



Annual Report on Surveillance for
Veterinary Residues in Food
in the UK, 2003





Establishment of the Committee

The Veterinary Residues Committee was established in January 2001 to ensure that there is independent scrutiny in the surveillance for veterinary residues in the UK. The Committee provides a source of advice for the Chief Executives of the Veterinary Medicines Directorate (VMD) and Food Standards Agency (FSA) on the residues surveillance programmes, and the significance of the results for consumer safety.

Terms of Reference

The VRC's terms of reference are:

- to interpret and advise on the incidence and concentrations of residues of veterinary medicines in samples collected under the Veterinary Medicines Directorate and Food Standards Agency's surveillance programmes
- to assess and advise on the scope and operation of the Veterinary Medicines Directorate statutory surveillance programme within the context of the requirements of European Community legislation
- to advise, with particular reference to food safety, on the Veterinary Medicines Directorate non-statutory and ad-hoc Food Standards Agency residue surveillance programmes and consider the need for further analytical surveys
- to set up Subgroups as necessary to further the work and objectives of the VRC
- to publish results as they become available in the Veterinary Medicines Directorate's Quarterly Medicines Act Veterinary Information Service; to publish a Veterinary Residues Committee Annual Report on Veterinary Residue Surveillance, which will include detailed results in the context of food safety, to report annually to the Veterinary Products Committee and the Food Advisory Committee¹.

How can I comment on the Committee's work?

The VRC welcomes your comments. You can send them to the Committee either in writing or by e-mail to:

The Veterinary Residues Committee,
Woodham Lane,
New Haw,
Addlestone,
Surrey KT15 3LS

secretariat@vet-residues-committee.gov.uk

Any comments received will be distributed to the Members.

¹ After the Veterinary Residues Committee was established, the Food Advisory Committee was disbanded.



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Chairman's introduction



On behalf of the Veterinary Residues Committee, I am pleased to present our third Annual Report. It sets out the work we have done during 2003 to assess the health implications from food containing any residues of authorised veterinary medicines or any unauthorised or banned substances, and also in helping plan the VMD's surveillance schemes.

Towards the end of the year Professor Jim Bridges, our first Chairman, resigned for personal reasons. We are grateful to him for the work he did in establishing the Committee. Defra will run an appointments exercise in 2004 for his post and other vacancies on the Committee.

As in previous years the Report is in two sections, the narrative presented here and the detailed surveillance results presented to us available separately in hard copy from our Secretariat or on our website www.vet-residues-committee.gov.uk.

We are grateful that a leading retailer has shared the results of their own surveillance with us. This is most valuable to the Committee and we very much hope that others will follow their example in 2004.

The Committee planned and commenced a pilot brand naming survey to detect any continued malachite green use in salmon production. The Committee hope that this will send out a clear message that the use of banned substances is unacceptable.

Previous Annual Reports explained that the VRC had recommended prioritising the Non-Statutory Surveillance Scheme in the area of banned substances in imported produce. The Committee is concerned at the continued presence of these substances, chiefly in chicken, warm-water prawns and honey.

We were again pleased that an additional £300,000 was provided to boost the Non-Statutory Surveillance Scheme, but think that the level of funding remains inadequate to continue targeting banned substances and also cover other areas where surveillance would still be useful to ensure unwelcome trends are not developing.

The Committee also remain concerned at the incidence of feed additives, notably lasalocid and nicarbazin in eggs and poultry meat respectively. Whilst the advice we receive from our own toxicologists and those from the VMD and FSA is that these do not pose a risk to human health, we consider they indicate a level of contamination that could undermine consumer confidence in these foods.

However, overall, our work in 2003 has demonstrated that consumers can remain confident that the food they buy for themselves and their families is safe, taking account of the incidence and concentrations of the residues detected.

Dorothy Craig
Acting Chairman

Key Results and Actions Taken on Residues in the UK in 2003

National Surveillance Scheme for UK produce

Of 35,399 analyses, 89 contained detectable residues of Veterinary Medicinal Products at concentrations above the relevant Maximum Residues Limit or Action Level (see page 24 for explanation of these terms). This compares to the 102 positives in some 35,800 analyses in 2002.

Overall, the results of the National Surveillance Scheme indicate that the UK authorised uses of veterinary medicinal products did not result in residues of human health concern. Only in the case of two authorised products did use result in residues of potential concern – both where the instructions for use had not been followed. A high concentration of benzimidazoles was found in one sample of sheep kidney and residues of phenylbutazone were discovered in three samples of horse plasma (phenylbutazone should not be administered to horses that are intended for human consumption).

A majority of the veterinary medicinal residues detected (71) were of the zotechnical feed additives, lasalocid and nicarbazin. **The Committee considers this continued occurrence of feed additive residues in poultry products unacceptable.** While advice is that they are not a concern for human health, the frequency of these findings could damage consumer confidence in poultry products. The Committee is disappointed that despite efforts to work with the industry, the residues continue to occur. The Committee is considering what further actions it might recommend to resolve the issue.

Residues of unauthorised and banned substances were found. Malachite green and leucomalachite green residues were found in samples of farmed fish. A residue of the nitrofurans, nitrofurazone, was also detected in one sample of sheep kidney (see below).

Non-Statutory Surveillance Scheme

The number of analyses revealing residues above the relevant MRL or Action Level reduced from 217 in 2002 to 74 (from 72 samples) in 2003. Much of the decrease is because the Committee recommended that environmental contaminants should not be sought this year. Previously, organochlorine and PCB residues were tested for in imported produce to mirror the National Surveillance Scheme, which is required by EU law to seek such substances. However, the Committee recommended that with the limited funds available, the VMD should target particular foods where intelligence suggested the possible presence of residues of banned substances being used as veterinary medicines. Environmental contaminants fall into the remit of the Food Standards Agency.

The targeting of imported commodities, such as chicken, honey and warm water prawns, has revealed residues of banned substances, as it did in 2002. The Committee think it valuable to investigate a full range of commodities and residues that may be of concern, but recognise that this would require significant additional funding.

Overall, the results of the National Surveillance Scheme indicate that the UK authorised uses of Veterinary Medicinal Products did not result in residues of human health concern.

The targeting of imported commodities, such as chicken, honey and warm water prawns, has revealed residues of banned substances, as it did in 2002.

Residues of potential concern

The residues detected that were of potential concern were:

UK produce

- benzimidazole residues in one sample of sheep kidney
- malachite green and leucomalachite green residues in farmed fish
- nitrofurazone residues in one sample of sheep kidney
- phenylbutazone residues in samples of horse plasma.

Imported produce

- chloramphenicol residues in one sample of honey and one sample of imported raw chicken
- leucomalachite green residues in samples of farmed fish
- nitrofurans residues in samples of raw chicken, honey and in warm water prawns.

UK produce from the National Surveillance Scheme

Benzimidazole residues in a sample of sheep kidney

Benzimidazoles are used to control internal parasites, such as worms. One sample of sheep kidney tested this year contained a total residue of oxfendazole, oxfendazole sulphone and fenbendazole at 4,590 µg/kg. This was a gross violation of the MRL of 500 µg/kg.

The Acceptable Daily Intake (ADI) for these residues is 420 µg for a 60 kg person. A person eating a standard 50 g portion of kidney containing the detected level of residue would consume 212.5 µg of the residue, approximately half the ADI. Toxicological advice is that the residue detected would be unlikely to result in adverse health effects, but the theoretical possibility could not be ruled out for an extreme consumer of kidney.

Because of the high concentration, the case was referred to Defra's Legal Department for investigation and they are considering if there is sufficient evidence for a prosecution.

Nitrofurazone residue in a sample of sheep kidney

Nitrofurans, such as nitrofurazone were veterinary medicines authorised to treat some infections in farm animals. In 1995, they were banned in the European Union. This was because of an increased risk of cancer if foods containing their residues were eaten over a long period. Nitrofurans are in Annex IV of Council Regulation 2377/90/EC, because no safe concentration can be set.

This follow-up investigation found no evidence of nitrofurans use on the farm. It is highly unusual to find such a residue in UK produce. The concentration found, 0.3 µg/kg is below the European Minimum Required Performance Limit of 1.0 µg/kg (see page 25).

To underline that unauthorised substances, such as malachite green should not be used in food-producing species, the VRC recommended that the VMD undertake a pilot brand-name survey of retail samples of farmed salmon on their behalf.

Malachite green and leucomalachite green residues in farmed fish

Of 168 samples of farmed salmon and trout tested, 7 contained residues of leucomalachite green, two of which also contained the parent compound, malachite green. This is compared to leucomalachite green residues being detected in 17 of 99 samples tested in 2001 and 16 of 141 samples tested in 2002. Movement restrictions were placed on the farms while follow-up investigations were carried out. Where the follow-up investigations confirmed the presence of these substances, the restrictions were maintained to stop contaminated fish entering the food chain.

Malachite green has never been authorised as a veterinary medicine. Therefore, its safety and that of its metabolite leucomalachite green have never been established. The Committee has expressed its concerns over such residues and supported the announcement made by the Department for Environment, Food and Rural Affairs (Defra) in June 2002 that all use of malachite green in farmed fish must stop.

To underline that unauthorised substances, such as malachite green should not be used in food-producing species, the VRC recommended that the VMD undertake a pilot brand-name survey of retail samples of farmed salmon on their behalf. The Committee remains keen to see continued surveillance for any residues and would support prosecutions where there is sufficient evidence.

Phenylbutazone residues in horse plasma

Phenylbutazone can be used as a painkiller and an anti-inflammatory drug to treat joint problems in horses. It can, in rare cases, cause serious blood disorders in humans, such as aplastic anaemia. In the UK, horses are not usually regarded as food-producing animals; thus on welfare grounds, phenylbutazone is allowed for treating certain conditions. However, the UK does export horses for human consumption and phenylbutazone residues should not be present in these. These three cases were referred for investigation.

Defra will be implementing the EU horse passport scheme in 2004. This will help ensure that horses entering the human food chain do not contain any unacceptable residues.

Imported produce

Chloramphenicol residues in imported raw chicken and imported honey

Chloramphenicol residues were detected in one sample of imported chicken and one of imported honey. This substance is banned in the EU for food producing animals. This is because toxicological advice is that no safe concentration can be set. Chloramphenicol can cause aplastic anaemia in rare cases. The Food Standards Agency was informed of the findings in order to issue Rapid Alerts. The VRC is concerned that all necessary actions continue to be taken.

Leucomalachite green residues

As detailed above, malachite green and its metabolite leucomalachite green have not been fully evaluated for safety and is not permitted for use in food-producing animals in the European Union. The Food Standards Agency was informed of the residues. Four of the six violative samples were from Chile. The Chilean authorities were concerned over the cases and have had a meeting with Defra to resolve the issue. The other two samples were from Taiwan.

Nitrofurans residues

Nitrofurans residues were detected in:

- one of 298 samples of imported chicken
- 11 of 106 samples of imported honey, and
- 29 of 307 samples of imported warm water prawns.

In all but two cases, the Chief Veterinary Officer of Defra wrote to the authorities in the country concerned and asked for an investigation into the causes and for steps to be taken to prevent recurrence. In the other two cases, concerning imported honey, the VMD wrote to the retailers asking for them to supply more information. The Food Standards Agency was also informed of all of the results, so that they could issue Rapid Alerts to the European Commission.

The significance of nitrofurans residues was explained above.

Protective measures under European Commission Decisions

An extra layer of protection is afforded to consumers via EU-wide measures introduced by the European Commission. These include complete bans on certain products and compulsory testing of consignments of particular commodities from specific countries.

The Commission monitors the frequency and pattern of the occurrence of unauthorised substances in specific commodities from third countries reported by Member States via the Rapid Alert system. The EU's Food and Veterinary Office then investigate potential problems and can consider measures that could be introduced to protect consumers where necessary. Examples of such measures in place in 2003 included specific testing requirements for nitrofurans in poultry originating from Brazil and prawns from South East Asia. Consignments testing positive under these measures are withdrawn from the foodchain and destroyed.

The Commission monitors the frequency and pattern of the occurrence of unauthorised substances in specific commodities from third countries reported by Member States via the Rapid Alert system.

