated feed.

Sulphonamides

In addition to the analysis of samples by an antimicrobial screening method, specific analyses for sulphonamides in cattle, pigs and sheep are included in the surveillance programme. Out of 1,181 samples tested for sulphonamides, 1,176 were free of residues. Five samples of pig kidney contained residues of sulphadimidine or sulphadiazine above the MRL of 100µg/kg at concentrations between 110µg/kg and 4,250µg/kg. Defra's Legal Department completed an investigation into the sample containing a residue of over 4,000µg/kg and a report on the result of the subsequent prosecution can be found on page 2 in this edition of MAVIS.

Coccidiostats

One sample of sheep liver contained a residue of monensin at a concentration of 56µg/kg. Monensin is a zootechnical feed additive and no MRL has been set. The SVS investigation into this residue indicates that it occurred as a result of lambs having access to spilt cattle feed containing monensin. The SVS have written to the farmer advising him of the action that should be taken to avoid such residues in future. Toxicological advice is that this residue is unlikely to pose a risk to human health.

Anthelmintics

One sample of cattle liver out of 252 analysed for avermectins contained a residue of doramectin above the MRL of 100µg/kg at a level of 130µg/kg. The Veterinary Officer was unable to establish the source of this residue.

Heavy Metals

Three samples of sheep kidney tested for cadmium and lead contained residues of cadmium in excess of the MRL of 1,000µg/kg at concentrations of 1,277µg/kg, 1,381µg/kg, and 2,180µg/kg. One sample is still being followed up

by the SVS. In one of the other two cases soil contamination from old smelting work was considered as the likely cause and in the last case the farm of origin of the animal could not be traced. This has been taken up with the MHS. Seven samples of horse kidney have also tested positive for cadmium at concentrations between 6,714µg/kg and 19,329µg/kg. There is an agreement with slaughterhouses that horse offal will be discarded and therefore it will not enter the food chain.

■ POULTRY

By 2 January 2003 a total of 8,651 analyses had been completed on 8,411 samples.

Synthetic Steroids, Beta-Agonists and Natural Hormones

Four poultry samples, 1 turkey liver and 3 broiler livers, contained residues of the beta-agonist salbutamol at concentrations between 0.1µg/kg and 0.7µg/kg. Further tests on these samples have indicated that these residues are due to contamination of the sample rather than any illegal use of this substance. Toxicological advice is that these residues are not harmful to human health.

Antimicrobials

1,769 kidney samples have been screened for a range of antimicrobial substances. 566 samples of turkey kidney were free of detectable residues of chlortetracycline. 25 samples of turkey kidney have been found to contain residues of chlortetracycline above the MRL of 600µg/kg, at concentrations between 640µg/kg and 1,690µg/kg. The State Veterinary Service are undertaking follow-up visits. The findings from the visits undertaken to date indicate that cross-contamination of unmedicated feed via a single bin feeding system is a probable cause. Toxicological advice has indicated that these concentrations do not pose a risk to human health.

Sulphonamides

In addition to the analysis of samples by an antimicrobial screening method, specific analyses for sulphonamides in poultry species are also included in the surveillance programme. Out of 260 samples tested for sulphonamides, one sample of turkey kidney contained a residue of sulphaquinoxaline at a level of 180µg/kg. The Veterinary Officer who carried out the follow-up visit was unable to establish the cause of this residue.

Nicarbazin

23 samples of broiler liver out of 272 tested were found to contain residues of nicarbazin above the JECFA MRL of 200µg/kg at concentrations between 210 and 2,610µg/kg. Investigations into the cause of these residues have been completed on 15 of these samples. Cross contamination of the withdrawal ration with medicated feed via a single-bin feeding system was thought to be the most likely cause of the residue for 12 of the samples.

A further fast-track study involving 39 samples was undertaken in November to establish a better picture of the causes of these positives. Farms that took part in the trial were asked to complete a short questionnaire on their feeding practices and the two samples that proved positive have been followed up by the SVS. As part of this follow-up further samples of the feed given to the birds from which the residue positive originated were taken. The Animal Medicines Inspectorate (AMI) Royal Pharmaceutical Society of Great Britain (RPSGB) will carry out follow-up visit to the feed mill if contamination there is suspected as being the cause of the residue. These residues are a food contaminant rather than a food safety issue: a person eating a standard 100g portion of liver, containing 2,160µg/kg would receive a one-off dose of 261µg, compared to an Acceptable Daily Intake of 24,000µg for a 60kg person.

■ Ionophores

3 samples of broiler liver have tested positive for monensin at concentrations between 1 and 5µg/kg. One sample of broiler liver tested positive for lasalocid at a concentration of 100µg/kg. Investigations by the SVS into 2 of these samples have been completed. In one case, the Veterinary Officer established that the bird was slaughtered as a thinning and the farmer had not observed the withdrawal period. The farm is implementing a 5-day withdrawal period prior to thinning in future. In the second case, the investigating officer considered that cross contamination of feed was a possible cause.

■ Heavy Metals

Two samples of hen liver out of 11 analysed contained residues of cadmium at levels of 650 and 670µg/kg respectively. The SVS feel that the positive so far followed up was a result of feed contamination or an event before the bird was placed on the farm from where it was slaughtered. One sample of duck's liver out of 5 analysed contained a residue of lead at a level of 1,125µg/kg. This is being followed up by the SVS.

■ FARMED FISH

By 2 January 2003 1,744 assayable samples of salmon and trout had been collected from fish farms throughout GB.

