

MAVIS

MEDICINES ACT VETERINARY INFORMATION SERVICE

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■ MAVIS - 50th EDITION

The Medicines Act Veterinary Information Service (MAVIS) is designed to provide readers with information on the VMD's work, plans and results, as well as general developments on the controls on veterinary medicines. The first edition of MAVIS was published in May 1992. MAVIS was originally conceived to improve the speed at which information on licensing and surveillance procedures was made available and to make this information accessible to the public. Since that time MAVIS has developed to cover general news regarding the VMD and its work, Licensing issues, EU Legislation, Enforcement, Antimicrobial Resistance updates, the Suspected Adverse Reaction Surveillance Scheme, the Veterinary Products Committee meetings, Residues Controls and Monitoring and Marketing Authorisation notifications.

MAVIS provides an important source of information for veterinary practices, veterinary related groups and relevant trade organisation with a circulation of approximately 6,500.

MAVIS is usually published at the end of January, April, July and October. To increase readership, all previous editions are available on our VMD website www.vmd.gov.uk under publications. As well as this, MAVIS on-line is updated regularly between hard copy publication, therefore providing the most up-to-date information on the work of the VMD.

We hope you find MAVIS an informative publication. If you have any ideas on how it could be improved we would welcome your comments (**Please send comments to: Julie Jones e-mail: j.jones@vmd.defra.gsi.gov.uk**).



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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

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ASSURING THE SAFETY, QUALITY AND EFFICACY
OF VETERINARY MEDICINES

MEMBERSHIP OF THE VETERINARY RESIDUES COMMITTEE

On 5 January 2004 the Veterinary Medicines Directorate issued a consultation letter inviting nominations/applications for the Chair and membership of the Veterinary Residues Committee (VRC) to replace those members whose terms of office came to an end on 31 December 2004 and would not be serving a second term of office.

Appointments will be made strictly on merit, in accordance with the Commissioner for Public Appointments guidance on appointment to public bodies and will, initially, be for a two year term. Selection will be in accordance with the Government's Equal Opportunities policy.

The closing date for receipt of completed application forms was 23 April 2004. A Sift Panel will meet shortly to consider the applications, and those applicants considered by the Panel to be suitable for appointment will be interviewed and their names submitted to Ministers for consideration.

A Defra News Release announcing the names of the new appointees will be issued in due course.

Further information on the VRC appointments' exercise may be obtained by consulting the Committee's website (www.vet-residues-committee.gov.co.uk) or from **Colin Bennett, VRC Appointments' Secretary, Veterinary Medicines Directorate, Woodham Lane, New Haw, Surrey KT15 3LS. Tel: 01932 338490, fax: 01932 336618, email: c.bennett@vmd.defra.gsi.gov.uk.**

VMD ANNUAL LIAISON MEETING WITH REPRESENTATIVES OF CONSUMER ORGANISATIONS

A report of the 2004 meeting has now been posted on our website (www.vmd.gov.uk). The meeting included discussions on the following issue:

- Update on the on-going situation in respect of antibiotics
- Consultation on implementing the Review 2001.
- Risk management and veterinary medicines.
- Withdrawal of antibiotic growth promoters.

If you would like a hard copy then please contact **Diane Biggs (VMD, 01932 338347, e-mail: d.biggs@vmd.defra.gsi.gov.uk)**

HORSE MEDICINES UPDATE

The Horse Medicines lists on the VMD website under publications, have recently been updated to include advice on the records that need to be kept in accordance with the Horse Passport Legislation. In particular, the updated information lists the medicines which must be recorded in the passport and also details that need to be kept in order that withdrawal periods may be monitored.

Further information: Heather Oliver (VMD, 01932 338326, e-mail: h.oliver@vmd.defra.gsi.gov.uk).

STAFF CHANGES

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

Lesley Johnson was promoted to Grade 6 - Head of Pharmaceuticals and Feed Additives Team on 8 March 2004.

Clare Main took up a permanent appointment as an Administrative Assistant in the Enforcement and Feed Additives Branch with effect from 19 February 2004.

Maureen Kelly retired from the VMD on 8 March 2004. Carol Underhill is filling Maureen's Administrative Officer post in finance on a temporary basis.

Rahel Mulugeta took up a permanent appointment as a Scientific Officer in the Suspected Adverse Reactions Surveillance Scheme (SARSS) team with effect from 15 March 2004.

Scott Price moved to a permanent appointment as a Scientific Officer in the Immunologicals team with effect from 15 March 2004.

Sheila West our receptionist left the VMD on 16 April 2004. The VMD receptionist post will be filled by a temporary member of staff until a recruitment can be completed.

Sandra Hillman left the VMD on 26 March 2004. Diane Biggs is filling Sandra's post in the Strategic Support team on a temporary basis.

ADVERTISING HUMAN MEDICINAL PRODUCTS TO VETERINARY SURGEONS

Questions have been raised about the practice of wholesale dealers advertising human medicinal products to veterinary surgeons. John FitzGerald, Director of Policy, wrote to all holders of veterinary medicines wholesale dealer licences on 31 March 2004 and this letter is repeated here.

"There have been a number of incidents recently where the advertising of human medicinal products to veterinary surgeons could be seen as encouraging the veterinary

surgeon to use the human products unlawfully. I wrote to the Veterinary Record to inform people of the issue and the current legal requirements. A copy of this letter is enclosed for information.

I know that one human medicines wholesaler has decided to put a label setting out how medicines may be used by a veterinary surgeon under the prescribing cascade on the front of their price list whenever it is sent to a veterinary surgeon. This is clearly good practice as it is an offence not only to administer to an animal a medicine which is not authorised for use with animals, but to cause or to permit such administration. You will no doubt wish to ensure that nothing you do in distributing your price lists could in anyway establish a causal or other link along these lines to an unlawful administration of a medicinal product to an animal.

The VMD considers that any distribution of wholesale price lists containing human medicinal products to veterinary surgeons must, therefore, be accompanied by a reminder of the legal requirements for the use of such medicines in animals. Ideally, each page that includes human medicines should also carry a strapline warning vets that these medicines are authorised for humans and may only be used in animals in accordance with the prescribing cascade.

I am arranging for both this letter and the attachment to be reprinted in MAVIS, the VMD's quarterly newsletter."

Please find below the letter to the *Veterinary Record*, 11 December 2003, from John FitzGerald.

"The VMD is aware of a Veterinary Wholesaler's price list that sets out authorised veterinary medicinal products and human medical generics on the same page. We are concerned that this may be seen as promoting the use of human generic products and encouraging vets to use them in an illegal way. We understand that the offending price list is no longer being issued and we are grateful for this. However, we feel it is nevertheless opportune to remind veterinary surgeons that human generic products may only be used in accordance with the provisions of the prescribing cascade.

Legislation prohibits the administration to animals of a veterinary medicinal product unless it is authorised. The prescribing cascade provides an exemption for veterinary surgeons. Where no authorised veterinary medicinal product exists for a condition in a particular species a veterinary surgeon is permitted to prescribe or administer, in descending order of preference:

- (i) a veterinary medicine authorised in the UK for a different condition or species;
- (ii) a medicine authorised in the UK for human use;

- (iii) a medicine made up on a one-off basis (prepared extemporaneously) by a veterinary surgeon or a properly authorised person in accordance with the veterinary surgeon's specifications.

The prescribing cascade options are only available where no authorised product exists for the condition and species being treated. There are, however, circumstances in which a veterinary surgeon may, on the basis of clinical and professional judgement, conclude that no authorised product exists in the circumstances of a particular case. Further guidance on this and other aspects of the prescribing cascade is contained in the Amelia 8 guidance note which is available on the VMD website (www.vmd.gov.uk) or in hard copy from the VMD at Woodham Lane, New Haw, Addlestone KT15 3LS (tel: 01932 338321)."

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

■ A NEW SURVEY AIMED AT IMPROVING OUR SERVICE

We are seeking feedback from companies who use the regulatory services of the VMD and who are included in our residue surveillance programmes, in order to better understand how well our service delivery is meeting their needs. We will use the findings of the survey to improve the service we provide and the results of the survey and any planned improvements will be made available.

Precision Prospecting Ltd (PPL), are carrying out the survey on our behalf. PPL are an independent market research company highly experienced in this type of work.

The survey has two parts. During the first phase, PPL investigated, in depth, the issues that were most important to our customers and the results formed the core of a specially designed questionnaire that PPL will employ more widely during the second phase. The second phase begins in May.

If they contact you, PPL would ideally like to meet you or speak to you on the phone for no more than half an hour. If they meet you, it will be at a location and at a time to suit you. Your responses will be anonymous, unless there is something you specifically ask to be passed on to the VMD. If you are selected for interview, we do hope you will be able to give your time, as your views will be vitally important to the success of the survey.

Further Information: David Lewsey (VMD, 01932 338332, e-mail: d.lewsey@vmd.defra.gsi.gov.uk).

LICENSING

■ ANIMAL TEST CERTIFICATES (ATCs)

In the last addition of *MAVIS*, we announced the new ATC scheme which came into force on 12 January. We will be running a seminar on the new scheme and this will take place at VMD in the afternoon of Tuesday 8 June. Invitation letters for the seminar will be sent out during May, but you may like to make a note of the date in your diaries now.

Further information: Sandra Russell (VMD, 01932 338439, e-mail: s.russell@vmd.defra.gsi.gov.uk)

■ LICENSING ADMINISTRATION BRANCH FEEDBACK QUESTIONNAIRE

During the next few weeks we are planning to introduce a questionnaire that seeks feedback on the administrative performance in dealing with individual applications. This questionnaire will be sent out as part of the documentation issued in respect to all new Marketing Authorisations and with a representative sample of documentation issued in respect of variations and renewals. Marketing Authorisation Holders would then be invited to submit feedback on that specific application.

The aim is to gather performance feedback on only the administrative elements of the process. In recent months we have improved the quality of the documentation being issued and we would like to continue this positive trend. We would also like to see where else we could improve our administrative processes. The questionnaire should take no more than 10 minutes to complete.

This type of feedback will become more important now that Licensing Administration Branch has formal targets for issuing MA documentation. Feedback from the industry will help us to maintain the right balance between meeting our issuing target and producing good quality documentation.