The Committee's Year

The full Committee met three times in 2003. As well as the VRC members and the Secretariat, provided by the VMD, a number of advisors have attended the meetings. The advisors were able to provide input to the Committee's discussions on a range of subjects. Organisations that provided advisors during the year were:

- Central Science Laboratory (CSL)
- Department of Agriculture and Rural Development of Northern Ireland (DARD)
- Food Standards Agency (FSA)
- State Veterinary Service (SVS) of Defra
- Veterinary Medicines Directorate (VMD).

The Committee was involved in a number of issues and activities during the year:

- planning the National Surveillance Scheme and Non-Statutory Scheme for 2004
- reviewing the results of these schemes
- communicating the work of the Committee
- recommending a pilot brand-naming survey on malachite green residues in farmed fish
- meeting with industry representatives to try to reduce residues of feed additives, such as nicarbazin and lasalocid in poultry products
- confirming the removal of the Differential Action Level for feed additive residues
- recommending how to implement the European Commission's initiative on harmonising analytical capabilities among Member States
- visiting the Tilbury Border Inspection Post to see the procedures for sampling imported produce
- receiving presentations of the FSA's work that overlaps with the VRC's interests
- deciding to hold an Open Meeting in 2004 to canvass views on the work of the Committee, especially in relation to the scope and operation of the Non-Statutory Surveillance Scheme.

Planning the Surveillance Schemes

VRC members have been actively involved in advising VMD on planning the surveillance programmes for 2004. In September 2003, two Members attended the National Surveillance Scheme planning meeting to help produce the 2004 plan. This plan was then approved at the VRC Meeting in October 2003. The National Surveillance Scheme is described in detail on page 12.

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In the 2001 and 2002 Annual Reports, the VRC's review of the strategy and operation of the second VMD surveillance scheme, the Non-Statutory Scheme, was described. The Committee's view was that the scheme should concentrate on raw, imported produce. The VMD produced a draft plan for 2004, based on the VRC's recommendations. The VRC was then able to discuss and comment on the plan before it was finalised.

Reviewing the results

At each of the three full VRC meetings, the Committee reviewed the latest results of the UK surveillance schemes and asked detailed questions of the advisors, requesting extra information where necessary on causes and follow-up actions. The Committee then advised the VMD and the Food Standards Agency on the actions they may wish to take.

Communicating the work of the Committee

The VRC wants people to understand the work of the Committee and the surveillance schemes. The Committee recognise that public confidence depends upon information being available in language that is clear and understandable. To help achieve this, the Committee has a Subgroup to oversee the communication of its work.

In early 2003, the Subgroup reviewed the VRC's 2001 Annual Report and the VRC website. The Subgroup was pleased with the positive feedback that they had received on the 2001 Report. In response to requests, the Members recommended that more explanation of the regulatory process should be included in the 2002 Annual Report. To this end, sections were drafted and included on:

- how an Acceptable Daily Intake (ADI) is set; and
- how a risk assessment is carried out.

For the VRC website, the 'Frequently Asked Questions' section requested by the Committee was developed. The Subgroup noted that as most documents on its website were in 'pdf' format, their content could not be searched easily. To overcome this, the Committee asked that documents are included in a format that can be searched (HTML). A better search facility has also been added.

If you have views on the Committee's work or its website, please do use the link at www.vet-residues-committee.gov.uk.

Pilot brand-naming survey on malachite green in farmed fish

The VRC recommended that the VMD carry out a pilot brand-name survey of malachite green and its metabolite leucomalachite green in retail samples of farmed fish on behalf of the Committee. This decision was reported on the VRC website as VRC/03/21. The Committee will review the operation and results of this pilot survey and publish the details in due course. (The principles of brand-name surveys are explained on page 16).

The VRC chose malachite green for the survey to send out a clear message that the use of banned substances is not acceptable. The Committee hopes that the brand-name survey will concentrate the minds of the

The Committee recognise that public confidence depends upon information being available in language that is clear and understandable.

If you have views on the Committee's work or its website, please do use the link at www.vet-residues-committee.gov.uk.

Malachite green is not an authorised veterinary medicine. But it has been used in many countries to protect the welfare of farmed fish. As it is not an authorised medicine, its safety has not been fully assessed. The Committee welcomed Defra's announcement in June 2002 that all use of malachite green in fish for human consumption must stop.

The Committee is concerned that despite a number of efforts to reduce the incidence and concentrations of nicarbazin and lasalocid residues in poultry products, they are still occurring.

industry and retailers. The VRC wish to see that only authorised medicines are used and that farmed fish and other foods do not, in future, contain unacceptable residues.

Residues originating from Feed Additives (such as nicarbazin)

The Committee is concerned that despite a number of efforts to reduce the incidence and concentrations of nicarbazin and lasalocid residues in poultry products, they are still occurring. However, the Committee was pleased that no residues of dimetridazole were detected in quail eggs in 2003. This followed the removal of Emtryl, the authorised product containing dimetridazole from the market.

The Committee set up a Subgroup in 2001 to look at the reasons for the lasalocid and nicarbazin residues and work with industry to reduce them.

Follow-up investigations into positive samples have identified two main causes:

- for lasalocid, cross contamination at the mills from medicated to unmedicated feed; and
- for nicarbazin, poor handling or separation of medicated and unmedicated feeds on poultry farms.

The Subgroup met again in August 2003. It discussed the findings of follow-up investigations on farms and produced a plan of possible solutions. Representatives of the poultry and feed industries, as well as government and regulatory bodies also attended the meeting. A note of this meeting and the Action Points are on the VRC website as VRC/03/29.

At the meeting, it was made clear to the industry that unless the residues are reduced, the VRC consider nicarbazin in poultry livers to be a very strong candidate for a brand-naming survey.

Removal of the Differential Action Level

In the 2002 Annual Report, there was an explanation of why a Differential Action Level 'DAL' was introduced in 1998 for residues of nicarbazin and in 1999 for lasalocid. These substances are not authorised as veterinary medicines, but under different regulations as feed additives, which have not required MRLs under EU legislation (however, there is a Codex Alimentarius MRL for nicarbazin in poultry liver of 200 µg/kg).

Where there is no MRL for a particular residue/tissue, normally every confirmed residue would have a follow-up investigation. The Advisory Group on Veterinary Residues, the forerunner to the VRC, set 'Differential Action Levels' of 100 µg/kg for both nicarbazin and lasalocid, allowing the VMD to prioritise its resources on any residues of these feed additives found at concentrations above the Differential Action Level.

The Veterinary Residues Committee has taken a very active interest in reducing these residues since it was set up in 2001. The Committee noted the advice from the Food Standards Agency that these residues do not pose a health risk. The Committee, however, considered that the contamination of foods in such a way was fundamentally undesirable.

In 2002, it recommended that the DAL should no longer apply. **All** confirmed residues of lasalocid and nicarbazin above the relevant Action Level should be investigated. The Committee considered that the extra information on the causes of such residues would help it to make recommendations on how to reduce the incidence and concentrations found. The Committee looked again and confirmed this decision in 2003 – such residues should be reported as ‘positive’ in MAVIS, the VMD’s quarterly newsletter, and follow-up investigations held.

Minimum Required Performance Limits

The VRC discussed the setting of Minimum Required Performance Limits (MRPLs) for chloramphenicol and nitrofurans at their October meeting. The Committee noted that substances are placed in Annex IV of Council Regulation 2377/90/EC because no safe concentration can be set. The Committee also noted that the MRPLs were set at concentrations that all Member States were expected to achieve and that UK laboratories were already able to detect these banned substances at concentrations below the MRPLs.

The VRC recognised that a harmonised level was needed to ensure consistency in analysing samples. But, the Committee recommended that UK laboratories should continue to report **all** confirmed residues of these substances as positives. It would be then for the authorities to consider what action was necessary in relation to the concentrations detected.

Visit to the Tilbury Border Inspection Post

In June, Committee Members visited the Tilbury Border Inspection Post. This was to help the Committee understand the process of taking samples of imported produce, both as part of the VMD’s Non-Statutory Scheme and also as a result of Commission Decisions. The Committee would like to thank John Ambrose and his colleagues at the Port of London Authority for organising the trip and the useful presentations and demonstrations that they gave to the Committee.

Presentations of the FSA’s work that overlaps with the VRC’s interests

The Committee would also like to thank the Food Standards Agency for hosting the Committee’s October meeting. FSA staff gave presentations on the areas of food contamination for which they take primary policy responsibility. Presentations were given on heavy metals, mycotoxins, and the work of the Advisory Committee on Animal Feedingstuffs. The Committee also heard a presentation on the FSA’s work on risk assessment.

The meeting helped the Committee to identify the boundaries of work undertaken elsewhere, to promote a joined-up approach to surveillance.

The Committee looked again and confirmed in 2003 that residues of lasalocid and nicarbazin where there was no MRL should be reported as ‘positive’ in MAVIS, the VMD’s quarterly newsletter, and follow-up investigations held.

What are MRPLs?

Commission Decision 2002/657/EC provides for Minimum Required Performance Limits (MRPLs) to be set for analytical performance where these are considered necessary. The aim was to lower the concentrations that some Member States were able to detect, thereby improving the level of consumer protection. In March 2003, Commission Decision 2003/181/EC set MRPLs of 0.3 µg/kg for chloramphenicol and 1 µg/kg for nitrofurans metabolites.

Committee Members visited the Tilbury Border Inspection Post. This was to help the Committee understand the process of taking samples of imported produce, both as part of the VMD’s Non-Statutory Scheme and also as a result of Commission Decisions.

Residues Surveillance

The National Surveillance Scheme

How does the National Surveillance Scheme work in Great Britain?

In the UK, the National Surveillance Scheme covers: red meat, poultry meat, wild and farmed game, farmed fish, milk, honey and eggs.

1. The basis for the scheme is European Directive 96/23/EC.

All EU Member States must carry out surveillance to see that their home-produced foods of animal origin are safe. In the UK, the National Surveillance Scheme covers: red meat, poultry meat, wild and farmed game, farmed fish, milk, honey and eggs. Annexes to the Directive set down the number of samples that Member States must take, based on forecast production. The Directive also lays down broad parameters on the groups of substances to be surveyed.

2. Planning the programme

The VMD organise a meeting of interested parties in September to agree the specific substances in each group which are to be included. The parties also discuss how many samples should be taken. Parties involved in considering the draft plan are:

- Veterinary Residues Committee
- Laboratory of the Government Chemist
- Food Standards Agency (FSA)
- Meat Hygiene Service (MHS) of the FSA
- State Veterinary Service (SVS) of Defra
- Department for Environment, Food and Rural Affairs (Defra)
- Department of Agriculture and Rural Development (DARD) of Northern Ireland.

The VRC approved the plan for 2003 at the Committee's November 2002 meeting.

3. The plan must be approved in Brussels

Officials from the European Commission (DG-SANCO) and all the Member States examine the plan in Residue Working Group meetings to ensure that it complies with Directive 96/23/EC.

4. The VMD puts the plan into action

The plan is entered onto the 'Residues in Meat' (RIM) database. This is the key database that allows the VMD to track the progress of samples and have an audit trail to identify the producers. The database is used to generate individually numbered sample requests. This is done in a way so that all registered abattoirs should have some samples taken each year. Samples are also targeted by officers in the field and by specific requests from the VMD identifying producers who have had 'positives' in the past and/or where particular problems are suspected.

The plan is entered onto the 'Residues in Meat' (RIM) database. This is the key database that allows the VMD to track the progress of samples and have an audit trail to identify the producers.

5. Samples are collected

Authorised officers of the different government agencies collect the samples on behalf of the VMD (a full list of agencies is given on page 21). For example, the MHS have officers at all abattoirs for meat hygiene checks; they also take samples when requested, or if they have suspicions about an animal. Defra's SVS officers visit farms for a number of reasons, such as tuberculin testing of cattle. They will often use these visits to collect samples and inspect medicines records. So, producers know that the SVS are visiting, but would not be aware when a sample or samples are to be taken from their animals or feed etc.