■ Leuco Malachite Green

Eight samples of salmon muscle have been found to contain residues of leucomalachite green at concentrations of 2µg/kg (2 samples), 3µg/kg (3 samples), 4µg/kg, 5µg/kg and 35µg/kg. The Fisheries Research Services have undertaken investigations into these positive samples. No evidence of use of malachite green in seawater was detected. Inspectors concluded that residues may have arisen from previous treatment in fresh water. The industry was informed in May 2002 that the use of malachite green at any stage of production should cease immediately and advised that prosecutions will be taken if the use of malachite green is proved.

■ EGGS

1,249 analyses have been completed on 555 samples of eggs collected from caged, perchery and free-range production.

■ Lasalocid

Twelve samples of eggs, nine from caged production, two from free-range and one from perchery have tested positive for residues of lasalocid at concentrations between 60µg/kg and 620µg/kg. The SVS have completed their follow-up investigations for 8 of these samples. In only one case was there evidence to suggest that feed containing lasalocid had been fed to laying birds by the farmer. In the remaining 7 cases the birds were on feed which should not have contained any lasalocid. Results from analysis of the follow-up samples of feed show that low levels of lasalocid have been detected in 3 samples. An investigation by the AMI into one of the mills supplying feed found that inadequate briefing of staff during a shift change resulted in incorrect scheduling of feed. This was identified as a potential cause of feed contamination. Toxicological advice is that these residues are not a risk to human health.

■ MILK

2,054 analyses have been carried out on 770 samples. No residues have been confirmed to date.

■ GAME

Sampling commenced in July and 184 assayable samples have been collected. One sample of muscle from a wild deer and one sample of muscle from a wild partridge have tested positive for residues of lead at levels of 12,969 and 342,611µg/kg respectively.

Further information: Maggie Green (VMD, 01932 338324, e-mail: m.green@vmd.defra.gsi.gov.uk).

* The Maximum Residue Limit (MRL) is the maximum concentration of residue resulting from the use of a veterinary medicine that is legally permitted or recognised as acceptable in or on a food.

** The Action Level is the concentration equal to the Maximum Residue Limit (MRL) where this has been set, or the Limit of Quantification where no MRL has been set. Where a substance has been entered into Annex IV of Council Regulation (EEC) 2377/90 (i.e. human consumption at any level is unsafe), any confirmed residue will be reported as in excess of the Action Level.

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN RED MEAT
RESULTS OF RANDOM SAMPLING IN GREAT BRITAIN - 1 JANUARY 2002-2 JANUARY 2003**

Type of Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level
■ 1 Hormones					
Stilbenes	Cattle	< 24	Bile	174	
	Cattle	< 24	Urine	70	
	Pigs		Bile	150	
	Sheep		Bile	70	
Methyltestosterone	Pigs		Feed	17	
	Pigs		Urine	123	
	Sheep		Urine	61	
Nortestosterone	Cattle		Bile	161	6
	Cattle		Serum	75	
	Sheep		Urine	117	4
Oestradiol	Cattle		Serum	222	1
Progesterone	Cattle		Serum	268	5
Testosterone	Cattle		Serum	165	
Trenbolone	Cattle		Bile	196	
	Cattle		Serum	80	
	Pigs		Urine	128	
	Sheep		Urine	150	
Zeranol	Cattle	< 24	Bile	162	1
	Cattle	< 24	Faeces	81	
	Pigs		Bile	121	
	Sheep		Bile	72	
■ 2 Pesticides Including PCBs					
Pyrethroids	Calves	< 6	Liver	50	
	Horses		Liver	8	
	Pigs		Liver	77	
	Sheep		Liver	222	
OC/PCBs	Cattle		Kidney Fat	54	
	Pigs		Kidney Fat	56	
	Sheep		Kidney Fat	104	
Organophosphorus	Cattle		Kidney Fat	192	
	Pigs		Kidney Fat	137	
	Sheep		Kidney Fat	458	
■ 3 Beta-Agonists					
	Calves	< 6	Liver	25	
	Cattle		Feed	174	
	Cattle	< 24	Liver	606	1
	Horses		Liver	11	
	Pigs		Feed	40	
	Pigs		Liver	654	
	Sheep		Liver	457	
■ 4 Heavy Metals					
Cadmium	Cattle		Kidney	8	
	Horses		Kidney	7	7
	Pigs		Kidney	13	
	Sheep		Kidney	11	2
Lead	Cattle		Kidney	8	
	Horses		Kidney	7	
	Pigs		Kidney	13	
	Sheep		Kidney	11	1
■ 5 Sulphonamides					
	Calves	< 6	Kidney	67	
	Cattle		Kidney	83	
	Pigs		Kidney	949	5
	Sheep		Kidney	82	