Further information: Natalie Shilling (VMD, 01932 338452, e-mail: n.shilling@vmd.defra.gsi.gov.uk)

■ QUALIFIED PERSON'S DISCRETION IN BATCH CERTIFICATION

The Inspector's Working Party of the EMEA has recently released the following document:

- EMEA/INS/GMP/47/04 of 27 January 2004

Statement on the Qualified Person's discretion in batch certification when a batch does not fully meet the requirements of the Marketing Authorisation.

In summary, this statement clarifies that Qualified Person's may not certify batches for release onto the EU market if the batches do not fully comply with the requirements defined in the Marketing Authorisation. In such circumstances, if the Qualified Person considers that a batch is suitable for release, the Supervisory Authority (which in the case of veterinary medicines manufactured in the UK or released into the EU, is the VMD) must be contacted in the first instance. If they have no objections, the Competent Authority, if different, should be contacted taking into account any national schemes that are operated. For UK authorised veterinary medicines the VMD is the Competent Authority and the relevant national scheme for pharmaceutical products is the specific batch control scheme as announced in *MAVIS*, edition 49 of January 2004. Details of this scheme can be found on the VMD website (www.vmd.gov.uk).

For further information contact: Jackie Atkinson (VMD 01932 338405, e-mail: j.atkinson@vmd.defra.gsi.gov.uk)

■ LICENSING PERFORMANCE FOR 2003/2004

The following table shows a summary of the high level Ministerial targets for the Licensing Business Performance during 2003/2004, further information is in the Annual Report.

New Marketing Authorisations

For new UK Marketing Authorisations (MAs), the achievements of the targets are evaluated and assessed for the 120 clock day¹ measured in the following way:

Excellent	> 90% completed
Effective	80-90% completed
Unacceptable	< 80% completed

For the 210 clock day measure, it is stated that we will meet our statutory obligations to determine all MAs within 210 clock days.

The first part of this target for the year was 'To Sign off² or refer to VPC new applications for MAs within 120 clock days', the VMD achieved 91.89%. The second part of the target was, 'To Determine³ all applications within 210 clock days', we achieved 100% compliance.

National Type I & II Variations and Renewal Applications

For National Type I & II Variations and Renewal applications, the achievements of the targets are evaluated and assessed for the 120 clock day measured in the following way:

Excellent	> 95% completed
Effective	90-95% completed
Unacceptable	< 90% completed

National Type I Variations

The first part of this target is 'To complete our initial assessment within 30 clock days, the VMD achieved 98.30%. The second part of this target is 'To aim to sign off applications within 60 clock days. The VMD achieved 100%.

National Type II Variations

The first part of this target is 'To complete our initial assessment within 60 clock days, the VMD achieved 99.50%. The second part of this target is 'To aim to sign off or refer to VPC, applications within 120 clock days. The VMD achieved 99.54%.

Renewals Applications

The first part of this target is 'To complete our initial assessment within 90 clock days, the VMD achieved 99.30%. The second part of this target is 'To aim to sign off or refer to VPC, applications within 180 clock days. The VMD achieved 98.93%.

European Applications

For new European procedure (centralised, maximum residue limits (MRLs), and decentralised), performance against timetables agreed with the European Medicines Evaluation Agency and within established legislative timetables.

The target is 'To achieve 100% performance against agreed timetables. Achieving predictability for industry in the regulatory authority in the EU. The VMD achieved 100%.

- 1 'Clock days' is that time when the application is under assessment by VMD and excludes that time when further information is awaited from applicants in response to VMD questions.
- 2 'Sign Off' is the time taken to complete scientific assessment.
- 3 'Determine' is the time taken to sign off and issue authorisation documentation.

■ NUMBERS OF ATCs RECEIVED AND DETERMINED BETWEEN 1 JANUARY AND 31 MARCH

No. ATCs Received	5
No. ATCs Issued	10
Stopped at End Quarter	1
No. Refused at Validation	1
No. Withdrawn during Assessment	1

Time taken for Assessment of Issued ATCs

Range of Days	0-15	16-31	32+
No. of Applications	1	6	3

Average Days = 29

Time during which these issued applications were with the company dealing with outstanding questions

Range of Days	0-30	31-63
No. of Applications	9	1

Average Days = 13 days

Total time from validation to determination

Range of Days	0-30	31-68
No. of Applications	6	4

Average Days = 31 days

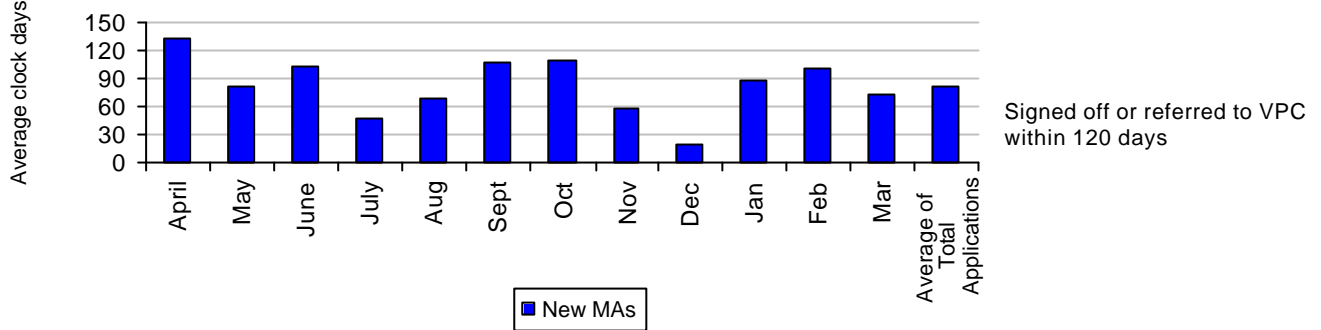
LICENSING BUSINESS PERFORMANCE AGAINST TARGETS

The Licensing Business is committed to providing information on 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 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.

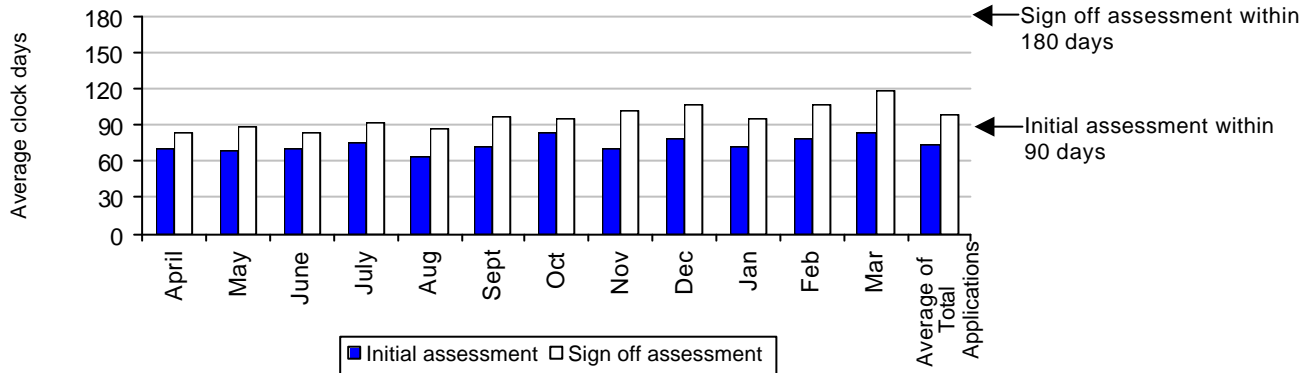
Further information on figures and charts: **Lea Stott** (VMD, 01932 338432, e-mail: l.stott@vmd.defra.gsi.gov.uk). For information in relation to licensing business performance contact **John O'Brien** (VMD, 01932 338387, e-mail: j.o'brien@vmd.defra.gsi.gov.uk).

New Marketing Authorisations

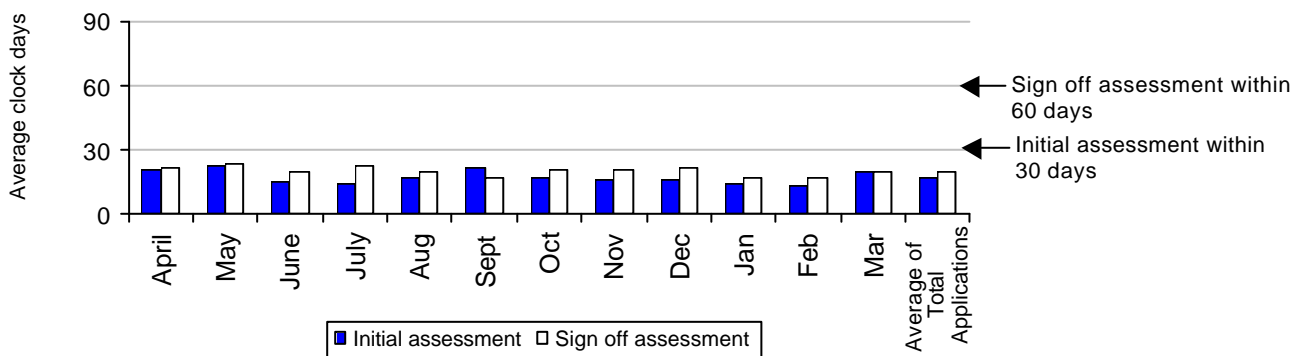
TARGETS (average clock days)



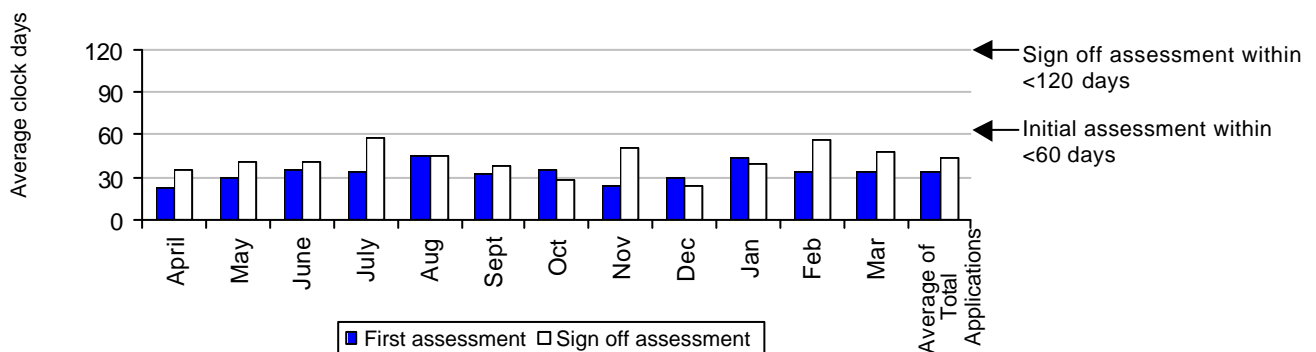
Renewals



National Type I Variations



National Type II Variations



■ EUROPEAN REVIEW OF VETERINARY MEDICINES LEGISLATION

The final package of changes was agreed by the Committee of Permanent Representatives on 3 March 2004 and adopted by Council on 11 March 2004. The new Regulation and amending Directives are expected to be published in the Official Journal by the end of April/early May. Changes in the internal workings of the EMEA necessary to accommodate the new Member States will come into force following publication of the Regulation. The remaining changes in the Regulation and the Directives will take effect 18 months from the date of publication. An informal consolidated version of the veterinary Directive, including all the amendments, has been placed on the VMD website and will be updated to show the final texts when they become available.