Each sample is secured with a tamper proof seal and labelled. This allows it to be traced back to its origin. This traceability for each sample is crucial to allow any follow-up action to be taken. In 2003, some 30,975 samples were collected and 35,399 analyses performed.

6. What constitutes a sample?

A sample will vary depending on the residue sought and species, also whether the sample is to be collected from live animals on farms or from abattoirs. It will often mean a portion of liver or kidney of an animal, but could involve collecting blood, urine, faeces or the retinas of animals. Usually, the sample is selected as the most sensitive for finding the particular residue. Milk samples are collected from individual farms to reduce the dilution of any residues with milk from other farms. A sample of eggs consists of a dozen eggs from the same batch.

7. Samples are sent to the analytical laboratory

The sealed samples are sent to the Laboratory of the Government Chemist, where they are entered onto the computer system. This ensures that the progress of the samples can be monitored and that there is an audit trail back to the producer. Samples are stored deep-frozen to avoid deterioration. Similar samples are usually analysed in batches, which can delay individual samples. But as the analytical equipment is not set up for a single sample only, it significantly reduces the costs of analysis.

8. The samples are analysed

The laboratory will normally perform a screening test to see if the particular residue or residues are present. If a potential residue is detected, the sample will then be subject to a confirmatory analysis to definitively identify the residue and usually measure the concentration.

9. The results are assessed

The results are presented at the VRC meetings during the year. This allows members to comment and ask questions. All of the results that are above the relevant MRL or Action Level are passed to the Food Standards Agency. Toxicologists at the VMD and FSA can give a scientific opinion on the relevance of any residues for human health.

10. Follow-up investigations

A follow-up investigation is carried out into every sample with a residue above the MRL or Action Level. This tries to find the cause of the residue and gives advice to the farmer to avoid residues in the future.

All of the results that are above the relevant MRL or Action Level are passed to the Food Standards Agency. Toxicologists at the VMD and FSA can give a scientific opinion on the relevance of any residues for human health.

A follow-up investigation is carried out into every sample with a residue above the MRL or Action Level.

Reports to the Committee are published on the VRC website. You can also find the results in the VMD's quarterly 'MAVIS' newsletter and on their website in 'MAVIS-on-line'.

If there is suspicion that the farmer has used a banned substance, or if a particularly high concentration of an authorised medicine has been found, an Investigation Officer from Defra's Legal Department performs the visit. A veterinarian or Fish Health Officer may accompany them to give expert advice. Where there is sufficient evidence, a prosecution is considered.

11. Results are available to everyone

Reports to the Committee are published on the VRC website. You can also find the results in the VMD's quarterly 'MAVIS' newsletter and on their website in 'MAVIS-on-line' and an annual summary of the results is available from both the VRC and VMD websites.

Types of Substances Analysed for in the National Surveillance Scheme

Not all substance types were analysed for in every industry sector. For example, examining honey for substances that promote growth in beef cattle or pigs would not be sensible. Below is a table of the types of substances that were sought in the different sectors. Full details of the individual residues that were sought in each sector are listed on the VMD website.

Table 1. Different groups of substances that were looked for in the different industry sectors.

Type of substance as listed in Directive 96/23/EC	Industry sector						
	Eggs	Farmed fish	Game	Honey	Milk	Poultry	Red meat
Hormones		X	X			X	X
Gestagens							X
β-agonists			X			X	X
Annex IV substances	X	X	X	X	X	X	X
Antimicrobial screen†	X	X	X	X	X	X	X
Sulphonamides	X	X			X	X	X
Tetracyclines		X		X	X	X	X
Streptomycin				X			
Thiamphenicol						X	
Quinalones		X			X	X	
Anthelmintics	X	X	X		X	X	X
NSAIDS						X	X
Coccidiostats	X		X			X	X
Thyrostats			X			X	X
Dexamethazone/ Betamethazone							X
Carbadox*							X
Sedatives							X
Pesticides and PCBs	X	X	X	X	X	X	X
Heavy metals		X	X	X	X	X	X
Mycotoxins		X		X	X	X	X
Malachite/ Leucomalachite green		X					

† A general screening method to detect antimicrobial substances and supplemented by specific tests for sulphonamides, tetracyclines and streptomycin.

* Carbadox is not specifically listed under Directive 96/23/EC. But because of concerns about possible use in the past, it is included in the UK's surveillance.

The Non-Statutory Surveillance Scheme

The Non-Statutory Scheme was set up to complement the National Surveillance Scheme. It did this by testing processed foods, such as sausages, bacon and pate, imported produce and for some substances not included in the National Surveillance Scheme.

The foods covered in the scheme were originally based on the foods eaten by average consumers and also by susceptible groups (e.g. babies). This led to the scheme being wide-ranging, covering many commodities. This breadth caused difficulties with interpretation of the results, as the number of samples for some foods could be relatively small.

Planning Subgroup review of the operation and scope of the scheme

Concentrate on imported raw produce

In 2002, the VRC agreed the recommendation of its Non-Statutory Planning Subgroup to reduce the variety of products sampled and increase the number of samples for the remaining foods tested. The aim was to sample sufficiently large numbers to have more confidence in the results. The effect on consumer safety of the reduction in products sampled was assessed to be minimal, because the principal reductions involved foods that were already included in the National Surveillance Scheme. The reasoning for the change in scope was that:

- UK produced foods are already sampled under the National Surveillance Scheme
- processed foods, such as sausages and burgers are made from raw meats
- samples previously allocated to sausages, bacon and ham can all be amalgamated to give a larger number of samples for imported raw pork
- intelligence from Europe was that there were problems associated with animal-based foods imported from some non-EU countries
- processed foods, might only contain 10% meat, making detecting veterinary residues more difficult
- raw produce gives a better audit trail back to the country of origin and producer.

Rolling programme and special surveys

As well as the rolling programme that collected samples of particular foods throughout the year, the Committee also wished to be able to conduct special surveys where intelligence suggested that there might be particular problems (see page 20).

Prioritising foods and residues

The Subgroup wanted a transparent system for prioritising sampling. A number of criteria were discussed to help determine a prioritised list of foods and residues. What could be achieved within the budget could then be assessed.

The Committee also wished to be able to conduct special surveys where intelligence suggested that there might be particular problems.

Brand-naming is a process where information about a sample purchased for testing is published.

The criteria decided by the Subgroup were:

- toxicology of the residue (particular concerns being the nature of adverse effects and estimated margins of safety)
- importance of a food in the diet
- higher risk for a small proportion of the population
- extent of use of a particular veterinary medicine or growth promoter or knowledge of environmental contamination by a chemical of concern
- potential for residues based on information on the likely persistence of the medicine/promoter/contaminant
- findings from previous monitoring results
- other intelligence of likely residues (e.g. probability of significant illegal use and sourcing of imported materials).

The Subgroup has also taken expert statistical advice on the numbers of samples of particular foods to take. This advice was taken into account when planning the programme.

Brand-naming surveys

What is brand-naming?

Brand-naming is a process where information about a sample purchased for testing is published. Brand-naming has been pioneered by the Food Standards Agency since 2000. The Pesticides Residues Committee has also adopted it. The types of information that might be collected and published could include:

- what the product was
- the brand – which may be the retailer's own brand or the name of a manufacturer
- best before date
- batch code
- pack size
- country of origin
- the name and address of the shop
- date the sample was bought
- any residue found and the concentration.

Can brand-naming be used in all surveillance?

No, brand-naming can't be applied to the VMD's statutory National Surveillance Scheme. This is because the samples are taken under legal powers to check compliance with particular legislation. Legal advice is that they may not be used for other purposes, such as brand-naming. However, the samples are taken at a point where an individual producer can be targeted for any follow-up action.

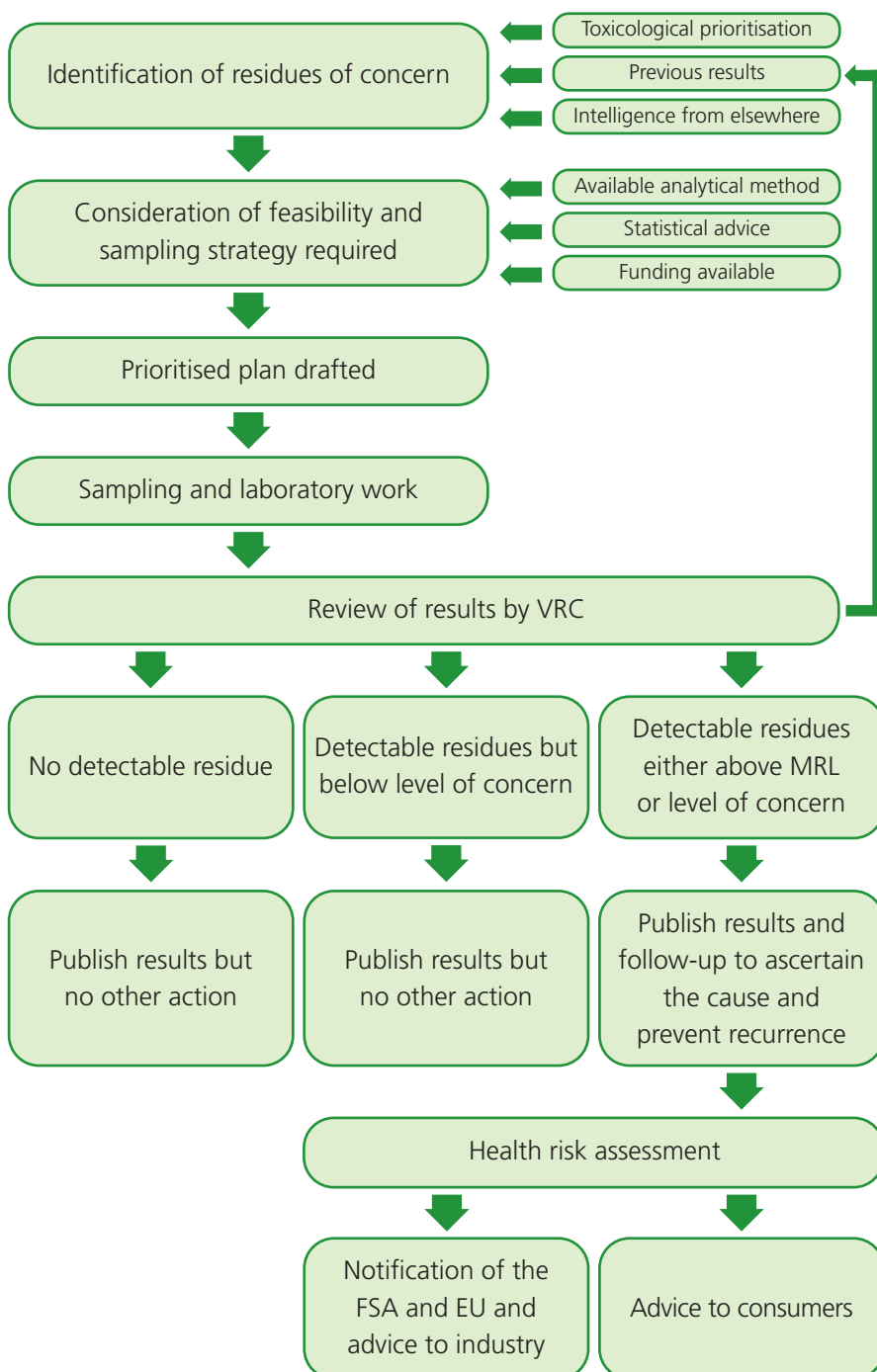
What is the VRC's view of brand-naming?

The Committee previously agreed in principle that it would recommend brand-naming. The Members think that it provides transparency and openness where surveys are carried out. Also, in some circumstances there are other benefits, such as concentrating the food retailers and suppliers' attention. But, the Committee are aware that there is a need to be fair and also allow those named the opportunity to comment.

In 2003, a recommendation was made to the VMD to run a pilot brand-naming survey for residues of malachite green and leucomalachite green in samples of salmon from shops.

The Members think that brand-name surveys provide transparency and openness where surveys are carried out. Also, in some circumstances there are other benefits, such as concentrating the food retailers and suppliers' attention.