Type of Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level		
■ 6 Antimicrobial Screen	Calves	< 6	Kidney	80			
	Cattle		Kidney	1,322			
	Horses		Kidney	9			
	Pigs		Kidney	964	6		
	Sheep		Kidney	3,094			
■ 7 Annex IV	Chloramphenicol	Calves	< 6	Feed	42		
		Calves	< 6	Kidney	26		
		Cattle		Feed	12		
		Cattle	< 24	Kidney	142		
		Pigs		Kidney	197		
		Sheep		Kidney	92		
	Dimetridazole	Calves	< 6	Kidney	14		
		Cattle	< 24	Kidney	60		
		Horses		Kidney	10		
		Pigs		Feed	7		
		Pigs		Kidney	206		
		Sheep		Kidney	92		
	Furazolidone	Calves	< 6	Feed	36		
		Calves	< 6	Kidney	13		
		Cattle		Feed	5		
		Cattle		Kidney	81		
		Pigs		Kidney	206		
		Sheep		Kidney	96		
Nitrofurans	Calves	< 6	Feed	52			
	Cattle		Feed	7			
	Pigs		Feed	9			
■ 8 Anthelmintics	Avermectins	Cattle		Liver	252	1	
		Horses		Liver	7		
		Pigs		Liver	266		
		Sheep		Liver	400		
	Benzimidazoles	Cattle		Liver	251		
		Horses		Liver	12		
		Pigs		Liver	280		
	Levamisole	Sheep		Liver	465		
		Cattle		Liver	115		
		Horses		Liver	9		
	Sheep		Liver	330			
■ 9 Gestagens	Altrenogest Gestagens	Pigs		Kidney Fat	123		
		Cattle	< 24	Kidney Fat	184		
		Sheep		Kidney Fat	75		
	NSAIDs	Cattle		Kidney	33		
		Pigs		Kidney	42		
		Sheep		Kidney	82		
	Phenylbutazone	Horses		Blood	41		
	■ 10 Coccidiostats	Ionophores	Calves	< 6	Liver	32	
			Pigs		Liver	11	
Sheep				Liver	391	1	
■ 11 Mycotoxins	Cattle		Liver	12			
	Pigs		Liver	13			
	Sheep		Liver	11			

Type of Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level
■ 12 Dexamethazone/Betamethazone					
Dexamethazone	Cattle		Liver	64	
	Pigs		Liver	44	
	Sheep		Liver	21	
■ 13 Carbadox					
	Pigs		Liver	45	
■ 14 Sedatives					
Sedatives	Calves	< 6	Liver	48	
	Pigs		Liver	212	
	Sheep		Liver	97	
	Pigs		Liver	3	
Carazolol	Pigs		Liver	98	
■ 15 Thyrostats					
	Cattle	< 24	Urine	264	
	Pigs		Urine	114	
	Sheep		Urine	66	
Total				18,634	41

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN POULTRY MEAT
RESULTS OF RANDOM SAMPLING IN GREAT BRITAIN - 1 JANUARY 2002-2 JANUARY 2003**

Type of Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 1 Hormones				
Stilbenes	Broilers	Liver	252	
	Ducks	Liver	10	
	Hens	Liver	11	
	Turkeys	Liver	59	
Trenbolone	Broilers	Liver	263	
	Ducks	Liver	11	
	Hens	Liver	11	
	Turkeys	Liver	57	
Zeranol	Broilers	Faeces	41	
	Broilers	Liver	140	
	Ducks	Faeces	3	
	Ducks	Liver	4	
	Hens	Faeces	2	
	Hens	Liver	5	
	Turkeys	Faeces	6	
	Turkeys	Liver	28	
■ 2 Pesticides Including PCBs				
Carbamates	Broilers	Liver	70	
	Ducks	Liver	4	
	Hens	Liver	6	
	Turkeys	Liver	26	
OC/PCBs	Broilers	Liver	218	
	Ducks	Liver	4	
	Hens	Liver	1	
	Turkeys	Liver	34	
■ 3 Beta-Agonists				
	Broilers	Feed	79	
	Broilers	Liver	423	3
	Ducks	Feed	5	
	Ducks	Liver	15	
	Hens	Feed	6	
	Hens	Liver	17	
	Turkeys	Feed	14	
	Turkeys	Liver	92	1

Type of Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 4 Heavy Metals				
Cadmium	Broilers	Liver	24	
	Ducks	Liver	5	
	Hens	Liver	11	2
Lead	Turkeys	Liver	17	
	Broilers	Liver	24	
	Ducks	Liver	5	1
	Hens	Liver	11	
	Turkeys	Liver	17	
■ 5 Sulphonamides				
	Broilers	Kidney	271	
	Ducks	Kidney	14	
	Hens	Kidney	12	
	Turkeys	Kidney	67	1
■ 6 Antimicrobial Screen				
	Broilers	Kidney	1,094	
	Ducks	Kidney	40	
	Guinea Fowl	Kidney	6	
	Hens	Kidney	38	
	Turkeys	Kidney	591	25
■ 7 Quinolones				
	Broilers	Kidney	343	
	Ducks	Kidney	11	
	Hens	Kidney	10	
	Turkeys	Kidney	95	
■ 8 Annex IV				
Chloramphenicol	Broilers	Liver	616	
	Ducks	Liver	26	
	Hens	Liver	28	
	Turkeys	Liver	144	
Dimetridazole	Broilers	Feed	96	
	Broilers	Liver	1,321	
	Ducks	Feed	4	
	Ducks	Liver	53	
	Hens	Feed	8	
	Hens	Liver	58	
	Turkeys	Liver	292	
Nitrofurans	Broilers	Feed	102	
	Ducks	Feed	4	
	Hens	Feed	2	
	Turkeys	Feed	58	
■ 9 Anthelmintics				
Benzimidazoles	Broilers	Liver	138	
	Ducks	Liver	10	
	Hens	Liver	17	
	Turkeys	Liver	48	
Levamisole	Broilers	Liver	142	
	Ducks	Liver	11	
	Hens	Liver	22	
	Turkeys	Liver	49	
■ 10 Coccidiostats				
Ionophores	Broilers	Liver	308	4
	Ducks	Liver	4	
	Hens	Liver	7	
	Turkeys	Liver	70	
Nicarbazin	Broilers	Feed	11	
	Broilers	Liver	311	25
	Ducks	Liver	1	
	Hens	Liver	6	
	Turkeys	Liver	6	
■ 11 Mycotoxins				
	Broilers	Liver	33	
	Ducks	Liver	3	
	Hens	Liver	3	
	Turkeys	Liver	12	
Total			8,651	62