The VMD is now focusing on the implementation of the changes. Work has begun on considering the significant issues involved and the options for how they may be implemented. Informal discussions on various issues will take place over the coming months and meetings have been arranged with several interested groups. We intend to produce proposals by the end of 2004 and, subject to Ministerial agreement, to send them out for formal consultation for four months early in 2005.

As part of the implementation exercise we will also be carrying out a full Better Regulation Review of the existing UK legislation on veterinary medicines (excluding feed additives and residues). The intention will be to simplify the legislation wherever possible, making it more transparent and easier to understand. We will aim to revoke or disapply much of the existing legislation (which includes more than 50 statutory instruments) and replace it with a single, or as few as possible, new statutory instrument(s) containing all the required provisions. We will also be taking forward any changes aimed at Defra arising from those recommendations of the Marsh and Competition Commission Reports that were accepted by the Government.

Further information: Heather Oliver (VMD, 01932 338316, e-mail: h.oliver@vmd.defra.gsi.gov.uk)

ENFORCEMENT

A key element in our strategy for assuring the safety, quality and efficacy of veterinary medicines is the action that we take against the illegal marketing and use of unauthorised products and to promote the responsible use of authorised products. This section describes the most significant developments and outcomes in this area.

■ RETAILER FINED £400 FOR SELLING UNAUTHORISED PRODUCTS

On 16 February 2004 at Nottingham Magistrates Court, Mr J D Atkin, trading as the Allandale Practice, pleaded guilty to two charges of placing on the market a veterinary medicinal product contrary to Regulations 3 and 16 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994. Mr Atkin was ordered to pay fines totalling £400.

■ RETAILER PAYS £9,423.50 FOR SELLING UNAUTHORISED PRODUCTS

On 3 February 2004 at Ilkeston Magistrates Court, Alliance Products (UK) Ltd pleaded guilty to six charges of placing on the market, by way of advertisements on a website, veterinary medicinal products contrary to Regulations 3 and 16 of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994. The company was ordered to pay fines totalling £6,000, and to contribute £3,423.50 towards costs.

ANTIMICROBIAL RESISTANCE

Antimicrobial resistance is a serious problem in human and veterinary medicines, resulting in increasing concerns about the use of antimicrobial products in human medicines, veterinary medicine, animal production, agriculture and horticulture. A Government Strategy has been developed to address this issue. The Veterinary Medicines Directorate is responsible for delivering key elements of this strategy, including the collection and publication of information on the quantities of antimicrobial products sold each year for veterinary use in the UK and providing a secretariat to the Defra Antimicrobial Resistance Coordination (DARC) Group. The following articles describe the most recent actions that the VMD has taken to progress this strategy.

■ DARC GROUP MEETING

The Defra Antimicrobial Resistance Coordination (DARC) Group met on 17 February 2004. Items discussed included: publication of the strategy for surveillance of veterinary antimicrobial resistance; tracking progress with implementing the recommendations made in the ACMSF Report; finalising details for a comparable list of human and veterinary antimicrobials; and the development of an over-arching Antimicrobial Resistance Report for the UK. The Chairman of SACAR attended the DARC Group Meeting as an information sharing exercise.

■ DARC GROUP WEBSITE

Following Ministers agreement, a DARC Group web site has been developed and is available on the internet. The site can be accessed via the VMD web site at www.vmd.gov.uk under the DARC Group tab on the left of the screen.

■ SACAR

The Specialist Advisory Committee on Antimicrobial Resistance (SACAR) met on 18 March 2004. Items discussed included the development of a SACAR Annual Report, updates from the Committees sub-groups, issues surrounding incidence of *Salmonella* Java and a Defra update on relevant veterinary antimicrobial resistance related issues.

■ SALES DATA REPORT - ANTIMICROBIAL PRODUCTS

VMD has sent letters to the relevant pharmaceutical companies inviting them to provide their sales data returns for the calendar year 2003. Sales of the following product groups have been sought: therapeutic antimicrobials, therapeutic antiprotozoals, therapeutic antifungals, growth promoters and coccidiostats. Copies of the Report detailing sales in 2002 can be obtained from the VMD web site at www.vmd.gov.uk under the publications and general tabs, or from **Dr Kay Goodyear (VMD 01932 338409, e-mail: k.goodyear@vmd.defra.gsi.gov.uk)**

■ OTHER ANTIMICROBIAL ISSUES

VMD, in collaboration with colleagues at the Department of Health and the Health Protection Agency, have prepared a list of comparable human and veterinary antimicrobials. This has been posted on the DARC Group web site under the heading 'Comparable Veterinary and Human Antimicrobials'. The list includes products that are classified as antibacterial, antiprotozoal or antifungal. Both DARC and SACAR believe that this will be a valuable tool for medical and veterinary practitioners and trainees. It is hoped that the list will develop in time to include further relevant information.

VMD representatives have visited a feed mill with members of the Royal Pharmaceutical Society of Great Britain (RPSGB). During the visit discussions were held about apportioning the sales of multi-species antimicrobials between the species for which they are authorised. All parties involved agreed that this would be a valuable piece of work and have agreed to work together to try to provide data to show how multi-species products are used between the species.

The VMD is revising the R&D web pages on the VMD web site. As part of this review, all antimicrobial resistance based projects are being revisited. Additional information is being added on the web pages about all projects totally or partially funded by the VMD, including project title, project duration, contractors and abstracts. Details of the antimicrobial projects can be viewed along with all other projects by clicking on the R&D link on the left side of the VMD web page at www.vmd.gov.uk.

SUSPECTED ADVERSE REACTION SURVEILLANCE SCHEME

The definition of a Suspected Adverse Reaction (SAR) is taken from article 1, paragraph 10, of the Directive 2001/82/EC: "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 11, of Directive 2001/82/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 January to 31 March 2004, the VMD received 436 suspected adverse reaction reports involving animals. Of these, 48 reports related to unauthorised use, one involved an unauthorised or unidentified product, and 15 reports were considered unlikely to be product related. There were no reports involving animal trials under Animal Test Certificates (ATCs) and 28 reports involved suspected lack of efficacy.

The remaining 344 suspected adverse reaction reports were associated with 110 licensed products.

The 344 reports were divided by marketing categories as follows:

324	Prescription Only Medicine (POM)
16	Pharmacists and Merchants List (PML)
4	General Sales List (GSL)

During the quarter 18, 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.

During the quarter, WIIS forwarded a report of an environmental incident attributed to a veterinary medicine. The incident occurred in August 2003. The incident was that of a young Red Kite which was found dead. Investigation confirmed the cause of death as propetamphos (an organo-phosphate) poisoning. Sheep dip was suspected, but the product used was not identified. Propetamphos has not been available in an authorised veterinary medicine since 1999. It was concluded that this was a case of non-accidental poisoning.

The SARSS Report for January 2004 was presented to the Veterinary Products Committee (VPC) at the meeting in February 2004.

The SARSS Report for February 2004 was presented to the VPC at the meeting in March 2004.

The SARSS Report for March 2004 will be presented to the VPC at the meeting in April 2004.

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.*

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

The VPC met on 22 January, 19 February and 18 March. 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.

■ JANUARY MEETING

Applications

The Committee examined evidence relating to an application to vary a current UK Marketing Authorisation for a product for use in cattle, to establish TSE compliance.

The Committee provisionally concluded (subject to confirmation at its next meeting) that the application should be deferred to a future meeting.

General

The new Members were welcomed to the Committee and short presentations were given on:

- the VMD and the role of the VPC;
- the Role of a VPC Member;
- licensing procedures including the Suspected Adverse Reaction Surveillance Scheme; and
- administrative arrangements for VPC meetings.

The Committee considered and commented upon the contents of the report on VICH Phase II Guidelines.

The Committee considered and commented upon the USA draft report on malachite green and leucomalachite green.

The Committee considered and commented upon the Report of the VPC Working Group on the Suspected Adverse Reaction Surveillance Scheme (SARSS).

The Committee also considered the contents of the 4th SARSS Quarterly Report for 2003 for the period 1 October to 31 December.

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 the **VPC Secretariat at the VMD, Woodham Lane, New Haw, Addlestone, Surrey, KT15 3LS (Tel: 01932 338491, Fax: 01932 336618, or e-mail: vpc@vmd.defra.gsi.gov.uk).**

Corrected VPC Summary Minutes for the meeting of 18 December 2003 are available on the VPC website or by request from the VPC Secretariat.

It also received the following papers for information, which are publicly available [see direct link: Public Papers] or by request from the VPC Secretariat:

- copies of *The Veterinary Record* Contents (front page) "This Week's Issue", Vol 153 number 25 and Vol 154 numbers 1 to 3 [further information mailto: www.vetrecord.co.uk];
- VMD staff telephone list and organogram;
- Invitation to nominate candidates for membership of the Veterinary Residues Committee; and
- A call for expressions of interest in Membership of a scientific panel of the European Food Safety Authority <http://europa.eu.int/eur-ex/en/archive/2003/ca30720031217en.html>.

Additionally it received the following paper, which is not available for publication:

- Report to the VPC on current ATC applications.