Outline of the Operation of the Non-Statutory Scheme



Operation of the Non-Statutory Surveillance Scheme

1. Planning the year's programme

The VMD produced a draft plan for 2003, taking account of the criteria on toxicological significance and importance in the diet approved by the VRC. At a meeting of the full VRC, the draft plan was examined and discussed. The Committee were able to make recommendations to amend the plan.

2. VMD puts the plan into action

The plan was loaded onto the Non-Statutory database. After consulting the Border Inspection Posts (BIPs) about the foods that would pass through their port, each BIP was allocated a number of samples for each food and residue for the year, along with a monthly sampling schedule.

The VMD supplied Mintel, a market research company, with a monthly sampling schedule for the foods their 'shoppers' were to buy. They then divided this among 'shoppers' in different parts of the country.

3. Samples are collected

Port Health Officers collected the samples of imported foods at selected BIPs, such as at Tilbury Docks. The Port Health Officers also collected samples as part of testing programmes under the EU's Veterinary Checks Directive and specific Commission Decisions applied to countries whose produce was suspected of containing residues of substances banned in the EU. Care was taken not to duplicate the sampling under the Commission Decisions when implementing the Non-Statutory sampling. Mintel 'shoppers' collected samples from shops throughout the UK.

Both the Port Health Officers and Mintel staff worked to protocols that instruct them to collect information that would allow the VMD to identify the sample and, where possible, allow its origin to be traced.

4. What constitutes a sample?

This depends on what food is being sampled and was calculated to be large enough to allow accurate analysis for the suspected residue. For example, for imported raw chicken collected at a Border Inspection Post, a sample was 250 g of muscle.

5. Samples are sent to the laboratory

Both Mintel and the Port Health Officers sent the sealed samples to the Central Science Laboratory for delivery before 11.00 am the next day. On receipt, they were logged onto the computer system. This ensured that the progress of the samples could be monitored and there was an audit trail back to the producer or country of origin. The samples were stored deep-frozen to avoid deterioration. Samples to be analysed for the same substance were batched, to reduce costs, without effect on the accuracy of detection.

6. The samples are analysed

The laboratory normally performed a screening test to see if the particular residue or residues were present. If they detected a residue, the sample would then be subject to confirmatory analysis to definitively identify the residue and usually measure the concentration.

Both the Port Health Officers and Mintel staff worked to protocols that instruct them to collect information that would allow the VMD to identify the sample and, where possible, allow its origin to be traced.

7. Results are assessed

In common with the National Surveillance Scheme, the Non-Statutory Scheme results were presented at the VRC meetings during the year. This allowed members to comment and ask questions on the results and assess their significance for consumers.

8. Follow-up investigations and issuing Rapid Alerts

The VMD told the retailer of any samples bought from their stores with residues above the relevant MRL or Action Level. The VMD also informed the Food Standards Agency (FSA). If the food concerned was imported, the Chief Veterinary Officer of Defra was informed. In nearly all cases, he wrote to his opposite number in the country concerned and asked them to investigate and report on the cause of the residue and steps taken to avoid recurrence.

If residues of health concern were detected – for instance, of banned substances – the FSA could decide to ask local authorities to investigate and can also request and oversee product withdrawals where this is appropriate. The FSA operate the EU's 'Rapid Alert System for Feed and Food' or RASFF in the UK. Under this system, all EU Member States are required to alert the European Commission when foods or feed containing residues of concern are discovered. The Commission can then inform other Member States. This happened in all the cases where chloramphenicol or nitrofurans residues were detected.

The Commission could then consider what actions were appropriate as a result of RASFFs it received. This could have meant issuing a Commission Decision on extra testing of particular foods of animal origin entering the EU from a specified country. Consignments would then not be allowed to leave the port until samples were taken and analysis showed them not to contain such residues. If such residues were detected, the goods would be destroyed.

9. Results are available to everyone

The reports on the Non-Statutory Scheme updating the Committee on the results are put on the VRC and VMD websites. You can also find the results in the VMD's quarterly 'MAVIS' newsletter and they are updated on their website in 'MAVIS-on-line'. An annual summary of the results is available from the VRC and VMD websites.

The reports on the Non-Statutory Scheme updating the Committee on the results are put on the VRC and VMD websites.

Foods analysed under the Non-Statutory Surveillance Scheme

Rolling programme

The Committee was pleased that the extra funds allocated for 2002 were maintained for 2003. Based on the criteria listed earlier, the foods selected for analysis under the rolling programme, which runs from April to December were:

- Raw beef – imported
- Raw chicken – imported
- Farmed fish – imported
- Warm fresh water prawns – imported
- Warm sea water prawns – imported
- Honey – imported
- Quail eggs – domestic.

Not all foods were analysed for all the substances in the scheme. Based on intelligence and previous results, the analyses carried out on a particular food were prioritised.

Special survey

A survey for chloramphenicol in dried milk was carried out. This was because intelligence had indicated that some samples of dried milk imported into other EU Member States had been found to contain chloramphenicol residues.

The VRC also recommended in June 2003 that a pilot brand-name survey of farmed fish for residues of malachite green and leucomalachite green be carried out. The samples were to be collected in early 2004.

Who is involved in the VMD's Surveillance for Veterinary Residues?

The VMD operates the surveillance programmes and provides the Secretariat for the VRC, but many other organisations have a role:

Collecting samples

- Border Inspection Posts (BIPs) – Port Health Officers at the BIPs collect samples of imported foods for the Non-Statutory Scheme.
- Centre for Environment, Fisheries and Aquaculture Science (CEFAS) of Defra – collects statutory samples and carries out follow-up investigations on fish farms in England and Wales.
- Department for Agriculture and Rural Development (DARD) in Northern Ireland – collects and analyses samples for the National Surveillance Scheme in Northern Ireland on behalf of the VMD. DARD also carries out follow-up investigations in Northern Ireland.
- Egg Marketing Inspectorates (EMI) of Defra and Scottish Executive Environment and Rural Affairs Department – collect statutory samples of eggs from packing stations.
- Fisheries Research Services (FRS) of the Scottish Executive – collect statutory samples and carries out follow-up investigations on fish farms in Scotland.
- Meat Hygiene Service (MHS) of the FSA – collects statutory samples from abattoirs, it also has powers to detain animals suspected to have been treated with unauthorised substances or contain residues above the Maximum Residue Limit.
- Mintel, a market research company, was contracted to buy samples of foods from shops for the Non-Statutory Surveillance Scheme in 2003.
- State Veterinary Service (SVS) of Defra – collects statutory samples from stock farms in Great Britain, and carries out follow-up investigations for samples above the MRL or Action Level collected from farms or abattoirs.

Analysing samples

- Central Science Laboratory, York (CSL) – analyses samples collected under the Non-Statutory Scheme.
- Laboratory of the Government Chemist, Teddington (LGC) – analyses samples collected under the National Surveillance Scheme.

Investigate positive samples

- CEFAS, DARD, FRS and the SVS also investigate the reasons for positive samples in their areas (see collecting samples, above).
- Legal Department of Defra – prepare the national legislation in GB covering the Statutory Surveillance Scheme and has an Investigations Branch to carry out investigations where a positive sample may result in a prosecution.

- Royal Pharmaceutical Society (Great Britain) (RPS(GB)) – inspects feed mills that produce medicated feed.

Overseeing the Surveillance

- The Veterinary Residues Committee examines the plans and makes recommendations over the surveillance and also scrutinises the results.
- European Commission – in conjunction with the other Members States, examines and approves the National Surveillance Plans.
- Food Standards Agency (FSA) – organises local authority investigations, operates the EU Rapid Alert system for the UK and its officials also attend VRC meetings as advisors and have a responsibility for food safety.
- The SVS attend VRC meetings as advisors.

Explanation of the Significance of Veterinary Residues

The Acceptable Daily Intake – part of the regulatory process

Before any medicine is authorised in food-producing animals, its active ingredient must be assessed for safety. The result of this is the setting of an 'Acceptable Daily Intake' (ADI). This is defined as 'an estimate of the amount of a substance, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable health risk'.

Establishing a dose that is safe

Most substances, even everyday ones will result in adverse or toxic effects if we are exposed at a sufficient dose. So to set an ADI, expert scientific committees, such as the Joint Expert Committee on Food Additives (JECFA) or the EU's Committee on Veterinary Medicinal Products (CVMP) assess data from a wide range of tests (see page 26 for information on these committees). They will be looking for the dose of the active ingredient that results in no adverse effects.

Types of tests assessed may include:

- **Pharmacodynamics** – potential adverse pharmacological effects on the normal functions of the body.
- **Pharmacokinetics** – data on the absorption, distribution, metabolism and excretion of the substance in animals (and humans).
- **Acute (single dose) toxicity** – short-term adverse effects resulting from single, high dose exposure to the substance.
- **Repeated dose toxicity** – adverse effects resulting from daily exposure to lower levels of the substance, usually over periods from 90 days to one year.
- **Genotoxicity** – in this case, a general term covering the adverse effects of a substance on genetic material (DNA).
- **Reproductive and developmental toxicity** – adverse effects on reproduction, fertility, the developing embryo and foetus, and neonatal organism.
- **Carcinogenicity** – long term feeding studies to investigate the potential of the substance to cause tumours.
- **Neurotoxicity** – adverse effects on the central nervous system (brain and spinal cord and peripheral nerves).
- **Immunotoxicity** – adverse effects on the immune system.
- **Antimicrobial activity** – adverse effects on the normal microflora of the intestinal tract.
- **Human data** – this may be available from clinical trials, volunteer studies or reports of accidental or deliberate ingestion of the substance.

Before any medicine is authorised in food-producing animals, its active ingredient must be assessed for safety.

Most substances, even everyday ones will result in adverse or toxic effects if we are exposed at a sufficient dose.

Most ADIs will have been set based on a NOAEL from long-term exposure to a residue or substance, so one-off exposure at a concentration above the ADI is unlikely to result in harm.

Setting the safety limits

From these data, the Committees can set the 'No Observed Adverse Effect Level', or NOAEL. They will then take account of the data that they have assessed and add in uncertainty factors. These are used to take account of the robustness of the data and because there will be variations between species in their reaction to a drug and there may also be variations between individuals. Typically, the NOAEL is divided by a safety factor of 100-1000 times to give the ADI.

Are residues above ADI always unsafe?

No, most ADIs will have been set based on a NOAEL from long-term exposure to a residue or substance, so one-off exposure at a concentration above the ADI is unlikely to result in harm.

Maximum Residue Limits (MRLs), Action Levels and Minimum Required Performance Limits

These terms are used to describe concentrations of residues, which, if present or exceeded, trigger a follow-up investigation on the cause. Any concentrations above these limits will also be assessed for any potential health effects in consumers.

Maximum Residue Limits – when a medicine is submitted for authorisation, its active ingredient is evaluated for safety. In Europe, the Committee for Veterinary Medicinal Products (CVMP), part of the European Medicines Evaluation Agency, does this. It sets a concentration that it considers, having reviewed all the available evidence, will not represent a health risk to consumers. In doing this, it will take account of all foods that might contain residues of the particular substance and the ADI.

For some substances and foods there is no European MRL. For these there may be MRLs set by the Codex Alimentarius (see page 26), if so, these are used to guide action in the UK residues programme. This is the case for nicarbazin residues in chicken liver.

How the process works and fits into surveillance is described on page 26.

Action Level – for many veterinary residues an MRL is not set or may not be relevant for a variety of reasons:

- substances banned from use in food animals, such as growth promoting hormones
- analysis of tissues and substances not normally eaten, such as retina and urine
- substances in the surveillance scheme that are not veterinary medicines, such as mycotoxins and heavy metals
- feed additives, such as lasalocid, which legislatively are not classed as veterinary medicines.

For such substances the Action Level is usually any confirmed residue. These are based on the limitations of the analytical methodology and may not necessarily imply health concerns if exceeded. Each case is examined individually.

Minimum Required Performance Limits – the European Union is a single market. This means that while foods from non-member states can be checked at ports as they enter the EU, once they have been imported into one Member State, they can be moved to others without further checks. This system relies on all Member States having robust systems to check incoming foods for veterinary residues or other substances that may potentially pose a risk to consumer health.