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN FARMED FISH
RESULTS OF RANDOM SAMPLING IN GREAT BRITAIN - 1 JANUARY 2002-2 JANUARY 2003**

Type of Compound\Substance	Species	Age	Matrix	No. of Analyses	No. above Action Level
■ 1 Hormones					
Methyltestosterone	Salmon	Young	Muscle	44	
	Trout	Young	Muscle	5	
Nortestosterone	Salmon	Young	Muscle	37	
■ 2 Pesticides Including PCBs					
Pyrethroids	Salmon	Market	Muscle	55	
OC/PCBs	Salmon		Muscle	63	
Trout	Market		Muscle	8	
Organophosphorus	Salmon	Market	Muscle	38	
■ 3 Heavy Metals					
Cadmium	Salmon	Market	Muscle	5	
	Trout	Market	Muscle	5	
Lead	Salmon	Market	Muscle	5	
	Trout	Market	Muscle	5	
■ 4 Sulphonamides					
	Salmon	Market	Muscle	69	
	Trout	Market	Muscle	10	
■ 5 Antimicrobial Screen					
	Salmon	Market	Muscle	144	
	Trout	Market	Muscle	7	
■ 6 Tetracyclines					
	Salmon	Market	Muscle	135	
	Trout	Market	Muscle	4	
■ 7 Quinolones					
	Salmon	Market	Muscle	80	
	Trout	Market	Muscle	7	
■ 8 Annex IV					
Chloramphenicol	Salmon		Muscle	185	
	Trout	Market	Muscle	20	
Dimetridazole	Salmon	Young	Muscle	197	
	Trout	Market	Muscle	15	
■ 9 Anthelmintics					
Benzimidazoles	Salmon	Market	Muscle	87	
	Trout	Market	Muscle	11	
Ivermectin	Salmon		Muscle	167	
	Trout	Market	Muscle	5	
Levamisole	Salmon	Market	Muscle	38	
	Trout	Market	Muscle	11	
■ 10 Mycotoxins					
	Salmon	Market	Muscle	6	
	Trout	Market	Muscle	5	
■ 11 Malachite Green					
Malachite Green	Salmon	Market	Muscle	52	
Leuco Malachite Green				52	8
Malachite Green	Trout	Market	Muscle	49	
Leuco Malachite Green				48	
Total				1,574	8

NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN EGGS
RESULTS OF RANDOM SAMPLING IN GREAT BRITAIN - 1 JANUARY 2002-2 JANUARY 2003

Type of Compound\Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 1 Pesticides Including PCBs				
OC/PCBs	Caged	Eggs	25	
	Free Range	Eggs	10	
	Perchery	Eggs	5	
■ 2 Sulphonamides				
	Caged	Eggs	64	
	Free Range	Eggs	26	
	Perchery	Eggs	10	
■ 3 Antimicrobial Screen				
	Caged	Eggs	180	
	Free Range	Eggs	75	
	Perchery	Eggs	30	
■ 4 Annex IV				
Chloramphenicol	Caged	Eggs	47	
	Free Range	Eggs	14	
	Perchery	Eggs	7	
Dimetridazole	Caged	Eggs	107	
	Free Range	Eggs	53	
	Perchery	Eggs	19	
Furazolidone	Caged	Eggs	61	
	Free Range	Eggs	23	
	Perchery	Eggs	10	
■ 5 Anthelmintics				
Benzimidazoles	Free Range	Eggs	19	
■ 6 Coccidiostats				
Ionophores	Caged	Eggs	159	9
	Free Range	Eggs	66	2
	Perchery	Eggs	23	1
Nicarbazin	Caged	Eggs	135	
	Free Range	Eggs	58	
	Perchery	Eggs	23	
Total			1,249	12

NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN MILK
RESULTS OF RANDOM SAMPLING IN GREAT BRITAIN - 1 JANUARY 2002-2 JANUARY 2003

Type of Compound\Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 1 Pesticides Including PCBs				
OC/PCBs	Bovine	Milk	53	
Organophosphorus	Bovine	Milk	22	
■ 2 Heavy Metals				
Cadmium	Bovine	Milk	8	
Lead	Bovine	Milk	8	
■ 3 Sulphonamides				
	Bovine	Milk	134	
■ 4 Antimicrobial Screen				
	Bovine	Milk	548	
■ 5 Tetracyclines				
	Bovine	Milk	127	

Type of Compound\Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 6 Quinolones	Bovine	Milk	185	
■ 7 Annex IV				
Chloramphenicol	Bovine	Milk	192	
Dimetridazole	Bovine	Milk	220	
■ 8 Anthelmintics				
Avermectins	Bovine	Milk	221	
Levamisole	Bovine	Milk	109	
■ 9 NSAIDs	Bovine	Milk	150	
■ 10 Mycotoxins	Bovine	Milk	77	
Total			2,054	0

NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN GAME RESULTS OF RANDOM SAMPLING IN GREAT BRITAIN - 1 JANUARY 2002-2 JANUARY 2003