■ FEBRUARY MEETING

Applications

The Committee examined evidence relating to an application for a UK Marketing Authorisation for an oil-adjuvanted vaccine for administration to future breeder turkeys and provisionally concluded (subject to confirmation at its next meeting) that the application should be refused unless further data were supplied by the applicant to demonstrate compliance with one or more of the licensing requirements as to safety, quality and efficacy.

The Committee also examined evidence relating to the meat withdrawal period of a product currently authorised for use in Atlantic salmon and concluded (subject to confirmation at its next meeting) that the data were inadequate to support the current withdrawal period.

General

The Committee considered topics for discussion at its Special meeting in July.

The Committee considered and commented upon the first draft of its Annual Report 2003.

The Committee considered and commented upon proposals to amend legislation to allow lay vaccination of livestock in the event of a future outbreak of foot and mouth disease.

The Committee considered and commented upon an Appraisal Panel Report: Human SARs to Veterinary Medicines Containing Isopropyl Alcohol (IPA).

The Committee considered and commented upon the contents of the first SARSS Monthly Report for 2004 for the period 1 - 31 January.

Corrected VPC Summary Minutes for the meeting of 22 January 2004 are available on the VPC website or by request from the VPC Secretariat.

It also received the following papers for information, which are publicly available [see direct link: Public Papers] or by request from the VPC Secretariat,

- copies of *The Veterinary Record* Contents (front page) "This Week's Issue" for the period 24 January to 14 February [further information mailto: www.vetrecord.co.uk];
- reply to *Veterinary Times* letter: Call to cease annual vaccination policy;
- the Advisory Committee on Dangerous Pathogens (ACDP) Chair vacancy;
- Defra News Release: New Science Advisory Council for Defra; and
- Advisory Committee on Pesticides (ACP) seeking nominations for Membership.

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

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

■ MARCH MEETING

Applications

The Committee examined evidence relating to an application for a Provisional Marketing Authorisation for a bivalent, adjuvanted vaccine for administration to Atlantic salmon for the prevention of furunculosis and reduction of clinical signs and mortality caused by infectious pancreatic necrosis virus.

The Committee provisionally concluded (subject to confirmation at its next meeting) that the application should be recommended for authorisation subject to certain conditions being met by the applicant.

The Committee also considered the assessment of the safety data submitted in support of applications for Marketing Authorisations for two products for the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome) in dogs.

The Committee agreed with the assessment and confirmed that further data were required.

General

The Committee considered the contents of a report relating to products that contain diazinon or tetrachlorvinphos as part of its review of products (other than sheep dips) with an organophosphorus ingredient.

The Committee considered and commented upon the contents of the SARSS Monthly Report for 2004 for the period 1 – 29 February 2004.

The Committee considered and commented upon the second draft of its Annual Report for 2003.

The Committee considered the format and agenda of its Open Forum 2004.

The Committee also considered and commented upon The Medicines and Healthcare products Regulatory Agency's proposals to review the structure of those Advisory Committees established under the Medicines Act 1968, for which it is the lead department.

Corrected VPC Summary Minutes for the meeting of 18 February 2004 are available on the VPC website (www.vpc.gov.uk) or by request from the VPC Secretariat.

It also received the following papers for information, which are publicly available [see direct link: Public Papers] or by request from the VPC Secretariat,

- Copies of *The Veterinary Record* Contents (front page) "This Week's Issue" for the period 21 February to 13 March 2004 [further information mailto: www.vetrecord.co.uk].

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

- report to the VPC on current ATC applications;
- report from the Scientific Secretariat and the Biological Committee; and
- update on progress with the Recommendations made in the VPC WG Report on Antimicrobial Resistance in Relation to Veterinary Medicines.

■ MEMBERSHIP OF THE VETERINARY PRODUCTS COMMITTEE AND ITS SUB-COMMITTEES

We expect to begin a consultation exercise in the autumn to seek nominations for members of the Veterinary Products Committee, the Appraisal Panel for Human Suspected Adverse Reactions and the Medical and Scientific Panel, for terms of office beginning on 1 January 2006.

Full details will be included on the VPC website (www.vpc.gov.uk) in due course and in the next edition of MAVIS.

RESIDUES CONTROLS & MONITORING

The VMD operates two complementary surveillance programmes for residues of veterinary medicines and other substances. The larger programme, the National Surveillance Scheme (NSS), implements EU legislation and therefore has a statutory basis. This programme covers the products set out below, and is funded by the industry sectors in accordance with EU legislation.

The second programme is smaller and non-statutory. It focuses more on surveillance of imports of certain products where the presence of banned substances are most likely to be found. The programme is funded by Defra.

The independent Veterinary Residues Committee scrutinises and advises on the content of the VMD's (and FSA's) surveillance work.

■ STATUTORY SURVEILLANCE IN 2003

The National Surveillance Scheme (NSS) operates in accordance with the requirements of Annexes I-IV of Council Directive 96/23/EC and Commission 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 for the 2003 Programme completed between 1 January 2003 and 10 March 2004 are given in the accompanying tables. Details of the positive samples are given below. Totals reported are the cumulative results for the whole year.

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 10 March 2004 20,106 analyses had been completed on 20,607 samples. 29 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

Eight samples of cattle serum out of 351 tested have confirmed positive for progesterone at concentrations of 0.6µg/l (3), 0.7µg/l, 1µg/l, 1.1µg/l, 1.6µg/l and 2.0µg/l. The SVS has completed its follow-up investigations into the residues of 1.1µg/l and 1.6 µg/l and there was no evidence

of abuse of this substance on the farms in question. It is likely that the concentrations detected were due to natural causes. Animals from the farms where the other positives were detected will be targeted for further sampling in 2004.

Two samples of cattle serum out of 363 tested have confirmed positive for testosterone at concentrations of 1µg/l and in excess of 1µg/l. These samples have been followed up by the SVS. No evidence of abuse has been detected in either case. Follow-up samples taken from one of the farms were all negative. At the second farm the animal in question was in calf at the time the original sample was collected which could account for the residue detected. A further sample has been taken and the result of the follow-up sample was negative.

One sample of sheep urine out of 183 tested has confirmed positive for a residue of nortestosterone at 18µg/l. The follow-up visit indicated no evidence of abuse of this substance and the investigating officer considered it was probable that this residue was a natural occurrence as the animal was an entire male.

Zeranol

One sample of cattle urine out of 272 tested has confirmed positive for a residue of zeranol. The analysis carried out on this sample indicates that this is the result of ingestion of feed contaminated by the fusarium fungus rather than any abuse of this substance. No further investigation of this sample has been undertaken.

Nitrofurans

A residue of the nitrofurans metabolite semicarbazide has been confirmed in one sample of sheep kidney out of 102 tested. The concentration detected was below the MPRL (Minimum Required Performance Limit)*** of 1mg/kg set by the Commission. A second laboratory also confirmed the presence of this residue. The use of nitrofurans in food producing animals in the EU is prohibited. The follow-up investigation revealed no evidence of the use of nitrofurans on the farm in question.

Antimicrobials

5,686 samples of kidney from calves, cattle, sheep, pigs and goats have been screened for a range of antimicrobial substances. One sample of pig's kidney out of 827 analysed, tested positive for a residue of chlortetracycline at a level of 860µg/kg. The follow-up visit indicated that this

residue was probably the result of inadequate feed bin management. The SVS has written to the farmer concerned outlining the action that must be taken to avoid further residue violations.

Anthelmintics

2,176 samples of liver from goats, cattle, pigs, sheep and horses had been screened for a range of anthelmintics. Three samples of sheep liver out of 406 screened for benzimidazoles have confirmed positive for residues of fenbendazole and oxfenbendazole at concentrations of 660µg/kg, 840µg/kg and 4,390µg/kg respectively (MRL 500µg/kg). The residue of 4,390µg/kg has been referred to Defra for investigation in view of the level detected. The SVS has completed its investigations into the other two samples. In one case, they found that the animal in question had been slaughtered before the withdrawal period for the product used had elapsed. The carcass was returned to the farmer for his own consumption. The SVS has written to the farmer concerned outlining the action that must be taken to avoid further residue violations. In the second case they were unable to establish the cause of the residue. The animals concerned had been recently purchased and may have been treated by the previous owner.

NSAIDs

One sample of horse plasma out of 30 tested has confirmed positive for a residue of phenylbutazone. The investigation by Defra's investigation branch is complete. The case file has been passed to lawyers for consideration.

Ionophores

One sample of pig's liver, out of nine tested, has confirmed positive for a residue of the ionophore salinomycin at a level of 11µg/kg. Salinomycin is a zootechnical feed additive and should only be used under the terms of its entry in the Annexes to Directive 70/524EC (as amended). The investigation into the cause of this residue indicated there may have been a problem with the incorporation in the feed. The farmer has sought the advice of his veterinarian and will no longer be using salinomycin.

Heavy Metals

Ten samples of horse kidney out of 11 tested, contained residues of cadmium at concentrations between 5,700µg/kg and 68,200µg/kg. There is an agreement with slaughterhouses that horse offal will be discarded and therefore it will not enter the food chain.

POULTRY

By 10 March 2004 the laboratory had completed a total of 8,052 analyses on 7,652 samples, including follow-up feed samples taken by the SVS as part of its investigations.

Antimicrobials

Chlortetracycline

Three samples of poultry kidney were confirmed positive for residues of chlortetracycline (CTC) above the MRL of

600µg/kg. One sample of hen kidney contained a residue of CTC at a concentration of 1,300µg/kg and a sample of broiler kidney contained a residue of CTC at a concentration of 780µg/kg. The follow-up visits by the SVS indicated that the likely cause of these residues was cross contamination of feed in the feed bin. The residue of 856µg/kg of CTC detected in the turkey sample is subject to further investigation. Toxicological advice is that these residues do not pose a risk to human health.

Sulphonamides

One sample of broiler muscle confirmed positive for the presence of sulphadiazine at a level of 300µg/kg. This has been followed-up by officers of the State Veterinary Service. The farm will be targeted for further sampling in 2004. Toxicological advice is that there is unlikely to be a significant risk to human health from this residue.

Quinolones

A sample of broiler muscle also confirmed positive for the presence of ciprofloxacin/enrofloxacin above the MRL of 100µg/kg at a concentration of 920µg/kg. This case has been referred to Defra Investigation Branch for further action.