The Commission were aware that some Member States had less sensitive analytical methods than others. It would be possible for these countries to be targeted as ports of entry for produce containing unacceptable residues. To combat this, the Commission brought in Minimum Required Performance Limits (MRPLs) for certain banned substances, such as chloramphenicol and nitrofurans. There are now set concentrations of these residues that all Member States must be able to detect – 0.3 µg/kg for chloramphenicol and 1.0 µg/kg for nitrofurans.

In the UK, the analytical laboratories were already able to detect concentrations lower than the relevant MRPLs. The VRC have recommended that **all** confirmed residues of these banned substances are reported as positive.

The UK's Surveillance Schemes as Part of the Regulatory Process for Veterinary Medicines

The UK's surveillance schemes are part of the regulatory process for veterinary medicines. The schemes are a check that veterinary medicines are being used as authorised and that any residues are at acceptable concentrations.

Understanding the regulatory process for veterinary medicines can help us put the results of surveillance in context. Central to the process is that the use of veterinary medicines should not result in any consumer exceeding the Acceptable Daily Intake, or ADI.

Who Sets Maximum Residue Limits?

International committees of scientific experts set MRLs.

In the European Union, the Committee for Veterinary Medicinal Products (CVMP) assesses safety data to set MRLs. The CVMP is part of the European Medicines Evaluation Agency.

The Codex Alimentarius is an international committee that also sets MRLs. It is advised by the Joint Expert Committee on Food Additives (JECFA) – a committee of scientific experts jointly administered by the Food and Agriculture Organisation of the United Nations and the World Health Organisation.

Set the Acceptable Daily Intake (ADI) for the Active Substance

the amount we could eat every day without harm



Set Maximum Residue Limits for Edible Tissue

such that the ADI is not exceeded

Set Withdrawal Periods for the Medicine

to make sure any residues are below the relevant MRL

Analyse Samples of Foods

the UK's surveillance schemes check that MRLs are not exceeded – action is taken where they do

Setting the Acceptable Daily Intake

International regulatory bodies assess data from a wide range of short and long-term studies. From these, they identify a concentration that had no adverse effect in any of the studies – the 'No Observed Adverse Effect Level' or NOAEL.

This concentration is then divided by a safety factor, typically 100-1000, to allow for possible differences between species and individuals and compensate for other uncertainties in the data.

This concentration is the Acceptable Daily Intake, or ADI. This is the amount of a residue that is considered safe for a person to eat every day over a lifetime.

Identify Residues of Human Health Concern

Different species of animals may be treated with a particular medicine. Also, each might convert the active substance in the medicine to other substances, called metabolites. The regulatory process takes account of this.

Setting Maximum Residue Limits (MRLs)

The ADI is divided among all the edible tissues, taking account of:

- how much of a particular food may be eaten each day
- how much of the substance occurs in each food
- how much the substance is changed in the animal's body
- other possible sources of residues, as some substances are also used as pesticides or human medicines.

MRLs are set so that even if **all** of the foods contain residues at the respective MRLs, the ADI will not be exceeded. In practice, residues are not found in most foods that are tested.

Setting Withdrawal Periods

The amount of a medicine or its residue in an animal will deplete over time as it is metabolised and excreted. The length of time that must elapse after the end of treatment with a medicine before that animal is slaughtered, or animal product is taken, for human consumption is the Withdrawal Period. It is set for each veterinary medicinal product that contains the active substance so that the residues in each food will be below the relevant MRL.

Analyse Samples of Foods – the VMD Surveillance Programmes

We have seen that the regulatory process sets conditions on the use of medicines. When these are followed, any residues will be at concentrations that are safe to eat every day over a lifetime.

The UK's surveillance schemes check that any residues are indeed below the MRLs that the regulatory authorities have set. Where a residue at a concentration greater than the relevant MRL is found, the cause is investigated and further action taken where appropriate.

Acceptable Daily Intake or ADI

– is an estimate of the amount of a substance, expressed on a body-weight basis, that can be ingested daily over a lifetime without appreciable health risk.

Maximum Residue Limit or MRL

– is the maximum concentration of a residue that is legally permitted or acceptable in or on a food. It is expressed in $\mu\text{g}/\text{kg}$ of that food. When determining MRLs, the ADI must not be exceeded after considering intake from all sources.

No Observed Adverse Effect Level or NOAEL

– is the highest concentration of an active substance that was found to have had no adverse effect in a safety test.

Veterinary Hypothetical Diet

– in setting MRLs, the amounts of particular foods in our diet are taken into account. The upper quantities of foods that we are assumed to eat are each day are:

- 100g liver
- 20g honey
- 300g muscle (muscle and skin for fish)
- 1.5 litres of milk
- 50g kidney
- 100g of egg
- 50g fat (fat and skin for pork and poultry)

Withdrawal Period

– is the length of time after the end of treatment with a veterinary medicine that must pass so that any residues in edible tissues will have depleted to below the MRL. The CVMP or the particular national approvals authority can set these, which for the UK is the Veterinary Medicines Directorate.

Where a residue at a concentration above the MRL is found in the National Surveillance Scheme, the State Veterinary Service would normally send a Veterinary Officer (VO) to investigate the cause.

What happens when a residue above the MRL or Action Level is discovered?

Where a residue at a concentration above the MRL is found in the National Surveillance Scheme, the State Veterinary Service would normally send a Veterinary Officer (VO) to investigate the cause and to give advice to the farmer on how to avoid such residues. Among the things the SVS look for are:

- the medicines records to see if they are being kept appropriately
- what standard of husbandry is employed
- how was the medicine administered – by water, feed or injection etc
- were the withdrawal periods observed
- if administered by feed, where was this mixed
- how were the animals fed – on the floor or in troughs etc
- how was the feed stored – was there the opportunity for cross-contamination.

What happens when a violative residue is found?

However, when a gross violation of the MRL or a residue of an unauthorised substance is detected, the case may be allocated to an Investigation Officer (IO) from Defra. The IO's role is to gather evidence, which will be later assessed by Defra's lawyers to see if there is sufficient to warrant a prosecution. On the initial visit to a farm, a veterinarian or a Fish Health Officer may accompany the IO to give technical advice.

Outline of actions following the discovery of a residue of an unauthorised substance

The VMD would arrange for an Investigation Officer to visit the farm, accompanied by a veterinarian or Fish Health Officer. The IO may:

- serve a restriction notice to stop all movement of livestock from the farm into the food chain
- investigate the cause of the residue, including taking a statement under PACE (the Police and Criminal Evidence Act)
- examine the medicines records
- take further samples from the farm to confirm the previous finding and
- the follow-up samples would be analysed at the Laboratory of the Government Chemist.

Intensive sampling

If the follow-up sample or samples were positive, the Fish Health Officer or veterinarian would return and carry out more intensive sampling from livestock and possibly feed. Movement restrictions on the livestock would be kept in place.

Testing at the farm's suppliers

It may be that contaminated feed or livestock bought in are suspected as the source of the residue. In this case, the feed mill or the breeding farm supplying the original farm would be visited and inspected.

Continued surveillance

If the intensive sampling above finds more positive samples, further visits may be made to the farm and more samples taken. Restriction notices on the farm may also be maintained.

Conclusion

At the end of the enquiry, the information would be submitted to the lawyers in Defra's Legal Branch. They would decide if there was sufficient evidence for a successful prosecution. Restriction notices could be kept in place until we are sure that there are no more unacceptable residues. The farm would also be targeted for sampling in future years.

The Risk Assessment Process

In this report, residues found above the MRL or the relevant Action Level are listed. What does this mean in terms of any risk to consumers? Whenever such residues are found, their health significance to consumers is assessed using a process of 'Risk Assessment'. This consists of four stages:

- 1. Hazard identification** – identifying the toxicological, pharmacological and microbiological properties of drug residues that may be present in food of animal origin and might be capable of causing adverse health effects to consumers.
- 2. Hazard characterisation** – nearly all substances will cause harm if exposure is sufficiently high. So the amount of a residue that might cause adverse effects has to be determined. The information used is taken from a range of sources such as:
 - any experience of exposure in humans, such as use as a human medicine
 - studies in laboratory animals
 - studies done *in vitro* (such as cell culture techniques).

Most effects have a threshold level and exposure to doses below this will not result in adverse effects. Using the most relevant 'no observable adverse effect level' identified in these studies, an acceptable daily intake (ADI) can be determined by applying uncertainty factors to allow for differences in susceptibility between animals and humans, and between individuals. Additional uncertainty factors may be used depending on the nature and severity of the effect and the robustness of the data. Overall, these uncertainty factors can typically be 100 – 1000 times.

3. **Exposure assessment** – the surveillance schemes measure the concentrations of any residues of veterinary medicinal products and certain other substances in foods of animal origin. From these data and from estimates of how much of a particular food consumers may eat, the amount of a residue consumers might be exposed to is calculated.
4. **Risk characterisation** – by comparing the exposure and hazard information generated in stages 1 to 3, an estimate of the probability of adverse effects occurring and their severity in consumers exposed to the residue can be determined.

Stages 1 and 2 of this process are carried out before a substance is authorised for use in veterinary medicinal products as part of the regulatory process. However, the risk characterisation stage is repeated in response to the findings of the residues surveillance programmes, and may involve identifying alternative endpoints to the ADI, especially if a residue exceeds statutory limits, or if the substance involved is not authorised as a medicine and has no ADI.

Risk Assessment on an Ivermectin Residue in Cattle Liver

It can help to understand a process using a real example.

Ivermectin is used in humans to treat parasitic diseases and in cattle to control parasites, such as lice, lungworms and intestinal worms. In 2001, the surveillance programme revealed a sample of cow's liver with residues of ivermectin at a concentration of 350 µg/kg. This exceeded the MRL for bovine liver of 100 µg/kg. The follow-up investigation by the SVS had found that the animal had been injured in an accident and had been slaughtered on welfare grounds. This had happened before the end of the withdrawal period for the ivermectin, hence the residue above the MRL.

The carcass had been returned to the farmer for his own use. Although the meat had not been sold to the general public, it was eaten by the farmer's family. In this case, the Food Standards Agency (FSA) was asked to carry out a risk assessment.

Hazard identification and hazard characterisation

The ADI was established from the NOAEL for maternal neurotoxicity in a developmental toxicity study in the CF-1 strain of mouse. This strain lacks a particular protein that helps eliminate some foreign chemicals from the body. This allows them to accumulate in the brain. The dose that was assessed to show no adverse effect (NOAEL) was 100 µg/kg body weight/day.

The human toxicity studies had shown no evidence of developmental or neurotoxic effects and the CF-1 mouse is now considered to be overly sensitive to the effects of substances such as ivermectin compared to humans. From this JECFA decided that an uncertainty factor of 100 should be applied to the NOAEL, giving an Acceptable Daily Intake (ADI) of 1.0 µg/kg body weight. The Codex Alimentarius and the EU's Committee for Veterinary Medicinal Products adopted this ADI.

Exposure assessment

From the concentration of the ivermectin residues and the amount of liver that a person might eat, we can estimate the exposure to ivermectin

residues a person might have had. An initial calculation was made to find the amount of liver containing 350 µg/kg of ivermectin a consumer would have to eat to reach an intake equal to the ADI. Assuming an adult of 60 kg, this suggested that 171 g of liver per day would be safe.

A standard diet, developed by JECFA, is used for MRL and exposure calculations. This assumes that a 60 kg person might eat 100 g of liver per day. But, we know that some people eat more liver than others, so the FSA looked at the National Dietary and Nutrition Survey (NDNS). This shows the amounts that more extreme consumers of liver might eat and the consumption figures for particular groups, such as toddlers.

The exposure to ivermectin was then calculated based on:

- the quantity of liver eaten by the 2.5% of consumers who on average eat the most liver on a day-to-day basis (long-term high level)
- how much liver a high-level consumer might eat on a one-off basis (one-off high-level)
- the quantities that toddlers might eat either one-off or long-term.

The NDNS estimates that the average weight of adults is 70.1 kg and of toddlers is 14.5 kg.