Type of Compound\Substance	Species	Matrix	No. of Analyses	No. above Action Level	
■ 1 Hormones					
Stilbenes	Deer (Farm)	Liver	1		
Trenbolone	Deer (Farm)	Liver	1		
Zeranol	Deer (Farm)	Liver	3		
■ 2 Pesticides Including PCBs					
Carbamates	Deer (Farm)	Liver	5		
OC/PCBs	Deer (Farm)	Kidney Fat	8		
■ 3 Beta-Agonists	Deer (Farm)	Liver	4		
■ 4 Heavy Metals					
Cadmium	Deer (Farm)	Muscle	6		
	Deer (Wild)	Muscle	16		
	Partridge	Muscle	14		
	Pheasant (Wild)	Muscle	9		
	Lead	Deer (Farm)	Muscle	5	
		Deer (Wild)	Muscle	16	1
		Partridge	Muscle	14	1
		Pheasant (Wild)	Muscle	9	
		■ 5 Antimicrobial Screen			
	Deer (Farm)	Kidney	10		
	Quail	Muscle	9		
■ 6 Annex IV					
Dimetridazole	Deer (Farm)	Liver	3		
	Partridge	Muscle	20		
	Pheasant (Wild)	Muscle	17		
■ 7 Anthelmintics					
Benzimidazoles	Quail	Muscle	11		
Ivermectin	Deer (Farm)	Liver	6		
Levamisole	Deer (Farm)	Liver	5		
■ 8 Coccidiostats					
Ionophores	Quail	Muscle	21		
Nicarbazin	Deer (Farm)	Liver	4		
■ 9 Thyrostats	Deer (Farm)	Liver	1		
Total			218	2	

■ RESULTS OF NON-STATUTORY SURVEILLANCE

Non-Statutory Surveillance 2002

The non-statutory veterinary medicine residue surveillance programme covers imported and home produced foods that are not part of the National Surveillance Scheme (NSS). The programme can carry out short surveys for areas of potential concern that are brought to our attention.

Since the start of the 2002 programme in April, the Central Science Laboratory has received 1,185 samples and completed 4,385 analyses. Since the last report in MAVIS 44 (October 2002), 32 samples have been found to contain residues of veterinary medicines above the Maximum Residue Limit/Action Level. Details of these positive residues are given below.

Streptomycin

Residues of streptomycin have been found in 10 samples of imported honey at concentrations between 24-290µg/kg. No MRL has been set for streptomycin in honey. The samples were collected from consignments from Mexico (2), Zambia (1) Argentina (3), USA (1), Romania (2) and India (1) by Port Health officials at the Border Inspection Posts. The Chief Veterinary Officer (CVO) has asked officials in the countries of origin to investigate these residues and report back their findings. Previous toxicological advice is that these residues would not be harmful to human health. The residues have also been reported to the Food Standards Agency (FSA) for further action.

Nitrofurans

Two samples of warm water prawns, imported from Burma (now Myanmar) and Bangladesh contained residues of the nitrofurans metabolite semicarbazide. The concentrations detected were 3.1 and 2.4µg/kg respectively. A further sample, imported from Vietnam, contained residues of the AOZ metabolite at 17µg/kg. Nitrofurans are in Annex IV of EC Council Regulation 2377/90. Their use in food producing species is prohibited. This information has been passed to the FSA for further action. The CVO has asked officials in the countries of origin to investigate how these residues have occurred and to report what steps have been taken to ensure such substances are not used in future. Toxicological advice is that it is not possible to identify a "safe" residue concentration.

Chloramphenicol

A residue of chloramphenicol has been confirmed in a sample of black tiger prawns at a concentration of 0.8µg/kg. The sample was of Vietnamese origin. The retailer has been notified and requested to provide details from the supplier to help to establish an audit trail. This information has been passed to the FSA for further action. Toxicological advice is that it is not possible to identify a "safe" residue concentration. The CVO is writing to the Vietnamese authorities asking them to investigate the cause of the residue and report what steps have been taken to ensure this substance is not used in the future.

Dimetridazole/2-hydroxydimetridazole

A sample of quail eggs was found to contain residues of dimetridazole and its metabolite 2-hydroxydimetridazole at concentrations of 3 and 8µg/kg respectively. Dimetridazole is in Annex IV of EC Council Regulation 2377/90. Its use in food producing animals is therefore prohibited. The same sample was also found to contain residues of nicarbazine at a concentration of 40µg/kg.

Nicarbazine

Twelve samples of quail eggs (including the sample referred to above) have been found to contain residues of nicarbazine at concentrations ranging between 20 and 490µg/kg. Recent toxicological advice states that at these levels the residue is unlikely to present a significant risk to consumers.

Sulphonamides

A sample of rabbit, imported from France, was found to contain sulphadimethoxine at a concentration of 370µg/kg and a sample of trout imported from Denmark was found to contain residues of sulphadiazine at a concentration of 1,800µg/kg. A sample of honey imported from the USA which contained streptomycin (referred to above) was also found to contain sulphathiazole at a concentration of 44µg/kg. This information has been passed to the FSA for further action. Toxicological advice states that there is no MRL for sulphonamides only a tolerance value of 100µg/kg and though this has been exceeded there is unlikely to be a significant risk to human health. The CVO has been asked to write to the countries of origin asking them to investigate this matter and to report what action has been taken to prevent such residues occurring again. A sample of quail eggs imported from France was found to contain sulphadimethoxine at a concentration of 320µg/kg. The CVO is writing to the French authorities to ask them to investigate this matter.

Malachite green/Leucomalachite green

Three samples of salmon imported from Chile and collected by Port Health officials at a Border Inspection Post were found to contain residues of leucomalachite green, a metabolite of malachite green at concentrations between 4-18µg/kg. Malachite green has never been authorised as a veterinary medicine in the EU and should not be present in imported farmed fish. This information has been passed to the FSA for further action. The CVO has been asked to write to the Chilean authorities to ask them to investigate this matter.