Monensin

Two samples of broiler liver out of 269 tested have confirmed positive for residues of the ionophore monensin at concentrations of 25µg/kg and 2.5µg/kg. The investigation into the residue of 25µg/kg indicated that cross contamination due to inadequate feed bin management was the likely cause of the residue. In the second case the farm has separate bins for medicated and non-medicated feed. The investigating officer considered that an error at the mill was a possible cause of this residue.

Nicarbazin

By 10 March 2004, analyses on 258 samples of broiler liver had been completed. 46 samples have confirmed positive above the JECFA MRL at concentrations between 205µg/kg and 5,520µg/kg. Follow-up investigations into 42 of these results have been completed. They have identified a number of possible causes. The results of the analysis of feed samples taken as part of the follow-up investigations are included in table 1 below. They show that contamination of feed during manufacture is not a likely cause for the majority of these residues. SVS officers have indicated that cross contamination of feed on farm from the use of a single feed bin or poor bin management where two or more feed bins were being used was the most likely cause of the residues in the majority of these samples. Officers identified that the transfer of surplus feed from other farms could also result in contaminated feed being fed to the birds during the withdrawal period. In one case where a follow-up sample of withdrawal ration tested positive for residues of nicarbazin further investigations will be undertaken at the feed mill.

These residues are a food contaminant rather than a food safety issue: a person eating a standard 100g portion of liver containing 5,520µg/kg would receive a one-off dose of 552µg compared to an Acceptable Daily Intake of 24,000µg for a 60kg person.

The Veterinary Residues Committee and its Feed subgroup are considering the results of the investigations to identify ways of reducing the incidence of these residues.

Sample Results taken as part of follow-up investigations into residues of nicarbazin in broiler liver

Analyte	Species	Matrix	Number of samples below LOQ	Number of positive samples
Nicarbazin	Broilers	Feed	24	1

■ FARMED FISH

By 10 March 2004 1,569 analyses had been completed on 1,680 samples. 29 samples – 23 trout and six salmon – contained residues above the Action Level. 21 of the trout and one of the salmon samples are follow-up samples taken as a result of earlier positive sampling.

Malachite/leucomalachite green:

A total of 123 samples of trout have been analysed for residues of malachite and leucomalachite green. Out of the 79 samples taken as part of the scheduled surveillance programme, three samples have tested positive for residues of leucomalachite green at concentrations between 2.4 to 9µg/kg. Two of these samples are currently the subject of follow-up action by CEFAS officers. Investigations into the third sample have been completed. The site remains under restriction and further samples will be obtained.

In addition to the scheduled sampling, 44 samples have been collected as part of the follow-up investigations carried out by CEFAS (see table 2 below). A total of 27 samples have been taken from a farm whose fish tested positive for malachite and leucomalachite green at the end of 2002. Twelve of these follow-up samples tested positive for residues of leucomalachite green at concentrations between 2.2 and 60.1µg/kg. One of these samples also contained a residue of malachite green at a concentration of 2.9µg/kg. Movement restrictions remain in force on all fish that have tested positive on this site. Ten samples have been collected at a second farm whose fish tested positive for leucomalachite green in 2003. Nine of these samples have tested positive for residues of leucomalachite green at concentrations between 16 and 117µg/kg. As part of the investigation, a further seven samples have been taken from two sites that supplied fish to the farms in question. All these samples tested negative.

A total of 115 samples of salmon have been analysed for residues of malachite green and leucomalachite green. Out of 84 scheduled samples, two have confirmed positive for residues of malachite green and leucomalachite green at concentrations of 8.4µg/kg (malachite green) and 376µg/kg (leucomalachite green) and 4.8 (malachite green) and 18.9 (leucomalachite green). Two further samples

contained residues of leucomalachite green at concentrations of 2.3µg/kg and 5µg/kg. Officers of the Fisheries Research Services have followed up all these results and 31 further samples have been taken from eight sites. Results of tests on fish from six sites are negative. Results for two samples are still awaited. Fish movement restrictions remain in place at two sites.

Sample Results taken as part of follow-up investigations into residues of malachite and leucomalachite green in salmon and trout

Analyte	Species	Matrix	Number of samples tested	Number of samples positive
Malachite green	Trout	Muscle	44	1*
Leucomalachite green	Trout	Muscle	44	21*
Malachite green	Salmon	Muscle	31	0
Leucomalachite green	Salmon	Muscle	31	1

* 1 sample of trout contained residues of both malachite green and leucomalachite green

■ MILK

By 10 March 2004 the laboratory had completed a total of 2,385 analyses on 836 samples.

Aflatoxins

One sample confirmed positive for a residue of aflatoxin M1 above the MRL (0.05µg/kg) at a concentration of 0.06µg/kg. The SVS on-farm investigation indicated that this was probably the result of feed contamination. A further milk sample taken during the investigation has tested negative.

■ EGGS

By 10 March 2004 the laboratory had completed 1,303 analyses on 535 samples, including feed samples taken as part of follow-up investigations by the SVS.

Lasalocid

Residues of lasalocid have been confirmed in 32 out of 250 samples of eggs at concentrations between 50 and 3,450µg/kg. Officers of the State Veterinary Service have completed investigations into the cause of 28 of these residues. In a high proportion of cases cross contamination of feed during manufacture is the likely cause. Twenty-three samples of feed, taken as part of the follow-up investigations into these residues, have confirmed positive for residues of lasalocid at concentrations between 140µg/kg and 1,900µg/kg. Investigations undertaken at four mills, which supplied feed to 10 of the farms whose eggs tested positive, have identified issues of cross contamination during feed manufacture. On 24 of the farms there was no evidence that the farmer had ever used feed containing lasalocid on farm and in one of these cases the eggs were from an accredited organic producer.

Sample Results taken as part of follow-up investigations into residues of lasalocid in hen eggs

Analyte	Species	Matrix	Number of samples below LOQ	Number of samples positive
Ionophores	Hen	Feed	43	23

Nicarbazin

One sample out of 223 tested for residues of nicarbazin has confirmed positive for the presence of nicarbazin at a concentration of 115µg/kg. Officers of the State Veterinary Service will be carrying out a follow-up investigation at the farm from which this sample originated.

■ GAME

Up to 10 March 2004, 371 analyses had been completed on 235 samples. One sample of partridge muscle confirmed positive for a residue of lead at a level of 33,953µg/kg. No further action is being taken on this sample.

■ STATUTORY SURVEILLANCE IN 2004

■ RED MEAT

Sample collection commenced in January 2004. Up to 10 March, 2,859 analyses had been completed on 3,505 samples. To date one sample has tested positive for a residue of veterinary medicines in excess of the Maximum Residue Limit/Action Level*. A sample of pig liver was found to contain a residue of chlorotetracycline/epichlorotetracycline at a concentration of 940µg/kg. Officers of the SVS will be carrying out a follow-up visit to the farm in question.

■ POULTRY

Sample collection commenced in January. Up to 10 March 1,025 analyses had been completed on 1,494 samples. Six samples had been confirmed as containing residues of zotechnical feed additives or contaminants in excess of the MRL/Action Limit. Three samples of broiler liver contained residues of nicarbazin at concentrations of 215µg/kg, 245µg/kg and 775µg/kg. Two samples of turkey liver and one of hen's liver contained residues of cadmium at concentrations of 796µg/kg, 519µg/kg and 508µg/kg respectively. The SVS will be carrying out follow up visits to the farms concerned.

■ MILK

Sample collection commenced in February 2004 and 203 analyses have been completed on 489 samples. To date no positives have been confirmed.

■ FISH

Sample collection commenced in February 2004 and 30 analyses have been completed on 181 samples. To date no positives have been confirmed.

NOTE: Toxicological advice is that there is unlikely to be a significant risk to human health from the positive residues results.

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.
- *** The Minimum Required Performance Limit (MRPL) sets an analytical standard which all Member States are required to meet. Commission Decision 2003/181 set levels of 0.3µg/kg and 1µg/kg for chloramphenicol and nitrofurans metabolites respectively.

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN RED MEAT
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 10 MARCH 2004**

Type of Compound\Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level
■ 1 Hormones					
Stilbenes	Cattle	< 24	Urine	273	
	Pigs		Urine	147	
	Sheep		Urine	74	
Methyltestosterone	Pigs		Feed	23	
	Pigs		Urine	115	
	Sheep		Urine	84	
Nortestosterone	Cattle		Serum	174	
	Cattle		Urine	157	
	Sheep		Urine	183	1
Oestradiol	Cattle	Male	Serum	309	
Progesterone	Cattle	Male	Serum	351	8
Testosterone	Cattle	Female	Serum	363	2
Trenbolone	Cattle		Serum	176	
	Cattle		Urine	168	
	Pigs		Urine	119	
Zeranol	Sheep		Urine	177	
	Cattle	< 24	Urine	272	1
	Pigs		Urine	113	
Sheep		Urine	69		
■ 2 Pesticides Including PCBs					
Carbamates	Calves	< 6	Liver	51	
	Pigs		Liver	54	
	Sheep		Liver	256	
Pyrethroids	Calves	< 6	Liver	63	
	Pigs		Liver	66	
	Sheep		Fleece	77	
Oc/Pcbs	Sheep		Liver	425	
	Cattle		Kidney Fat	57	
	Pigs		Kidney Fat	57	
Organophosphorus	Sheep		Kidney Fat	111	
	Sheep		Kidney Fat	37	
	Cattle		Kidney Fat	203	
Organophosphorus	Pigs		Kidney Fat	162	
	Sheep		Kidney Fat	441	
■ 3 Beta-Agonists					
	Calves	< 6	Liver	34	
	Cattle	< 24	Feed	510	
	Cattle	< 24	Liver	510	
	Horses		Liver	10	
	Pigs		Feed	36	
	Pigs		Liver	564	
	Sheep		Liver	451	
■ 4 Heavy Metals					
Cadmium	Cattle		Kidney	9	
	Goats		Kidney	4	
	Horses		Kidney	11	10
	Pigs		Kidney	11	
	Sheep		Kidney	10	
Lead	Cattle		Kidney	9	
	Goats		Kidney	4	
	Horses		Kidney	11	
	Pigs		Kidney	11	
	Sheep		Kidney	10	
■ 5 Sulphonamides					
	Calves	< 6	Kidney	61	
	Cattle		Kidney	74	
	Pigs		Kidney	830	
	Sheep		Kidney	125	