Table 2 Amounts of liver eaten and exposure to ivermectin residues (based on residues in liver of 350 µg/kg)

Diet	Basis	Liver Portion (g)	Exposure (µg)	Exposure (µg/kg bw/day)
JECFA	Standard	100	35	0.58
NDNS	Adult long-term high-level	39.9	13.96	0.20
NDNS	Adult one-off high-level	206	72.1	1.02
NDNS	Toddler long-term high-level	41.5	14.5	1.00
NDNS	Toddler one-off high-level	96.9	33.9	2.33

Both the JECFA and NDNS data indicate that the exposure of adults was either very close or below, the ADI of 1.0 µg/kg body weight. The long-term high-level figure for toddlers was also at the ADI. As the ADI represents the amount of a residue that can be eaten each day without appreciable risk, the FSA concluded that these groups would be unlikely to suffer any adverse health effects.

The data do show that for toddlers, the most extreme eaters of liver might be exposed to a one-off dose above the ADI. The FSA concluded that they would not wish to see a situation where consumers would be exposed to such concentrations of ivermectin over a prolonged period. However, the safety margins built into the ADI assessment were such that as the contaminated liver would be consumed over a relatively short period the exposure was judged to be acceptable.

Results for 2003

UK National Surveillance Scheme – Residues above the MRL or Action Level

Sample	Analysed for	Number of samples	MRL (µg/kg)	Samples above the MRL/ Action Level	Concentration detected where sample was above MRL/Action Level (µg/kg)
Eggs	Lasalocid	275	Not set	34	50, 60, 60, 60, 70, 70, 70, 70, 80, 90, 90, 100, 110, 130, 130, 140, 145, 150, 180, 190, 200, 220, 230, 250, 250, 300, 310, 450, 770, 810, 820, 965, 3120, 3450
Eggs	Nicarbazin	246	Not set	1	77
Salmon muscle	Malachite green	84	Not set	2	5.0 ^a , 8.0 ^a
	Leucomalachite green	84	Not set	4	2.3, 5.0, 18.9 ^a , 367 ^a
Trout muscle	Leucomalachite green	84	Not set	3	2.4, 4.0, 9.0
Partridge muscle	Lead	19	UK statutory limit 10,000 excluding particles of shot	1	34000
Milk	Aflatoxins	174	0.05 (Aflatoxin M ¹)	1	0.06
	Aflatoxin M ¹				
Turkey kidney	Antimicrobial screen	79			
	Chlortetracycline		600	1	860
Hen kidney	Antimicrobial screen	11			
	Chlortetracycline		600	1	1310
Broiler kidney	Antimicrobial screen	264			
	Chlortetracycline		600	1	780
Broiler muscle	Antimicrobial screen	866			
	Sulphadiazine		100	1	300
Broiler muscle	Quinalones	372			
	Ciprofloxacin		100, sum of ciprofloxacin & enrofloxacin	1	20
	Enrofloxacin				900
Broiler liver	Ionophores	292			
	Monensin		Not set	2	3.0, 25
Broiler liver	Nicarbazin	281	200 (JECFA MRL)	36	201, 214, 228, 228, 241, 248, 248, 255, 315, 322, 352, 355, 362, 382, 402, 402, 482, 482, 496, 499, 710, 724, 817, 985, 992, 1005, 1005, 1139, 1199, 1420, 1608, 1729, 2064, 2241, 2553, 3698
Cattle serum	Progesterone	420	Not set	10	0.5, 0.5, 0.6, 0.6, 0.6, 0.7, 1.0, 1.0, 2.0, 2.0
Cattle serum	Testosterone	439	Not set	6	0.05, 0.08, 0.1, 0.2, 1.0, >1.0
Cattle urine	Zeranol	336	Not set	10	0.2, 0.2, 0.2, 0.3, 0.6, 0.6, 0.9, 0.9, 1.0, 1.6,
Cattle liver	Avermectins	292			
	Ivermectin		100	1	140
Horse plasma	NSAIDs	40			
	Phenylbutazone		Not set	3	0.9, 1.4, 140
Horse kidney	Cadmium	11	1000 (UK limit)	10	5700, 7100, 8000, 11900, 12500, 21000, 34000, 43300, 57500, 68200

Sample	Analysed for	Number of samples	MRL (µg/kg)	Samples above the MRL/ Action Level	Concentration detected where sample was above MRL/Action Level (µg/kg)
Pig kidney	Antimicrobial screen Chlortetracycline	908	600	1	860
Pig liver	Ionophores Salinomycin	9	Not set	1	11
Sheep urine	Nortestosterone	190	Not Set	1	18
Sheep kidney	Nitrofurans Semicarbazide	102	1 (MRPL)	1	0.3
Sheep kidney	Antimicrobial screen Chlortetracycline	3,480	600	1	740
Sheep kidney	Benzimidazoles	428	500	3	640, 840 ^b , 4590 ^c

Key

^a two samples contained residues of both malachite and leucomalachite green

^b sum of oxfendazole and fenbendazole residues

^c sum of oxfendazole, oxfendazole sulphone and fenbendazole residues

Semicarbazide is a metabolite of nitrofurazone

MRPL = Minimum Required Performance Limit (see page 25)

Results from sampling carried out during follow-up investigations on farms

Sample	Analysed for	Number of samples	Reference point ¹ (µg/kg)	Samples above the reference point	Concentration detected where samples were above the reference point (µg/kg)
Honey	Streptomycin	2	20 (LOQ)	0	
Milk	Aflatoxin M ¹	1	0.05 (MRL)	0	
Salmon muscle	Malachite green Leucomalachite green	31 ² 31 ²	2 (MRPL) 2 (MRPL)	0 2	2.38, 2.5
Trout muscle	Malachite green Leucomalachite green	44 ³ 44 ³	2 (MRPL) 2 (MRPL)	1 17	2.86 ⁵ 2.16, 2.48, 3.23, 4.79, 6.2, 7.58 ⁵ , 7.8, 12.1, 14.4, 16, 17.6, 26.7, 36.7, 38.4, 40.3, 60.07, 62.4
Poultry feed	Lasalocid	31	2 (LOQ)	25	140, 140, 150, 170, 190, 200, 230, 260, 320, 330, 340, 350, 370, 370, 395, 500, 540, 570, 690, 750, 840, 850, 905, 1380, 1900
Poultry feed	Nicarbazin	45	100 (LOQ)	2	4,904, 15,075
Cattle serum	Progesterone	22	0.5 (LOQ)	0	
Cattle serum	Testosterone	7	0.5 (LOQ)	0	
Cattle urine	Zeranol	4	0.2 ⁴	4	0.2, 0.3, 0.7, 0.8
Sheep urine	Nortestosterone	5	0.5 in males 5.0 in females	0	

Key

¹ Most of these substances do not have MRLs. The reference point is the concentration that if exceeded would be regarded as violative. This may be at the MRL, or Limit of Quantification, or for some of the hormones, a concentration that would be unlikely to occur naturally.

² The 31 samples were collected from the 4 farms where residues had previously been found.

³ The 44 samples were collected from the 3 farms where residues had previously been found.

⁴ A statistical model is used to identify whether residues were as a result of abuse of zeranol or from eating toxins from fusarium species present in the animal feed. Fusarium was concluded to be the cause of these residues.

⁵ One sample contained residues of both malachite green and leucomalachite green.

Toxicological advice was that very few of the residues detected were of human health concern. Any potential concerns are listed both in this section and in the Key Results and Actions section at the start of the report.

Significant Findings in UK-Produced Foods

In 2003, 30,975 samples were collected and 35,399 analyses performed. A total of 137 of the analyses revealed a residue above the relevant MRL or Action Level. Some of these, such as cadmium and leucomalachite green are not authorised veterinary medicinal products (VMPs). Overall, it is likely that 89 of these 'positives' resulted from the use of VMPs. These were mainly of the feed additives, lasalocid and nicarbazin (71 positives).

Toxicological advice was that very few of the residues detected were of human health concern. Any potential concerns are listed both in this section and in the Key Results and Actions section at the start of the report.

Residues of unauthorised substances were found. Malachite green was detected in two samples and leucomalachite green was also detected in these and other samples of farmed fish. Residues of the nitrofurans, nitrofurazone, were also detected in one sample of sheep kidney.

Eggs

- Residues of lasalocid were found in 34 of 275 (12.4%) egg samples at concentrations of between 50 and 3,450 µg/kg. State Veterinary Service investigations have found that 25 of 31 samples of what should have been unmedicated feed contained residues of lasalocid. This suggests that cross-contamination at the mill manufacturing the feed was the likely cause of most residues. Fuller details of the follow-up investigations are given on the VRC website as meeting paper VRC/04/05.
- Nicarbazin residues were found in 1 of 246 (0.41%) samples tested.

Farmed Fish

- No PCBs were detected in samples of UK farmed fish.
- Leucomalachite green residues were found in 4 of 84 salmon muscle samples at concentrations of between 2.3 and 367 µg/kg. Two of these also contained malachite green residues at concentrations of 5.0 and 8.0 µg/kg.

Malachite green has never been authorised as a veterinary medicine. Therefore, its safety and that of its metabolite leucomalachite green have never been established.

Follow-up sampling found detectable residues of leucomalachite green on two of the salmon farms. Fish movement restrictions remain in place on these farms.

- Leucomalachite green residues were found in 3 of 84 trout muscle samples tested.

Follow-up sampling on one of the farms found no detectable residues of malachite green or leucomalachite green. At two others, however, 17 samples were found to contain residues of leucomalachite green, one of which also contained residues of malachite green. Restriction orders stopping the fish entering the food chain have been served. Defra's Legal Department are investigating.

Game

- No residues of veterinary medicines were detected at concentrations above the relevant MRLs or Action Levels.
- A lead residue was found in 1 of 19 partridge samples tested. This was at a concentration of 34,000 µg/kg. The residues were likely to have resulted from splinters of lead shot contaminating the sample.

Honey

- No residues of veterinary medicines were detected at concentrations above the relevant MRL or Action Level.

Milk

- No residues of veterinary medicines above the relevant MRLs or Action Levels were detected.
- One sample of 174 samples tested (0.75%) contained residues of the fungal toxin Aflatoxin M¹. The on-farm investigation indicated that it occurred as a result of feed contamination.

Poultry Meat

- Chlortetracycline residues were found in 1 of 79 samples of turkey kidney at a concentration of 860 µg/kg.
- Chlortetracycline residues were found in 1 of 11 samples of hen kidney at a concentration of 1,310 µg/kg.
- Chlortetracycline residues were found in 1 of 264 (0.38%) samples of broiler kidney at a concentration of 780 µg/kg.
- Sulphadiazine residues were found in 1 of 866 (0.12%) samples of broiler muscle at a concentration of 300 µg/kg.
- Quinalone residues were found in 1 of 372 (0.27%) samples of broiler muscle tested. These were at concentrations of 20 µg/kg of ciprofloxacin and 900 µg/kg enrofloxacin.
- Monensin residues were found in 2 of 292 (0.68%) samples of broiler liver tested at concentrations of 3 and 25 µg/kg.
- Nicarbazine residues above the MRL of 200 µg/kg were found in 36 of 281 (17.6%) samples of broiler liver.

State Veterinary Service investigations have found that poor storage and handling practices for feed on the farm, and possible cross contamination at the feed mills are the likely causes of many of these residues. Fuller details of the follow-up investigations are given on the VRC website as meeting paper VRC/04/05.

Red Meat

- Cattle – low concentrations of progesterone in 10 of 420 (2.4%) samples from cattle at concentrations of between 0.5 and 2.0 µg/kg. Testosterone residues were found in 6 of 439 (1.4%) samples from cattle.

The concentrations of these natural hormones will vary according to the animal's age and physiological state. None of the samples taken in follow-up investigations into the progesterone and testosterone positives were found to contain concentrations that might suggest abuse. The State Veterinary Service in the UK or the Department of Agriculture and Rural Development in Northern Ireland found no evidence of abuse on the farms during follow-up investigations.