Two retail surveys of farmed salmon were undertaken in 2002; one of imported salmon and trout and one of home-produced.

Imported salmon and trout: 51 samples of imported salmon and 11 samples of trout were purchased at retail outlets and analysed for residues of malachite and leucomalachite green. Two samples of salmon imported

from the Faroe Islands tested positive for residues of leucomalachite green at concentrations of 10 and 11µg/kg. One sample also contained a confirmed residue of malachite green below the limit of quantification. These results have been reported to the retailer who is investigating. The CVO has notified the Faroese authorities who have confirmed that they will carry out a full investigation into the cause of these residues.

Home produced salmon and trout: 93 samples of salmon and 24 samples of trout were purchased at retail outlets and analysed for residues of malachite and leucomalachite green. Four samples of salmon contained residues of leucomalachite green at concentrations of 2.8, 10 (2), and 13µg/kg. The retailers of these samples have been contacted and asked to investigate the cause of these residues with their suppliers. The VMD has written to the Commission setting out the results of these surveys and explaining the further surveys that will be undertaken in 2003.

ENVIRONMENTAL CONTAMINANTS

Organochlorines/PCBs

Since MAVIS 44 there have been a further 25 samples found to contain residues of either organochlorines/PCBs or both, as follows:-

One sample of salmon imported from the USA and two samples from Chile were found to contain residues of DDE in the range of 4-30µg/kg (fat weight). Six samples imported from the USA and Chile (including those mentioned above) were found to contain residues of ICES 7 group of PCB congeners.

Three samples of trout imported from Denmark were found to contain residues of DDT and the breakdown products DDE and TDE at concentrations in the range of 2-163µg/kg (fat weight). No MRLs are set for residues of organochlorines in fish. These samples also contained residues of ICES 7 group of PCB congeners. A further sample, country of origin labelled as "produce of Denmark or France" was also found to contain residues of PCBs.

Fifteen samples of prawns imported from Vietnam (1), Malaysia (1), Thailand (3), India (3), Honduras (2), Indonesia (2), France (1), SE Asia (1) and one of unknown origin contained residues of ICES 7 group of PCB congeners.

An update will be provided on all investigations reported above as in progress in the next edition of MAVIS.

Follow up action from MAVIS 44

Chloramphenicol

MAVIS 44 reported a residue of chloramphenicol in a sample of honey imported from Cyprus. The Cypriot authorities have completed an urgent investigation into the cause of this residue. The results of further analysis of honey from this supplier carried out at a Canadian laboratory were negative for residues of chloramphenicol. The producer has indicated that this sample may have been contaminated with Chinese honey from a batch imported before the EU embargo was in place.

Dimetridazole/2-hydroxydimetridazole

Following the detection of residues of dimetridazole and its 2-hydroxy-metabolite at concentrations of 41 and 88µg/kg respectively in a sample of quail eggs as well as a residue of lasalocid at 130µg/kg, the Royal Pharmaceutical Society of Great Britain (RPS(GB)) has completed its investigation and their report is expected shortly.

Lasalocid

The report concerning the four samples of quail eggs reported as containing residues of lasalocid between 41-520µg/kg is due to be received shortly.

**NON-STATUTORY SURVEILLANCE RESULTS
2002**

Matrix	Analyte	No. of samples analysed	MRL/Action Level where set µg/kg	No. of samples above Action Level
Baby food chicken	Antimicrobial screen	50	Not set	
	Fluoroquinolones	8	Not set	
	Lasalocid	50	Not set	
	Nicarbazin	50	Not set	
	Sulphonamides	52	Not set	
Baby food lamb	Antimicrobial Screen	47	Not set	
	Fluoroquinolones	9	Not set	
	Organophosphates	26	Not set	
Baby food pork	Antimicrobial Screen	48	Not set	
	Sulphonamides	50	Not set	
Imported bacon	Antimicrobial Screen	107	Various	
	Carbadox	57	Not set	
	Dimetridazole/ronidazole	17	Not set	
	Fluoroquinolones	101	100 (total)	
	β-agonists	98	Not set	
	Sulphonamides	107	100 (total)	
	Tetracyclines	45	100	
	Tranquilisers	56	100 azaperone	
Imported honey	Antimicrobial Screen	68	Not set	2
	Cadmium	35	1,000	
	Chloramphenicol	67	Not set	1
	Lead	35	1,000	
	Organochlorines/PCBs	35	Various/Not Set	
	Organophosphates	35	100 coumafos	
	Pyrethroids	39	Not set	
	Streptomycin	49	Not set	14
	Tetracyclines	10	Not set	
	Imported rabbit	Antimicrobial screen	26	Various
Chloramphenicol		33	Not set	3
Dimetridazole/ronidazole		26	Not set	
Fluoroquinolones		33	100 (total)	
Organochlorines/PCBs		16	Various/Not Set	
Organophosphates		16	Various	
Tetracyclines		25	100	
Imported raw beef		Antimicrobial screen	146	Various
	Dimetridazole/ronidazole	131	Not set	
	Fluoroquinolones	150	100 (total)	
	Ivermectin	63	Not set	
	β-agonists	109	Not set	
	Trenbolone	151	Not set	
	Imported raw chicken	Antimicrobial Screen	129	Various
Benzimidazoles		67	50 flubendazole	
Chloramphenicol		146	Not set	
Dimetridazole/ronidazole		120	Not set	
Fluoroquinolones		144	100 (total)	
Furazolidone		26	Not set	
Lasalocid		93	Not set	
Nicarbazin		74	200	