Type of Compound/Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level	
■ 6 Antimicrobial Screen	Calves	< 6	Kidney	96		
	Cattle		Kidney	1,437		
	Goats		Kidney	10		
	Pigs		Kidney	827	1	
	Sheep		Kidney	3,316		
■ 7 Annex IV	Chloramphenicol	Calves	< 6	Kidney	32	
		Cattle		Feed	157	
		Cattle	< 24	Kidney	101	
		Pigs		Kidney	158	
		Sheep		Kidney	85	
	Dimetridazole	Calves	< 6	Kidney	20	
		Cattle	< 24	Kidney	64	
		Horses		Kidney	11	
		Pigs		Feed	14	
		Pigs		Kidney	201	
	Nitrofurans	Sheep		Kidney	102	
		Calves	< 6	Kidney	21	
		Cattle		Feed	157	
		Cattle		Kidney	68	
		Pigs		Feed	6	
		Pigs		Kidney	191	
	Sheep		Kidney	102	1	
■ 8 Anthelmintics	Avermectins	Cattle		Liver	235	
		Goats		Liver	9	
		Horses		Liver	11	
		Pigs		Liver	246	
		Sheep		Liver	370	
	Benzimidazoles	Cattle		Liver	243	
		Horses		Liver	11	
		Pigs		Liver	253	
	Levamisole	Sheep		Liver	406	3
		Cattle		Liver	103	
		Horses		Liver	10	
	Sheep		Liver	279		
	■ 9 Gestagens	Altrenogest	Pigs		Kidney Fat	125
Cattle			< 24	Kidney Fat	159	
Gestagens		Cattle	< 24	Serum	84	
		Sheep		Kidney Fat	86	
■ 10 NSAIDs	Cattle		Kidney	28		
	Horses		Blood	30	1	
	Pigs		Kidney	33		
	Sheep		Kidney	75		
■ 11 Coccidiostats	Ionophores	Calves	< 6	Liver	41	
		Pigs		Liver	9	1
		Sheep		Liver	331	
■ 12 Mycotoxins	Cattle		Liver	11		
	Pigs		Liver	9		
	Sheep		Liver	9		
■ 13 Dexamethazone/Betamethazone	Dexamethazone	Cattle		Liver	60	
		Pigs		Liver	37	
		Sheep		Liver	13	
■ 14 Carbadox	Pigs		Liver	59		

Type of Compound\Substance	Species	Age & Sex	Matrix	No. of Analyses	No. above Action Level
■ 15 Sedatives					
Sedatives	Calves	< 6	Liver	60	
	Pigs		Liver	195	
	Sheep		Liver	85	
	Pigs		Liver	195	
Carazolol					
■ 16 Thyrostats					
	Cattle	< 24	Serum	44	
	Cattle	< 24	Urine	120	
	Pigs		Urine	97	
	Sheep		Urine	57	
Total				20,106	29

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN POULTRY MEAT
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 10 MARCH 2004**

Type of Compound\Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 1 Hormones				
Stilbenes	Broilers	Liver	142	
	Ducks	Liver	11	
	Hens	Liver	13	
	Turkeys	Liver	62	
Trenbolone	Broilers	Liver	139	
	Ducks	Liver	10	
	Hens	Liver	12	
	Turkeys	Liver	56	
Zeranol	Broilers	Liver	138	
	Ducks	Liver	7	
	Hens	Liver	7	
	Turkeys	Liver	34	
■ 2 Pesticides Including PCBs				
Carbamates	Broilers	Liver	57	
	Ducks	Liver	10	
	Hens	Liver	3	
	Turkeys	Liver	26	
Pyrethroids	Broilers	Liver	48	
	Ducks	Liver	9	
	Hens	Liver	2	
	Turkeys	Liver	21	
OC/PCBs	Broilers	Liver	213	
	Ducks	Liver	5	
	Hens	Liver	4	
	Turkeys	Liver	33	
■ 3 Beta-Agonists				
	Broilers	Feed	211	
	Broilers	Liver	371	
	Ducks	Feed	10	
	Ducks	Liver	16	
	Hens	Feed	10	
	Hens	Liver	17	
	Turkeys	Feed	53	
	Turkeys	Liver	87	
■ 4 Heavy Metals				
Cadmium	Broilers	Liver	25	
	Ducks	Liver	6	
	Hens	Liver	12	
	Turkeys	Liver	23	
Lead	Broilers	Liver	25	
	Ducks	Liver	6	
	Hens	Liver	12	
	Turkeys	Liver	23	
■ 5 Sulphanomides				
	Broilers	Kidney	71	
	Broilers	Muscle	194	
	Ducks	Kidney	4	
	Ducks	Muscle	9	

Type of Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level
	Hens	Kidney	2	
	Hens	Muscle	10	
	Turkeys	Kidney	10	
	Turkeys	Muscle	29	
■ 6 Antimicrobial Screen	Broilers	Kidney	264	1
	Broilers	Muscle	747	1
	Ducks	Kidney	13	
	Ducks	Muscle	33	
	Geese	Muscle	2	
	Guinea Fowl	Kidney	2	
	Guinea Fowl	Muscle	1	
	Hens	Kidney	11	1
	Hens	Muscle	32	
	Turkeys	Kidney	79	1
	Turkeys	Muscle	211	
■ 7 Quinolones	Broilers	Kidney	92	
	Broilers	Muscle	253	1
	Ducks	Kidney	5	
	Ducks	Muscle	13	
	Geese	Muscle	3	
	Guinea Fowl	Kidney	1	
	Hens	Kidney	4	
	Hens	Muscle	12	
	Turkeys	Kidney	14	
	Turkeys	Muscle	34	
■ 8 Annex IV				
Chloramphenicol	Broilers	Liver	213	
	Broilers	Muscle	229	
	Ducks	Liver	10	
	Ducks	Muscle	12	
	Hens	Liver	10	
	Hens	Muscle	12	
	Turkeys	Liver	48	
	Turkeys	Muscle	45	
Dimetridazole	Broilers	Feed	203	
	Broilers	Liver	700	
	Ducks	Feed	10	
	Ducks	Liver	27	
	Hens	Feed	9	
	Hens	Liver	27	
	Turkeys	Liver	138	
Nitrofurans	Broilers	Feed	131	
	Broilers	Muscle	695	
	Ducks	Feed	4	
	Ducks	Muscle	25	
	Hens	Feed	6	
	Hens	Muscle	23	
	Turkeys	Feed	82	
	Turkeys	Muscle	147	
■ 9 Anthelmintics				
Benzimidazoles	Broilers	Liver	122	
	Ducks	Liver	15	
	Hens	Liver	12	
	Turkeys	Liver	46	
Levamisole	Broilers	Liver	124	
	Ducks	Liver	14	
	Hens	Liver	11	
	Turkeys	Liver	47	
■ 10 Coccidiostats				
Ionophores	Broilers	Liver	269	2
	Hens	Liver	7	
	Turkeys	Liver	76	
Nicarbazin	Broilers	Liver	258	46

Type of Compound\Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 11 Mycotoxins	Broilers	Liver	32	
	Ducks	Liver	5	
	Hens	Liver	3	
	Turkeys	Liver	13	
Total			7,984	53

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN FARMED FISH
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 10 MARCH 2004**

Type of Compound\Substance	Species	Age	Matrix	No. of Analyses	No. above Action Level
■ 1 Hormones					
Methyltestosterone	Salmon	Young	Muscle	19	
	Trout	Young	Muscle	5	
Nortestosterone	Salmon	Young	Muscle	33	
	Trout	Young	Muscle	2	
■ 2 Pesticides Including PCBs					
Pyrethroids	Salmon	Market	Muscle	42	
OC/PCBs	Salmon		Muscle	77	
	Trout	Market	Muscle	12	
Organophosphorus	Salmon	Market	Muscle	36	
■ 3 Heavy Metals					
Cadmium	Salmon	Market	Muscle	5	
	Trout	Market	Muscle	5	
Lead	Salmon	Market	Muscle	5	
	Trout	Market	Muscle	5	
■ 4 Antimicrobial Screen					
	Salmon	Market	Muscle	132	
	Trout	Market	Muscle	10	
■ 5 Tetracyclines					
	Salmon	Market	Muscle	134	
	Trout	Market	Muscle	10	
■ 6 Quinolones					
	Salmon	Market	Muscle	122	
	Trout	Market	Muscle	10	
■ 7 Annex IV					
Chloramphenicol	Salmon		Muscle	83	
	Trout	Market	Muscle	10	
Dimetridazole	Salmon	Market	Muscle	193	
	Trout	Market	Muscle	17	
Nitrofurans	Salmon	Market	Muscle	35	
	Trout	Market	Muscle	10	
■ 8 Anthelmintics					
Benzimidazoles	Salmon	Market	Muscle	76	
	Trout	Market	Muscle	10	
Ivermectin	Salmon		Muscle	173	
	Trout	Market	Muscle	7	
Levamisole	Salmon	Market	Muscle	33	
	Trout	Market	Muscle	10	
■ 9 Mycotoxins					
	Salmon	Market	Muscle	5	
	Trout	Market	Muscle	5	
■ 10 Malachite Green					
{ Malachite Green	Trout		Muscle	79	
	Leucomalachite Green	Trout	Muscle	79	3*
{ Malachite Green	Salmon	Young	Muscle	84	2*
	Leucomalachite Green	Salmon	Young	84	4*
Total				1,657	9

* Two samples of salmon contained residues of both malachite green and leucomalachite green
{ One analysis which detects malachite green and leucomalachite green

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN EGGS
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 10 MARCH 2004**

Type of Compound\Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 1 Pesticides Including PCBs				
Pyrethroids	Free Range	Eggs	19	
Oc/Pcbs	Caged	Eggs	25	
	Free Range	Eggs	15	
	Perchery	Eggs	2	
■ 2 Antimicrobial Screen				
	Caged	Eggs	169	
	Free Range	Eggs	99	
	Perchery	Eggs	13	
■ 3 Tetracyclines				
	Caged	Eggs	56	
	Free Range	Eggs	33	
	Perchery	Eggs	5	
■ 4 Annex IV				
Chloramphenicol	Caged	Eggs	60	
	Free Range	Eggs	35	
	Perchery	Eggs	5	
Dimetridazole	Caged	Eggs	109	
	Free Range	Eggs	64	
	Perchery	Eggs	8	
Nitrofurans	Caged	Eggs	56	
	Free Range	Eggs	33	
	Perchery	Eggs	5	
■ 5 Anthelmintics				
Benzimidazoles	Free Range	Eggs	19	
■ 6 Coccidiostats				
Ionophores	Caged	Eggs	149	15
	Free Range	Eggs	89	12
	Perchery	Eggs	12	5
Nicarbazin	Caged	Eggs	134	
	Free Range	Eggs	79	1
	Perchery	Eggs	10	
Total			1,303	33

