



Annual Report on Surveillance for
Veterinary Residues in Food
in the UK **2008**



The Use of Veterinary Medicines in Farm Animals

Why are veterinary medicines needed?

Like us, farm animals can suffer from diseases. Farmers have a duty to protect the health and welfare of their animals, so may use medicines to treat or prevent disease. If they didn't, unnecessary suffering could be caused to their animals.

What sort of medicines are there?

There are a range of medicines for different uses, for example:

- antibiotics to control bacterial diseases
- coccidiostats to control protozoal diseases, particularly in poultry
- dips to control external parasites
- pain killers and anti-inflammatory medicines
- wormers to control internal parasites.

If animals have been treated with medicines, how do we know our food is safe?

Before a medicine can be authorised for farm animals, it has to undergo rigorous and extensive testing. This ensures that its use would not result in residues that could be of consumer health concern. One of the steps following the testing is to set Withdrawal Periods. These are the lengths of time that must pass after the end of treatment with a medicine before that animal can be slaughtered, or an animal product is taken, for human consumption.

This report explains how we test UK and imported produce to check that any residues are at acceptable concentrations (normally measured in parts per billion). This provides reassurance that the system of authorisation has worked correctly. The surveillance also checks that unauthorised substances are not being used. All EU Member States are required by legislation to test their domestic produce.

Does this testing of foods show the system of authorising veterinary medicines is working well?

Yes, when used as directed, it is very rare that the UK authorised uses of veterinary medicines result in residues that are of consumer health concern.

Are hormones and antibiotics used to promote growth?

No. The EU banned the use of hormones for growth promotion more than 20 years ago. Very small amounts of antibiotics were added to feed to increase growth, but this practice was also banned in 2006, as a precautionary measure, to avoid promoting antimicrobial resistance.

What is the Role of the Veterinary Residues Committee?



The Committee's Terms of Reference are on page 50.

The Committee has its Terms of Reference, but what do these mean in practice? Why is there an independent Committee?

The Committee ensures that there is independent oversight into how the UK's surveillance for residues of veterinary medicines is carried out. We advise on, and question, the choices that are made and also the actions taken when residues are detected.

We can publicise where we think changes should be made, such as in the issue of funding for the Non-Statutory Surveillance Scheme. Of course, we recognise it is for government to make the final choices. But, we are able to draw attention to issues we think need addressing and make sure these are publicised.

Having an independent Committee, with a wide range of expertise, means that government can draw on experience and information it would not otherwise have. For example, the Committee can make recommendations, based on its knowledge of which substances are being used overseas.

We know food safety is a concern for many consumers. Our consumer representatives can help judge which issues could cause particular concern. We can also think about how we can explain the issues simply, from a lay person's point of view, and put them into context.



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Chairman's report



Regretfully, we have said goodbye at the end of 2008 to those members who had served two terms on the Committee. They took with them my sincere thanks and appreciation of their efforts in helping to build up the Committee since its inception in 2001. They can be proud of their role in creating a genuinely independent body, based on sound scientific principles. In their place we welcome eight new members who, though independent, will bring a wealth of expert advice and knowledge to meetings. This includes a new post covering aquaculture in view of the importance of this sector both domestically and in terms of imports.

The introduction of multi-residue methods into some areas of our work is welcome in further increasing consumer reassurance in surveillance measures. Inevitably some non-compliant results appear to have risen and care must be taken in interpreting overall results for species/substance combinations covered by these methods, as we explain in the Report. Please take a few minutes to read this section on page 28.

In respect of home production it was again reassuring to note that the incidence of residues of authorised veterinary medicinal products remained low. Unfortunately, a non-compliant result for ibuprofen occurred, owing to cross-contamination of the sample in the abattoir by the sampling officer. This, added to previous non-compliant results for chloramphenicol and salbutamol in poultry over the years, suggests more attention needs to be given to this area. The Committee does recognise that the increasing sensitivity of analytical methods makes it easier to pick up cross-contamination. I trust all the collection agencies will review procedures to ensure they are sufficiently robust to avoid this in the future. The Committee will return to this issue in 2009.

The Committee has also continued its interest in the issue of phenylbutazone in horses, where the passport system plays a key role in ensuring treated horses do not enter the food chain. It is disappointing that non-compliant results continued to be found in a small number of animals at the abattoir where they are processed, prior to transport to the Continent. The Committee hopes that the combination of the requirement for Food Chain Information from 1 January 2009, and new European Equine Identification legislation in the summer will tighten up compliance with the rules.