- Zeranol residues were detected in 10 of 336 (3.0 %) urine samples from cattle. Some strains of fusarium moulds can produce zeranol and after investigation, fungal contamination of the feed was concluded to be the most likely cause.
- Ivermectin residues were detected in 1 of 292 (0.34%) samples of cattle liver tested.
- Horse – phenylbutazone residues were confirmed in 3 of 40 samples of horse plasma tested. These were at concentrations of 0.9, 1.4 and 140 µg/kg. The cases were referred to Defra's Legal Department for investigation.
- 10 of 11 horse kidney samples tested contained residues of cadmium above 5,500 µg/kg. Horse kidney is removed from the carcass and does not enter the human food chain.
- Pig – chlortetracycline residues above the MRL were found in 1 of 908 (0.11 %) of pig kidney samples. This was at a concentration of 860 µg/kg.
- Salinomycin residues were found in 1 of 9 samples of pig liver tested at a concentration of 11 µg/kg.
- Sheep – Nortestosterone was detected in 1 of 190 (0.52%) samples of sheep urine tested at a concentration of 18 µg/kg. Five samples were taken in a follow-up investigation, but none contained detectable residues of nortestosterone.
- Nitrofurazone (semicarbazide) residues were detected in 1 of 102 (0.70%) samples of sheep kidney tested. This was at a concentration of 0.3 µg/kg, compared to an EU MRPL of 1.0 µg/kg (see page 25). Nitrofurazone is a nitrofurans compound. The follow-up investigation found no evidence of use on the farm.

Nitrofurans are in Annex IV of Council Regulation 2377/90. This is because no safe concentration can be set and as such, their use in food-producing animals is banned. Toxicological advice is that one-off exposure to such residues is unlikely to result in harmful effects as the risk with nitrofurans is related to long-term exposure.

- Residues of chlortetracycline were detected in 1 of 3,480 (0.029%) samples of sheep kidney tested.
- Benzimidazole residues above the MRL were found in 3 of 428 (0.70%) samples of sheep kidney tested. These were at concentrations of between 640 and 4,590 µg/kg.

The Acceptable Daily Intake (ADI) for benzimidazoles is 420 µg for a 60 kg person. A person eating a standard 50 g portion of kidney contaminated at the highest concentration found would consume 212.5 µg of the residue, approximately half the ADI. Toxicological

advice is that the residue detected would be unlikely to result in adverse health effects, but the theoretical possibility could not be ruled out for an extreme consumer of kidney.

Follow-up investigations revealed that the lowest concentration detected occurred because the withdrawal period had not been fully observed. The second had occurred because stock bought in for breeding had subsequently been sold on for slaughter soon afterwards. The sample with the highest concentration was passed to Defra's Legal Department for investigation.

Non-Statutory Surveillance Scheme – Residues above the MRL or Action Level

Results from the Rolling Non-Statutory Programme

Food	Analysed for	Number of samples	MRL (µg/kg)	Samples above the MRL/ Action Level	Concentration detected where the sample was above MRL/Action Level (µg/kg)
Imported raw beef	Avermectins Abamectin	300	Not set	1	11
Imported raw chicken	Nitrofurans AOZ	298	1.0 (MRPL)	1	50
	Chloramphenicol	300	0.3 (MRPL)	1	0.4
Imported honey	Chloramphenicol	106	0.3 (MRPL)	1	0.2
	Nitrofurans AOZ	106		11	
	AMAZ			0.1 ^a , 0.1, 0.1, 0.1, 0.2 ^a , 0.3, 0.9, 1.4, 1.6, 5.5	
	SC			1.4	
	Streptomycin	106	Not set	6	0.7 ^a , 2.1 ^a
	Sulphonamides Sulphadiazine Sulphamethazine	106	Not set	1	30, 40, 49, 62, 120, 190 1,687 177
Imported farmed fish	Leucomalachite green	198	Not set	6	2.6, 2.6, 4.2, 5.0, 8.2, 20
Imported warm water prawns	Nitrofurans AOZ	307	1.0 (MRPL)	29	0.2, 0.4, 0.8, 3.0, 3.5, 26, 34 0.9, 1.2, 1.3, 1.3, 1.4, 1.5, 1.5, 2.0, 2.1, 2.1, 2.2, 2.6, 2.7, 2.8, 3.1, 3.4, 3.5, 3.9, 4.5, 4.5, 8.2, 8.3
	SC				
Domestic quail eggs	Lasalocid	30	Not set	12	41, 42, 64, 77, 110, 110, 110, 110, 140, 150, 900, 1,700
	Nicarbazin	30	Not set	3	31, 160, 220

Key

^a = Residues of both AOZ (3-amino-2-oxazolidinone) and SC (semicarbazide hydrochloride) were detected in two samples of imported honey.

AMAZ = 3-amino-5-morpholinomethyl-2-oxazolidinone.

MRPL = Minimum Required Performance Limit (see page 25)

Results from the Special Survey

Food	Analysed for	Number of samples	MRL (µg/kg)	Samples above the MRL/ Action Level	Concentration detected where the sample was above MRL/Action Level (µg/kg)
Dried milk powder	Chloramphenicol	103	Not set	0	

Residues of substances either not authorised for the particular use or banned in the EU were found in some imported foods.

Significant Findings

A total of 74 of the 5,468 analyses in the rolling programme revealed residues above the relevant MRL or Action Level. This compares to 217 positives in some 8,039 analyses in 2002. In the retail survey of dried milk powder for chloramphenicol, none of the 103 samples analysed had a detectable residue.

Part of the reduction in positives recorded this year was because environmental contaminants, such as organochlorine pesticide residues and PCBs were not sought this year. This was because the Committee wished to prioritise its efforts on banned substances that intelligence suggested might be present in some imported foods.

Residues of substances either not authorised for the particular use or banned in the EU were found in some imported foods. These included: chloramphenicol, nitrofurans metabolites, streptomycin and leucomalachite green.

Whenever a residue of a banned substance was detected, the Food Standards Agency was informed. They could then issue a Rapid Alert to the European Commission and so inform all other EU Member States. The FSA could also decide to ask local authorities to investigate and can also request and oversee product withdrawals where this was appropriate.

In almost all cases, Defra's Chief Veterinary Officer (CVO) wrote to his opposite number in the country concerned, requesting an investigation into the origin of the residue and the steps that would be taken to avoid them recurring. In the two cases of nitrofurans residues in honey, the VMD instead contacted the retailer for more information.

Rolling Programme

Imported beef

- Abamectin residues were detected in 1 of 300 (0.33%) samples of imported raw beef tested. This sample was from Brazil. There is no formal MRL for abamectin in muscle, but toxicological advice is that at the concentration found, there is probably no toxicological concern for consumer health.

Imported chicken

- Nitrofurans metabolites were found in 1 of 298 (0.36%) samples of imported chicken tested. This sample was from Thailand. These residues were of concern, as nitrofurans are in Annex IV of Council Regulation 2377/90 (see Key Results and Actions). As such, they are not permitted for use in food-producing species and a similar ban applies to foods exported to the European Union. Toxicological advice is that one-off exposure to such residues is unlikely to result in harmful effects as the risk with nitrofurans is related to long-term exposure.

- Chloramphenicol residues were detected in 1 of 300 (0.33%) samples tested. This sample of Thai chicken had a concentration of 0.4 µg/kg. This residue was of concern, as chloramphenicol is in Annex IV of Council Regulation 2377/90 (see Key Results and Actions). Toxicological advice is that it is not possible to identify a 'safe' concentration.

The Thai authorities have contacted the CVO to express their concern and are carrying out an investigation.

Imported honey

- Chloramphenicol residues were detected in 1 of 106 (0.94%) samples of imported honey in the rolling programme. The sample of honey had been imported from Tanzania. It contained a residue of chloramphenicol at 0.2 µg/kg (indicative concentration), which is below the EU Minimum Required Performance Limit (MRPL) of 0.3 µg/kg.

This residue was of concern, as chloramphenicol is in Annex IV of Council Regulation 2377/90 (see Key Results and Actions). Toxicological advice is that it is not possible to identify a 'safe' concentration.

- Nitrofurans residues were detected in 11 of 106 (10.4%) samples of honey tested. They had been imported from Turkey (4), Guatemala (1), Argentina (2), Spain (1), Italy (1), Caribbean (1) and Argentina/Australia (1). These residues were of concern, as nitrofurans are in Annex IV of Council Regulation 2377/90. This is because no safe concentration can be set. Therefore, they are not permitted for use in food-producing species and a similar ban applies to foods exported to the European Union.

Toxicological advice is that one-off exposure to such residues is unlikely to result in harmful effects as the risk with nitrofurans is related to long-term exposure.

- Streptomycin residues were found in 6 of the 106 (0.94%) samples of imported honey tested as part of the rolling programme. Honey in the EU may not legally contain streptomycin. Advice from the FSA is that its presence is not a food safety issue.
- Sulphonamide residues – sulphadiazine and sulphamethazine – were detected in 1 of 106 (0.94%) samples of imported honey tested. The total concentration of the residues detected was 1,864 µg/kg. The sample was from Cyprus. Toxicological advice is that there is unlikely to be a significant risk to human health.

Imported farmed fish

- Residues of leucomalachite green were found in 6 of 198 (3.0%) samples tested, at concentrations between 2.6 and 20 µg/kg. Four samples were of salmon imported from Chile and 2 samples of catfish imported from Taiwan.

Malachite green has never been authorised as a veterinary medicine in the EU and should not be present in imported farmed fish. Its safety and that of its metabolite leucomalachite green has never been established. A meeting has taken place in London between representatives of the Chilean government, Defra's Animal Health and Welfare, International Trade Division, the VMD and the FSA to discuss the residues of leucomalachite green found in the Chilean salmon.

Imported warm water prawns

- Nitrofurans residues were found in 29 of 307 (9.4%) samples of warm water prawns tested in the rolling programme. Nitrofurans are in Annex IV of EC Council Regulation 2377/90. As such, no safe concentration can be set. Their use in food-producing animals is banned. Toxicological advice is that one-off exposure to such residues is unlikely to result in harmful effects as the risk with nitrofurans is related to long-term exposure.

The samples of warm water prawns were imported from Bangladesh (13), India (10), Ecuador (2), Vietnam (2) and Indonesia (2).

As a result of this action, the Indian authorities have advised that they now have the ability to test samples of warm water prawns by LC-MS-MS² and are confident that the incidence of these residues will reduce in the future. The Ecuadorian authorities are liaising with the UK authorities. The authorities in Bangladesh have responded that their method of analysis for the detection of nitrofurans is now at 0.1 µg/kg (below the EU MRPL of 1.0 µg/kg).

Domestic quail eggs

- Lasalocid residues were detected in 12 of 30 quail egg samples tested. These were at concentrations of between 41 and 1,700 µg/kg. Toxicological advice is that these residues were unlikely to result in adverse health effects.

The retailers and suppliers concerned were contacted. The egg supplier for eleven of the positive samples has provided ten feed samples from the relevant batches for analysis. Apart from one sample of feed these were all found to contain residues of lasalocid at concentrations between 350 and 1,090 µg/kg. These residues should not have been present in the feed.

The feed suppliers concerned were visited again in January 2004 by an inspector from the Royal Pharmaceutical Society of Great Britain to review all aspects of production. Since the inspector's previous visit the feed manufacturers had met with the egg suppliers and introduced modifications and changes to procedures. It was agreed that these would be left in place. At the time of the inspector's latest visit the feed suppliers have manufactured six runs using the new system and the inspector has taken samples from these runs and sent them for analysis to validate the action.

- Nicarbazin residues were detected in 3 of 30 quail egg samples. Toxicological advice is that these residues were unlikely to result in adverse health effects.

The retailers and the supplier of these samples have been informed of the results and asked to investigate the cause of the residues. The egg supplier for two of the positive samples has sent retained feed samples for analysis.

² LC-MS-MS is a very sensitive analytical technique that uses both liquid chromatography and mass spectrometry to identify residues.

Special survey

Dried milk powder – for residues of chloramphenicol (see pages 20 and 37)

No residues of chloramphenicol were detected in the 103 samples tested.