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN MILK
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 10 MARCH 2004**

Type of Compound\Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 1 Pesticides Including PCBs				
OC/PCBs	Bovine	Milk	67	
Organophosphorus	Bovine	Milk	26	
■ 2 Heavy Metals				
Cadmium	Bovine	Milk	8	
Lead	Bovine	Milk	8	
■ 3 Sulphonamides				
	Bovine	Milk	164	
■ 4 Antimicrobial Screen				
	Bovine	Milk	580	
■ 5 Tetracyclines				
	Bovine	Milk	159	
■ 6 Quinolones				
	Bovine	Milk	256	
■ 7 Annex IV				
Chloramphenicol	Bovine	Milk	97	
Dimetridazole	Bovine	Milk	285	

Type of Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 8 Anthelmintics				
Avermectins	Bovine	Milk	268	
Levamisole	Bovine	Milk	137	
■ 9 NSAIDs	Bovine	Milk	175	
■ 10 Mycotoxins	Bovine	Milk	155	1
Total			2,385	1

**NATIONAL SURVEILLANCE SCHEME FOR RESIDUES IN GAME
RESULTS OF TARGETED SAMPLING IN GREAT BRITAIN: 1 JANUARY 2003 – 5 JANUARY 2004**

Type of Compound/Substance	Species	Matrix	No. of Analyses	No. above Action Level
■ 1 Hormones				
Stilbenes	Deer (Farm)	Liver	2	
Trenbolone	Deer (Farm)	Liver	2	
Zeranol	Deer (Farm)	Liver	2	
■ 2 Pesticides Including PCBs				
Carbamates	Deer (Farm)	Liver	4	
Pyrethroids	Deer (Farm)	Liver	4	
OC/PCBs	Deer (Farm)	Kidney Fat	8	
■ 3 Beta-Agonists	Deer (Farm)	Liver	4	
■ 4 Heavy Metals				
Cadmium	Deer (Farm)	Muscle	9	
	Deer (Wild)	Muscle	54	
	Partridge	Muscle	19	
	Pheasant	Muscle	17	
Lead	Deer (Farm)	Muscle	9	
	Deer (Wild)	Muscle	54	
	Partridge	Muscle	19	1
	Pheasant	Muscle	17	
■ 5 Antimicrobial Screen				
	Deer (Farm)	Kidney	27	
	Quail	Muscle	10	
■ 6 Annex IV				
Dimetridazole	Deer (Farm)	Liver	5	
	Partridge	Muscle	19	
	Pheasant	Muscle	17	
	Quail	Muscle	7	
■ 7 Anthelmintics				
Benzimidazoles	Quail	Muscle	11	
Ivermectin	Deer (Farm)	Liver	11	
Levamisole	Deer (Farm)	Liver	10	
■ 8 NSAIDs	Deer (Farm)	Liver	5	
■ 9 Coccidiostats				
Ionophores	Quail	Muscle	21	
Nicarbazin	Deer (Farm)	Liver	4	
Total			371	1

■ RESULTS OF NON-STATUTORY SURVEILLANCE

The non-statutory veterinary medicine residue surveillance programme covers mainly imported produce and some home-produced foods that are not part of the National Surveillance Scheme (NSS). The programme can also carry out short surveys for areas of potential concern based on intelligence received.

Non-Statutory Surveillance 2003

Rolling programme

Sample collection and analysis for the 2003 non-statutory rolling programme is now complete. Port Health Inspectors and shoppers from a market research company have collected 1,246 samples. The Central Science Laboratory has completed 5,468 analyses. Details of all the analyses undertaken are set out in the table on page 24.

A summary of all residues detected above the Maximum Residue Limit or Action Level is given below.

Nitrofurans

Residues of semi-carbazide (SC) a metabolite of nitrofurazone were detected in 24 samples of warm water prawns from Bangladesh (13), India (10), and Indonesia (1) at concentrations between 0.9 (indicative value) and 8.3µg/kg. Two of the samples from India also contained residues of the AOZ metabolite of furazolidone. A further five samples from Ecuador (2), Vietnam (2) and Thailand/Indonesia (1) were found to contain residues of AOZ at concentrations between 0.2 (indicative value) and 26µg/kg.

Eight samples of honey from Argentina (2), Guatemala (1), Spain (1) and Turkey (4) contained residues of AOZ at concentrations between 0.9 (indicative value) and 5.5µg/kg. A sample of blended honey labelled as Argentina/Australia was found to contain traces of both SC and AOZ at concentrations between 0.2 (AOZ) and 0.7(SC)µg/kg (indicative values). A sample from Italy contained residues of the AMOZ metabolite of furaltadone at 1.4µg/kg and a sample of blended Caribbean honey contained residues of SC at 2.1µg/kg.

A sample of chicken from Thailand/Brazil was found to contain residues of AMOZ at a concentration of 50µg/kg. Authorities in both countries have been notified.

Nitrofurans are in Annex IV of EC Council Regulation 2377/90. Their use in food producing species in the EU, and in produce exported to the EU, is prohibited.

The Chief Veterinary Officer has written to the authorities in the countries of origin asking them to investigate these residues and report their findings. The results have also been reported to the Food Standards Agency (FSA) which will issue Rapid Alerts.

The Indian authorities have responded advising that as they now have the ability to test samples by LC-MS-MS they are confident that the incidence of the residues in

prawns will reduce in the future. The Indian authorities have more recently reported that action has been taken against establishments defaulting from the laid down protocol for export of prawns into the EU. The Bangladesh authorities have reported that the method of analysis used to detect nitrofurans residues is HPLC with UV detection. The Ecuadorian authorities are liaising with the UK authorities.

Streptomycin

Six samples of honey imported from Mexico and sampled at a Border Inspection Post (BIP) by Port Health Inspectors have been found to contain residues of streptomycin at concentrations between 30 and 190µg/kg. Toxicological advice is that at these concentrations the residues would not be harmful to human health. The results have been passed to the FSA for the issue of Rapid Alerts. The FSA has advised that two of the consignments involved have been returned to Mexico.

Malachite green/leucomalachite green

Six samples of imported farmed fish, four salmon from Chile and two catfish from Taiwan, have been found to contain residues of the malachite green metabolite leucomalachite green at concentrations between 2.6 and 20 µg/kg. Malachite green has never been authorised as a veterinary medicine in the EU and should not be present in imported fish. The CVO has written to officials in the countries of origin notifying them of these results. The FSA has been informed and asked to raise Rapid Alerts. The FSA has advised that two of the samples were from the same consignment, which has been destroyed.

Avermectins

A sample of beef from Brazil has been found to contain residues of abamectin at a concentration of 11µg/kg. The FSA has been informed and asked to issue a Rapid Alert and the CVO has written to the Brazilian authorities notifying them of this result. Toxicological advice states that at the level found there would be no significant risk to human health.

Nicarbazin

Three samples of quail eggs have been found to contain residues of dinitrocarbanilide at concentrations between 31 and 220µg/kg. As a result of investigations undertaken by the producer of two of these samples, they are progressing a plan to put quail onto feed from a medicine free mill. Toxicological advice is, that at the levels found, there is no significant risk to human health.

Lasalocid

Twelve samples of quail eggs have been found to contain residues of lasalocid at concentrations between 41 and 1,700µg/kg. Investigations are on-going at the feed mills concerned to try to establish the cause of these residues. Toxicological advice is, that at the levels found, there is no risk to human health.

Chloramphenicol

A sample of honey imported from Tanzania contained a residue of chloramphenicol at a concentration of 0.2µg/kg (indicative value). The FSA has been informed and asked to raise a Rapid Alert and the CVO has notified the authorities in the country of origin asking them to investigate the cause of the residue.

A retail sample of chicken from Thailand was found to contain a concentration of 0.4µg/kg of chloramphenicol. A sample from the consignment was tested before leaving Thailand using the sophisticated LC-MS-MS analytical method and gave a negative result.

A separate sub-sample from the consignment was taken at the Port of Entry to the UK and this also tested negative. The Thai authorities have traced the retail sample back to the farm of origin and could find no evidence of the use of chloramphenicol.

The European Commission issued a Rapid Alert on 17 November 2003 and the FSA has written to the UK importer.

Chloramphenicol is in Annex IV of EC Council Regulation 2377/90. Its use in food producing species in the EU and in produce exported to the EU is prohibited.

Sulphonamides

A sample of honey from Cyprus was found to contain residues of sulphamethazine at a concentration of 177µg/kg and sulphadiazine at a concentration of 1,687µg/kg. The FSA has been informed and asked to raise a Rapid Alert and the results have been reported to the authorities in Cyprus. Toxicological advice is that at the concentrations found they would be unlikely to pose a risk to human health.