Matrix	Analyte	No. of samples analysed	MRL/Action Level where set µg/kg	No. of samples above Action Level
Imported raw lamb	Antimicrobial screen	69	Various	
	Ionophores	7	Not set	
	Organochlorines/PCBs	26	Various/Not set	
	Organophosphates	32	Various	
	Pyrethroids	13	Various	
	Tetracyclines	69	100	
Imported raw pork	Antimicrobial screen	58	Various	
	Carbadox	30	Not set	
	Dimetridazole/ronidazole	47	Not set	
	Fluoroquinolones	70	100 (total)	
	Streptomycin/ dihydrostreptomycin	14	500	
	Tranquilisers	22	100 azaperone	
Imported raw turkey	Antimicrobial Screen	40	Various	
	Benzimidazoles	29	50 flubendazole	
	Chloramphenicol	48	Not set	
	Dimetridazole/ronidazole	29	Not set	
	Fluoroquinolones	44	100 (total)	
	Ionophores	6	Not set	
	Lasalocid	29	Not set	
Imported salmon	Antimicrobial screen	25	Various	
	Avermectins	11	100 emamectin	
	Diflubenzuron/Teflubenzuron	4	500/1,000	
	Dimetridazole/ronidazole	14	Not set	
	Malachite green/ leucomalachite green	14	Not set	3
	Organochlorines/PCBs	7	Various/Not Set	6
	Quinolones	18	300 oxolinic	
Imported trout	Antimicrobial screen	16	Various	1
	Avermectins	10	100 emamectin	
	Diflubenzuron/Teflubenzuron	8	500/1,000	
	Dimetridazole/ronidazole	10	Not set	
	Malachite green/ leucomalachite green	10	Not set	
	Organochlorines/PCBs	9	Various/Not Set	9
	Quinolones	10	300 oxolinic	
Quail eggs	Antimicrobial Screen	33	Not set	1
	Dimetridazole/ronidazole	27	Not set	2
	Fluoroquinolones	34	Not set	
	Lasalocid	17	Not set	5
	Nicarbazin	20	Not set	12
Warm water prawns	Antimicrobial screen	101	Various	
	Chloramphenicol	90	Not set	1
	Furazolidone	32	Not set	4
	Organochlorines/PCBs	36	Not set	15
	Quinolones	89	Not set	
	Streptomycin	13	Not set	

**MARKETING AUTHORISATIONS ISSUED UNDER THE MARKETING AUTHORISATIONS FOR
VETERINARY MEDICINAL PRODUCTS REGULATIONS 1994 GAZETTED BETWEEN
6 SEPTEMBER - 6 DECEMBER 2002**

Company	Vm Number	Product Name	Legal Category
Boehringer Ingelheim Ltd	00015/4057	Rupinal	POM
Evans Vanodine International Plc	03940/4082	Venture 321	GSL
Fort Dodge Animal Health Ltd	01596/4199 01596/4309	Kavak Galaxy DA2Pip + L Duvaxyn IE PLUS	POM POM
Intervet International BV	01708/4480	Nobilis MG 6-85	POM
Intervet UK Ltd	01708/4467	Panacur Favourites for Cats	PML
Lohmann	16894/4003 16894/4004	Avipro Precise TAD Salmonella vac T	POM POM
Sinclair Animal and Household Care Ltd	02548/4048	Armitage Felt Flea Collar Twin Pack	GSL
Vetoquinol (UK) Ltd	08007/4105	Lignadrin 2%	PML

**VETERINARY MARKETING AUTHORISATION FOR PARALLEL IMPORTS GRANTED
UNDER THE VETERINARY MEDICINAL PRODUCTS REGULATIONS 1994 SI 1994/3142
GAZETTED BETWEEN 6 SEPTEMBER - 6 DECEMBER 2002**

Company	Vm Number	Product Name	Legal
Chanelle Animal Health Ltd	11990/4027	Synolux Ready To Use Injection	POM
Dowelhurst Ltd	05662/4000 05662/4001 05662/4002	Equest Oral Gel Equest Oral Gel Equest Oral Gel	PML PML PML

**VETERINARY MARKETING AUTHORISATION FOR
EU CENTRALLY AUTHORISED PRODUCTS GRANTED
UNDER COUNCIL REGULATION (EEC) NO 2309/93
GAZETTED BETWEEN 6 SEPTEMBER - 6 DECEMBER 2002**

Company	Product Name	Legal
Intervet International BV	Nobivac Bb for Cats	POM

The following tables list authorised variations which may affect the use of the product:

VARIATIONS APPROVED - 6 SEPTEMBER - 6 DECEMBER 2002

Company	Product Name	Brief Details
Alpharma Animal Health Ltd	Aurofac 100 Granular	Additional pack size
Alpharma AS	Alpha Ject 5200	Change in packaging composition
Bayer Plc	Advantage for Small Cats, Small Dogs and Pet Rabbits	Indications modified to include larvicidal activity
	Advantage for Small Cats and Small Dogs	Indications modified to include larvicidal activity
Bayer UK Ltd	Baytril 2.5% Injection	Additional safety warnings re: ocular toxicity in cats
	Baytril 5% Injection	Additional safety warnings re: ocular toxicity in cats
	Baytril Tablets 15mg	Additional safety warnings re: ocular toxicity in cats
	Fleegard 8 for Cats	Shelf life extended
	Fleegard 10 for Dogs	Shelf life extended
Boehringer Ingelheim Ltd	Trinacol Injection	Withdrawal period increased
Chanelle Animal Health Ltd	Clinacin 75mg Tablets	Shelf life extended
Dales Pharmaceuticals Ltd	Millophyline V Tablets 300mg	Change of MA holder to Arnolds Veterinary Products Ltd
	Millophyline V Tablets 200mg	Change of MA holder to Arnolds Veterinary products Ltd
	Millophyline V Injection	Change of MA holder to Arnolds Veterinary Products Ltd
Day Son and Hewitt Ltd	Radiol Insecticidal Soapless Shampoo with Conditioner	Additional pack size
DiverseyLever Ltd	Deosan Super Ex-Cel	Additional pack size
Grampian Pharmaceuticals Ltd	Vitenium Injection	Pigs removed as target species
	Plt Tablets	Change of MA holder to Novartis Animal Health UK Ltd
Intervet International BV Akzo	Nobilis RT+IBmulti+G+ND	Change to in process controls
Intervet UK Ltd	Panacur 2.5% Suspension	Withdrawal period decreased for sheep
	Heptavac	Change in shape of bottle from flat to round
	Blackleg Vaccine	Change in shape of bottle from flat to round
	Eryvac	Change in shape of bottle from flat to round
	Eryorb Plus	Change in shape of bottle from flat to round
	Lambivac	Change in shape of bottle from flat to round
	Ovovac P Plus	Change in shape of bottle from flat to round
	Nobilis Pasteurella Erysipelas	Change in shape of bottle from flat to round
	Heptavac P Plus	Change in shape of bottle from flat to round
Janssen Cilag Ltd	Ovispec S & C 2.5%	Additional packs
	Ovispec S & C 10%	Additional packs
Lohmann	Tad Salmonella Vac E	Change in contra-indications
Merial Animal Health Ltd	Frontline Spot On Dog	Addition of Safety Warnings re ocular irritancy. Modifications of indications re puppies and nursing bitches

Company	Product Name	Brief Details
Norbrook Laboratories Ltd	Levafas Fluke and Worm Drench Norworm Endoworm Calciject 20 Cm Calciject 40 Cm Alamycin LA 300 Levafas Diamond	Withdrawal period decreased for cattle and sheep meat Legal category changed from PML to GSL Meat withdrawal period decreased Shelf life extended in plastic vials Shelf life extended in plastic vials Withdrawal period increased for cattle Withdrawal period decreased for cattle and sheep
Novartis Animal Health UK Ltd	Ovitrol Cat Collar Robust Telsol 800	Legal category changed from POM to GSL Shelf life extended Withdrawal period increased for chickens. New contra-indication for birds producing eggs for human consumption
Novartis Animal Vaccines Ltd	Bovidec	Additional pack size
Oropharma NV	Amoxicure	Shelf life extended
Pfizer Ltd	Orbenin Extra Dry Cow	Additional outer pack size
Pharmacia Animal Health Ltd	Chloromycetin V Redidrops	Change in container shape
Quay Equestrian Limited	Killitch	Pack changed from blue to white
Reckitt Benckiser Healthcare (UK) Ltd	Vetergesic	Address of distributor
Schering-Plough Ltd	Tribrissen Injection 48%	Withdrawal period increased for milk from cattle. Withdrawal period increased for meat
The Bob Martin Co	Bob Martin Flea & Tick Permethrin Spot On	Product name changed to Bob Martin Permethrin Dog Spot On . Change of name of MA holder to Bob Martin (UK) Ltd
Trouw (UK) Ltd	Calicide	Change in mixing instructions
Vetem	Galastop	Change of address of distributor
Vetoquinol (UK) Ltd	Epiphen Solution Cefalexin Tablets 250mg	Change of dropper insert Change of MA Holder to Forum Products Ltd

**EXPIRED MARKETING AUTHORISATIONS GAZETTED BETWEEN
6 SEPTEMBER - 6 DECEMBER 2002**

Company	Vm Number	Product Name
Bimeda Chemicals Ltd	02676/4140	Bimadine Powder
Diverseylever Ltd	15985/4000	Wormaway Fenben
	15985/4001	Wormaway Fenben 10
	15985/4017	Wormaway Levam
	15985/4019	Wormaway Fenben Sc
	15985/4016	Wormaway Levamisole Injection
Eli Lilly & Co Ltd	00006/4085	Apralan 200mg Injection
Emprasan (Chemical) Ltd	05568/4006	Emprasan Summer K Dip
Fort Dodge Animal Health Ltd	01596/4181	Duphamox 50mg
	01596/4219	Suvaxyn Aujeszky
Grampian Pharmaceuticals Ltd	12809/4097	Rycomec Drench
Intervet UK Ltd	01708/4216	Amfipen 30%
MAFF Weybridge	03326/4000	Mallein Ppd
Merial Animal Health Ltd	08327/4088	Copacaps Ewe Calf
	08327/4089	Copacaps Cattle
Novartis Animal Health UK Ltd	12501/4033	Superspray
Pfizer Ltd	00057/4122	Imuresp
Schering Plough Ltd	00201/4073	Autoworm 5 Pulse Release Bolus
	00201/4106	Zaquilan 15g 2 Day Bolus for Cattle
	00201/4111	Nilvern Plus Drench
	00201/4060	Zaquilan 600mg Tablets for Dogs
	00201/4062	Zaquilan 60mg
	00201/4117	Grisovin Veterinary Tablets
	00201/4120	Nilzan Drench Plus
Vetoquinol (UK) Ltd	08007/4031	Penillin Ps
Virbac SA	05653/4029	Johnsons Extra Guard Flea and Tick Spray with Permethrin