Industry data

The VRC have been keen to see surveillance data from other sources. In both of the last two years the VRC and its sister committee the Pesticides Residues Committee have written to a number of companies, including major retailers. The Committee was pleased to receive the data below. The Committee will write again for the 2004 Annual Report and hope that further data is submitted.

The VRC have been keen to see surveillance data from other sources. The Committee was pleased to receive the data below.

Sample	Analysis Undertaken	Number of samples	Residues detected	Concentration µg/kg
Chicken meat	Antimicrobial Screen Fluoroquinolones Nicarbazin Nitroimidazoles	15	1	70
Cajun style chicken	Antimicrobial Screen Chloramphenicol Fluoroquinolones Nicarbazin Nitrofurans Nitroimidazoles	2	0	
Turkey meat	Antimicrobial Screen Fluoroquinolones Nitroimidazoles	4	1	Trace chlortetracycline
Other poultry ^a	Antimicrobial Screen Nitroimidazoles	4	0	
Fish (salmon, trout and sea bass)	Avermectins Benzimidazoles Malachite green Leucomalachite green Pyrethroids	12	0	
Prawns	Antimicrobial Screen Chloramphenicol Nitrofurans Quinolones	12	1	0.6 - AOZ ^b
Eggs (hens and quail)	Antimicrobial Screen Ionophores Lasalocid Nicarbazin	5	1	Trace
Honey (imported)	Chloramphenicol Streptomycin	5	1	60

Key

^a poultry included were one sample each of, duck, duckling, partridge and quail.

^b AOZ = 3-amino-2-oxazolidinone, a nitrofurantoin compound.

Work of the Committee in 2004

In particular, the Committee will want to closely monitor the position over the unauthorised uses that are described in this report and any others that come to the VRC's attention.

To have a better picture of the residues that might be occurring, the VRC will again write out to companies and hopes that more will respond in the coming year.

The VRC will assess the possible effect of the ending of the 'Over Thirty Months Scheme' for cattle.

Advise over the surveillance schemes

The VRC will continue to advise over the planning of the VMD's surveillance schemes and advising on the results. In particular, the Committee will want to closely monitor the position over the unauthorised uses that are described in this report and any others that come to the VRC's attention. The Committee will assess the results of the brand-naming survey for malachite green and leucomalachite green residues, when they are available. It will consider what other action may need be taken to ensure that malachite green is no longer used. It will also consider if further brand-name surveys should be carried out.

The Committee was pleased to receive the results of surveillance carried out by a commercial company. To have a better picture of the residues that might be occurring, the VRC will again write out to companies and hopes that more will respond in the coming year.

Residues from feed additives

The VRC will continue to consider how best to take forward work on reducing the incidence of residues of nicarbazin and lasalocid. In particular, it will consider whether a brand-name survey of retail samples of poultry products would be helpful. The VRC will also consider if other organisations should play a role.

Assess the effect of ending the 'Over Thirty Months Scheme'

The VRC will assess the possible effect of the ending of the 'Over Thirty Months Scheme' for cattle. Under this scheme, brought in as a protective measure because of BSE, older bovines were not allowed to enter the food chain. As they were not going for human consumption there were less constraints on the animal medicines that farmers were allowed to administer to these animals. The Committee will look at making recommendations to ensure that consumers remain protected from unacceptable residues when these older animals re-enter the food chain.

Review its Terms of Reference

The Committee has now been in existence for three years and in 2004, the terms of office of some of the Members will end. The Committee thinks that this is a good time to review its terms of reference before the new members take up their posts in 2005.



Bid for extra money to support testing imports and other priority areas

The Committee considers that the residues of banned substances found in imported produce justify the extra funding that the Non-Statutory Scheme has been awarded by Defra in 2003 and 2004. The Committee will continue its work to produce a prioritised list of substances and produce to support a bid for permanent extra funding. As well as the testing of imports, the Committee still sees merit in testing produce that would represent the foods typically eaten in UK households – as previously covered in the Non-Statutory Scheme.

Open Meeting to consult consumers and others

The Committee will hold an Open Meeting in the autumn of 2004 to explain its work and canvass your views.

The Committee considers that the residues of banned substances found in imported produce justify the extra funding that the Non-Statutory Scheme has been awarded by Defra in 2003 and 2004.

Glossary

ACTION LEVEL – This is the concentration of a residue in an animal product that will spark a follow-up investigation. Where a Maximum Residue Limit (MRL) is set, this is the concentration used. Where no MRL has been set, the Limit of Quantification (LOQ) may be used. But, if a substance has been entered into Annex IV (see below) of Council Regulation (EEC) No. 2377/90, any confirmed residue will be reported as in excess of the Action Level.

AGVR – The Advisory Group on Veterinary Residues was the Committee that advised the VMD on its surveillance programmes before the Veterinary Residues Committee was formed.

ANALYTE – A substance in a test sample, the presence of which has to be detected and/or quantified.

ANNEX IV – The active ingredients of veterinary medicines used in food producing species must be assessed for safety and allocated to one of the annexes of Council Regulation 2377/90/EEC. Annex IV indicates that on safety grounds, no MRL can be set. Substances in Annex IV may not be administered to food-producing animals.

ANTIMICROBIALS – Compounds that, at low concentrations, exert an action against microorganisms and exhibit selective toxicity towards them. The term includes any substance of natural, synthetic or semi-synthetic origin that is used to kill, or inhibit the growth of, microorganisms (bacteria, fungi, protozoa and viruses). Antimicrobials include antibiotics, disinfectants, preservatives and other substances. Antimicrobials are used on farms to treat and prevent diseases, such as mastitis and foot rot, caused by microorganisms.

BRAND-NAMING – A one-off survey where information, such as the brand on the packet and name of the shop where it was bought is published. Samples taken under statutory powers may not be used for brand-naming.

COCCIDIOSTATS – Products that control coccidiosis, a protozoal disease that can cause diarrhoea and dysentery. Control of this infection is particularly important in the poultry industry where the prophylactic use of coccidiostats prevents the disease from developing.

DAL – Differential Action Level: Level agreed by the AGVR as a guideline below which there is no toxicological risk to the consumer. In 1997, the VMD set up an ad-hoc group of consumer, industry and retail representatives to consider the incidence and concentration of nicarbazine residues in eggs and to try to develop strategies to reduce them. The group agreed that the concept of a 'Differential Action Level' should be recommended to the AGVR. This was so that the VMD would not automatically follow-up 'positive' results that did not pose a toxicological risk to the consumer. In 1998, the AGVR endorsed the proposed DAL for nicarbazine in eggs at 100 µg/kg as a guideline, subject to annual review. In 1999, the AGVR agreed that this DAL would also apply to lasalocid.

Defra – Department for Environment, Food and Rural Affairs. The parent department for organisations such as the VMD and Centre for Environment, Fisheries and Aquaculture Science.

DETECTION LIMIT – See Limit of Quantification.

DG-SANCO – The European Commission body responsible for health and consumer protection.

HEAVY METALS – Cadmium and lead are not veterinary medicines. They are found in the environment and can accumulate in animals' body tissues. European law requires them to be sought in the National Surveillance Scheme.

HORMONES – Hormones include both naturally occurring and synthetic substances. The use of all hormones to increase growth rate in food-producing animals is banned in the EU. Natural hormones are produced by endocrine glands such as the ovaries, testes, thyroid, adrenal or pituitary and released into the blood stream to be carried to a particular organ or tissue, where they produce a specific response. Synthetic hormones include stilbenes, gestagens and thyrostats. Gestagens can be used to control animals' breeding cycles and treat threatened abortion.

INVESTIGATION OFFICER – A member of the Legal Department from the Department for Environment Food and Rural Affairs. Usually these are ex-police officers and are trained in taking statements.

IN VITRO – Literally means 'in glass'. It is used to describe experiments performed on biological processes outside the living organism, such as cell culture techniques.

LOD – Limit of Detection: the smallest analyte concentration that a method can detect with a reasonable statistical certainty.

LOQ – Limit of Quantification: the smallest analyte concentration for which a method has been validated with specified accuracy and precision.

MATRIX – The sample of, for example, liver, kidney or animal feed, analysed for the presence of a residue.

METABOLITE – Substances entering the body are usually converted into other chemicals, which are known as metabolites.

MRPL – Minimum Required Performance Limit: the European Commission set concentrations for residues of certain banned substances that all Member States must be able to detect – 0.3 µg/kg for chloramphenicol and 1.0 µg/kg for nitrofurans.

MYCOTOXINS – Toxic metabolites produced by some species of fungi – especially strains of *Aspergillus flavus*. These fungi grow on many plant-based foods, such as peanuts. When such mouldy foods are fed to animals, residues of the mycotoxins may later be detected in tissues of the animal.

NON-STATUTORY SURVEILLANCE – VMD's second, smaller, surveillance programme that collects samples from Border Inspection Posts and shops.

NSAIDS – Non-steroidal anti-inflammatory drugs. Capone and flunixin are examples sought in the National Surveillance Scheme. Aspirin is the most well known example used to treat humans.

ORGANOCHLORINES – Substances such as DDT, were previously used as insecticides. They degrade very slowly in the environment and can be ingested by animals and accumulate in their tissues.

OPs – Organophosphorus compounds which are used as veterinary medicines, such as sheep dips, to control ticks and mites. They are also widely used as insecticides.

'POSITIVE' – A 'positive' sample is a sample which on confirmatory analysis is shown to have a concentration of an authorised substance above the MRL or Action Level, or where this has not been set for the substance or the matrix concerned, in excess of the Limit of Quantification (LOQ) or the presence of an unauthorised substance.

RAPID ALERT SYSTEM FOR FOOD AND FEED, or RASFF – This is a European Union-wide system for alerting Member States when a residue of potential concern has been detected in home-produced or imported produce.

RESIDUE – That portion of the administered dose of a veterinary medicine or other substance present in the tissues, body fluids, products or excreta of an animal arising from treatment of the animal. The total residue includes the parent compound plus any metabolites.

STATUTORY SURVEILLANCE – The National Surveillance Scheme has a legal status. The VMD and the other agencies have powers under the legislation to take samples and to prosecute where results indicate that it is warranted.

VETERINARY MEDICINAL PRODUCT, or VMP – In this report, this technical term refers to both veterinary medicines, such as chlortetracycline and also to feed additives, such as nicarbazin, which are defined as zootechnical feed additives.

VPC – Veterinary Products Committee: an independent body of UK experts that advises Ministers on the safety, quality and efficacy of veterinary medicines.

ZOOTECHNICAL FEED ADDITIVES – Are products which are used as growth promoters or coccidiostats.

Membership of the Veterinary Residues Committee

The members were drawn from: consumers, the farming community, local authorities and industries associated with farming and food. Members having a wide range of expertise in residues surveillance were appointed. The members and the expertise they were appointed to bring to the Committee were:

Professor Jim Bridges	Chairman/Toxicology
Mrs Dorothy Craig MBE	Deputy Chair/Consumer
Mr John Ambrose	Local Authority
Professor Keith Anderson	Food Industry
Professor Alan Boobis OBE	Toxicology
Dr Paul Brantom ³	Toxicology/Food Safety
Vacancy	Retail Industry
Mr Neil Cutler	Farming
Professor Julie Fitzpatrick	Veterinary
Dr Keith Lawrence	Pharmaceutical Industry
Dr W John McCaughey	Analytical Chemistry
Mrs Freida Stack	Consumer
Dr Brian Vernon	Feed Industry

Short biographies of the members are on the VRC website.

³ Dr Brantom was nominated by the Food Standards Agency to advise on food safety and risk assessment.

Membership of the Subgroups

The Communications Subgroup members were:

Mrs Dorothy Craig MBE Chairman

Mr John Ambrose

Dr Paul Brantom

Mr Neil Cutler

Mrs Freida Stack

The Feed Additives Subgroup members were:

Dr Brian Vernon Chairman

Mrs Dorothy Craig MBE

Dr Keith Lawrence

Dr Paul Brantom

The Non-Statutory Surveillance Subgroup members were:

Professor Jim Bridges Chairman

Professor Keith Anderson

Dr Paul Brantom

Professor Julie Fitzpatrick

Dr W John McCaughey

Mrs Freida Stack



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