2003 NON-STATUTORY SURVEILLANCE RESULTS 1 APRIL – DECEMBER 2003

Matrix	Analyte	No. of samples analysed	MRL/Action Level where set µg/kg	No. of samples above Action Level
Imported farmed fish	Avermectins	198	100	
	Malachite green/ leucomalachite green	198	Not set	6
	Quinolones	198	300 (oxolinic)	
Imported honey	Antimicrobial Screen	106	Not set	1
	Chloramphenicol	106	Not set	1
	Nitrofurans	106	Various	11
	Pyrethroids	101	Not set	
	Streptomycin	106	Not set	6
Imported raw beef	Avermectins	300	Not set	1
	β-agonists	301	Not set	
	Trenbolone	301	Not set	
	Zeranol	301	Not set	
Imported raw chicken	Antimicrobial Screen	300	Various	
	Chloramphenicol	300		
	Clopidol	300	Not set	
	Fluoroquinolones	300	100 (total)	
	Nicarbazine	300	200	
	Nitrofurans	298	Not set	1
Quail eggs	Antimicrobial Screen	30	Not set	
	Dimetridazole/ronidazole	30	Not set	
	Lasalocid	30	Not set	12
	Nicarbazine	30	Not set	3
Warm water prawns	Antimicrobial Screen	307	Various	
	Chloramphenicol	307	Not set	
	Nitrofurans	307	Not set	29
	Quinolones	307	Not set	

**MARKETING AUTHORISATIONS ISSUED UNDER THE MARKETING AUTHORISATIONS FOR
VETERINARY MEDICINAL PRODUCTS REGULATIONS 1994 GAZETTED BETWEEN
5 DECEMBER 2003 – 29 FEBRUARY 2004**

Company	Vm Number	Product Name	Legal Category
Bayer Plc	00010/4135	Drontal Cat XL Tablets	PML
Bayer UK Ltd	00010/4084	Baycox 2.5% Solution	POM
Intervet UK Ltd	01708/4495	Butox Swish	PML
Janssen Cilag Ltd	00242/4052	Flubenol Easy Cat	PML
Laboratorios Calier, SA	20634/4000	Pluset	POM
Lohmann Animal Health GmbH & Co KG	16894/4005	AviPro Salmonella E	POM
Merial Animal Health	08327/4210	Frontline Combo Spot-on Cat	POM
	08327/4211	Frontline Combo Spot-on Dog Small	POM
	08327/4212	Frontline Combo Spot-on Dog Medium	POM
	08327/4213	Frontline Combo Spot-on Dog Large	POM
	08327/4214	Frontline Combo Spot-on Dog Extra Large	POM
Schering Plough Ltd	00201/4192	Isoxetol	POM

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

VARIATIONS APPROVED: 5 DECEMBER 2003 – 29 FEBRUARY 2004

Company	Product Name	Brief Details
Alpharma As	Alpha Ject 4000	Shelf Life extended
Aquaculture Vaccines Ltd	Aquavac ERM Oral Vaccine	Shelf Life extended
Bayer (UK) Ltd	Baytril 2.5% Injection	Change of MA holder address to Bayer Plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA
Bayer Ag	Bayovac Ibr Marker Inactivatum	Additional Pack Size
	Bayovac Ibr Marker Vivum	Additional Pack Size
	Bayovac Ibr Marker Inactivatum	Change of MA holder address to Pfizer Ltd, Ramsgate Rd, Sandwich, Kent, CT13 9NJ
	Bayovac Ibr Marker Vivum	" " " " "
Bayer Plc	Top Drop for Large Cats	Change of MA holder address to Bayer Plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berks RG17 1JA
	Top Drop for Large Dogs	" " " " "
	Top Drop for Medium Dogs	" " " " "
	Top Drop for Small Cats	" " " " "
	Top Drop for Small Dogs	" " " " "
	Top Drop for Extra Large Dogs	" " " " "
	Baytril 5% Injection	" " " " "
	Baytril Tablets 15mg	Change in Flavouring System of Product
	Baytril Tablets 50mg	Change in Flavouring System of Product
Baytril Tablets 150mg	Change in Flavouring System of Product	

Company	Product Name	Brief Details
Bayer Plc (cont...)	Baytril Tablets 150mg	Change of MA holder address to Bayer Plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berks RG17 1JA
	Bayvarol Strips	" " " " "
	Drontal Puppy Suspension	" " " " "
	Rompun Dry Substance	" " " " "
	Baytril 2.5% Oral Solution	" " " " "
	Baytril Max	" " " " "
	Baytril Tablets 50mg	" " " " "
	Bolfo Flea Spray	Shelf Life (Product)
	Baytril 10% Injection Solution	Change of MA holder address to Bayer Plc, Animal Health Division, Bayer House, Strawberry Hill, Newbury, Berks RG17 1JA
Baytril 10% Oral Solution	" " " " "	
Rompun 2% Solution	Withdrawal Period Decreased	
Boehringer Ingelheim Ltd	Voren Suspension	Withdrawal Period Decreased
Cross Vetpharm Group Ltd	Oxycomplex Ns	Withdrawal Period Increased
	Oxycomplex Ns	Target Species Deletion
Diverseylever Ltd	Star Iodocare Concentrate	Change of MA holder address to Weston Favell Centre, Northampton, NN3 8PD
Ecolab Ltd	Blu-Gard Teat Spray	Change of MA holder address to Lotherton Way, Garforth, Leeds, LS25 2JY
	Blu-Gard	" " " " "
Fort Dodge Animal Health Ltd	Duphamox 40 mg	Change of MA holder address to Sogeval SA, 200 Ave de Mayenne, BP2227, 53022 Laval, Cedex 9 France
	Duphamox 100 mg	" " " " "
	Duphamox 200 mg	" " " " "
	Cydectin 1% Injectable Solution for Cattle	Withdrawal Period Increased
	Duphatrim Bolus	Withdrawal Period Decreased
Forum Products Ltd	Cefalexin Tablets 250mg	Product name changed to Cephorum Tablets 250mg
	Cefalexin Tablets 250mg	Additional Pack Size
Intervet UK Ltd	Nobilis Paramyxo P201	Shelf Life Extended
Leo Laboratories Ltd	Leo Red Dc	Indications Modified
Merial Animal Health Ltd	Avinew	Change of MA holder address to Meriel SAS(P) Laboratoire de Toulouse, 4 Chemin du Calquet 31057 Toulouse, Cedex, France
	Gallivac SE	" " " " "
	Progressis	" " " " "
	Hyoresp	" " " " "
	Pastobov	" " " " "
	Friends Cat Flea Powder	Product Name changed to Canac Cat Flea Powder

Mr H.I. Moulds and Mrs S.J. Moulds	Hartz Control Pet Care System One Spot Flea and Tick Remedy For Dogs Armitage Pet Care Flea & Tick Drops (45) Vetzyme Flea and Tick Drops for Dogs Armitage Pet Care Flea & Tick Drops (45)	Safety Warnings Product Name changed to Zodiac Pet Protection Programme Flea & Tick drops for Dogs Safety Warnings Safety Warnings
Norbrook Laboratories Limited	Ultrapen La Norocarp Tablets 20mg Norocarp Tablets 50mg Combimox Injection Norixin Injection	Withdrawal Period Increased Additional Pack Type Additional Pack Type Additional Target Species Safety Warnings
Novartis Animal Health UK Ltd	Cosumix Plus Johnson's 4Fleas Tablets for Small Dogs and Puppies, Cats and Kittens Aurogran Aurogran 150 Johnson's 4Fleas 11.4mg Tablets for Cats and Kittens, Small Dogs and Puppies	Change of MA holder address to New Cambridge House, Littington, Herts, SG8 0SS Indications Deleted Dosage Particulars Dosage Particulars Indications Deleted
Pfizer Ltd	Dectomax Injectable Solution for Cattle & Sheep	Withdrawal Period Increased
Pfizer Ltd & Central Research Division	Rispoval	Shelf-life Extended
Schering-plough Ltd	Cepravin Dry Cow	Withdrawal Period Increased
Sinclair Animal & Household Care Ltd	Wilko Dog Flea Drops Canac Dog Flea And Tick Drops Friends Silent Action Cat Flea Spray Friends Silent Action Dog Flea Spray Friends Dog Flea Powder	Additional Safety Warnings Additional Safety Warnings Product Name changed to Canac Cat Flea Spray Product Name changed to Canac Dog Flea Spray Product Name changed to Canac Dog Flea powder
Vericore Ltd	Excis	MA Holder Name changed to Novartis Animal Health
Vet Medic OY	HY-50 Vet	MA Holder changed to Tyrwannontie, 769 FIN – 14610 Lepaa, Finland
Vetoquinol (UK) Ltd	Amoxinsol 50 Amoxinsol 100 Prilium 300mg Powder for Oral Solution	Withdrawal Period Increased Withdrawal Period Increased Shelf Life of reconstituted product extended
Virbac S.A.	Sedivet 1 mg/ml Solution for Injection	Change of MA holder address to Virbac SA 1 ERE Avenue, 2065 M - L.I.D., 06516 Carros, France

**MARKETING AUTHORISATION AND VARIATIONS FOR
EU CENTRALLY AUTHORISED PRODUCTS
UNDER COUNCIL REGULATION (EEC) NO 2309/93
GAZETTED BETWEEN 5 DECEMBER 2003 - 29 FEBRUARY 2004**

Company	Product Name	Brief Details
Pfizer Ltd	Draxxin 100mg/ml Solution for Injection	Shelf Life Extended
Intervet UK Ltd	Nobivac DHppi Nobivac PPI Nobivac Parro C	Change to required Vaccination regime " " " " " " " " " " " "

**EXPIRED MARKETING AUTHORISATIONS GAZETTED BETWEEN
5 DECEMBER 2003 – 29 FEBRUARY 2004**

Company	Vm Number	Product Name
Bayer Plc	00010/4084	Baycox 2.5% Solution
Evans Vanodine International Plc	03940/4048	Dari Klean Supreme Dip Chlorohexidine Teat Dip RTU
J M Loveridge Plc	00531/4038	Cetriad
Laboratories For Applied Biology Ltd	00118/4008	Ornimed Oxytetracycline
Merial Animal Health Ltd	08327/4172 08327/4122 08327/4125 08327/4018 08327/4019	Coyden 25 For Game Birds Embacillin Injection Ion Aid Qualamox 15 Qualamox La
Novartis Animal Health UK Ltd	12501/4072	Sure Ld
Schering Plough Ltd	00201/4133 00201/4054 00201/4114	Mylipen Dry Cow Oxytetrin 5 Streptopen Injection
Virbac Sa Downland	05653/4075	Pour On
Virbac Sa Niratil	05653/4041	Pour On

■ AMENDMENT TO VARIATIONS APPROVED - MAVIS 49

Please note that in the January 2004 edition of *MAVIS (49)* the products shown below were listed under Variations with a change to the MA/Holder name to Johnson Diversy Ltd. This was incorrect and this information should be disregarded, the approved variation is shown below.

Hybred Sa Products	Iodypro	MA/Holder <u>address</u> changed to 55 Boulevard Jules Verger, BP 10180, 35803 Dinard Cedex, France
	Propisderm	" " " " " "
	Hexiprotect Ws	" " " " " "
	Ioprotect Ws	" " " " " "
	Trepex	" " " " " "