Turning to our programme which looks mainly for prohibited substances in imported foods, far fewer nitrofurans metabolites in warm water crustaceans from Asia were found. This is a welcome reduction from the high level of non-compliant results found in 2003 to 2006. However, as with malachite green in farmed fish a few years ago, there are signs that neighbouring European countries are picking up more non-compliant results suggesting a small but significant shift in trade patterns when problems are found.

In light of these findings, and the response from stakeholders to our consultation exercise, the Committee is convinced that vigilance is still needed in respect of prohibited substances. Funding for this non-statutory surveillance programme therefore remains a hot topic for the Committee. Following pressure from the Committee, the amount available remained constant for the financial year 2008/09 – welcome news indeed. However, looking ahead in these very difficult economic times, we have a real concern that the programme may suffer a large cut in funding. The Committee will vigorously campaign for the programme to remain at a level sufficient to maintain consumer health in light of the continued use of prohibited substances in some third countries.

Clear and concise communication with stakeholders remains at the heart of the Committee's aims and we welcome comments on this Annual Report. The Committee was delighted with the publication of our leaflet earlier this year setting out the facts on the use of antibiotics and hormonal substances in domestic farming. It also strongly supports the work of the joint FSA/industry initiative aimed at the responsible use of nicrobazin in poultry production and eliminating careless practice.



**Dorothy Craig MBE,
Chairman**

It was good to visit Glasgow for our 2008 Open Meeting, and we were able to extend our knowledge of the salmon farming industry while in Scotland. We look forward to holding the 2009 meeting in Cardiff on 14 October. We hope that as many stakeholders as possible will attend from across the spectrum of the food chain. We intend to visit more regions in the future.

Finally, I return to the composition of the Committee. It may seem a long way off, but the tenure of several Committee members, including mine, will finish at the end of 2010. A recruitment exercise for these posts will start towards the end of 2009. I am glad to say that the last exercise resulted in some very good people joining us, who I am sure will uphold the Committee's growing reputation. I am hopeful that the coming exercise will result in a high level of interest and applications of similar quality.

With best wishes,



Dorothy Craig
Chairman

Key Results and Actions Taken on Residues in 2008

Summary for the National Surveillance Scheme of UK produce

Background

All EU Member States are required to have a system of surveillance for residues of veterinary medicines and certain other substances in domestic produce. The legislation also sets out how many samples must be taken and controls closely the groups of substances that must be analysed for. The National Surveillance Scheme (NSS) fulfils the UK's obligations under European law. The scheme is funded by charges on the livestock sector.

Results

A total of 37,971 samples were collected and 41,432 analyses were carried out in 2008. There were 184 residues in excess of statutory or other limits (see Reference Points inside the rear cover). Of these, 77 residues were likely to have occurred from the use of veterinary medicinal products (VMPs), four of which were of possible health concern.

Effect of new multi-residue methods

The figures for residues above the limits and those from VMPs were both significantly higher than for 2007, when 110 non-compliant results were noted, of which, 49 came from use of veterinary medicinal products. However, the numbers are not directly comparable.

The increase in the number of non-compliant results has mainly come about because of the introduction of new multi-residue methods as explained on page 28. The highest proportion of non-compliant results over recent years has occurred in poultry liver with nicarbazin residues. This year, the number of analyses of poultry liver for this substance almost doubled from 301 in 2007 to 598 in 2008. The rate of non-compliance was slightly higher at 8.8%, compared to 6.6 % in 2007. However the majority of the increase in non-compliant results from 20 in 2007 to 53 in 2008 is due to the extra samples being tested.

The number of samples of sheep urine non-compliant for nortestosterone and samples of cattle urine for boldenone and zeranol also increased significantly. These results were also associated with the use of the multi-residue methods, where there were large increases in the numbers of samples tested.

Actions taken

Usually, when residues were detected above the relevant Reference Point, a follow-up investigation was carried out on the farm of origin. The causes of the residues were assessed and advice given to farmers on how to avoid such residues in the future. However, the Committee agreed that in the case of nicarbazin residues in broiler liver, for concentrations below 1000 µg/kg, it would be sufficient to write to the farms of origin.

All EU Member States must have a national surveillance scheme that tests a fixed proportion of domestic produce for residues of veterinary medicines and certain other substances.

More details of the procedure followed when a non-compliant sample is detected are given on page 44.

Overall, the results of the National Surveillance Scheme indicated that the UK authorised uses of veterinary medicinal products did not result in residues of human health concern.

Each sample in the National Surveillance Scheme is tested for a specific substance or a range of substances.

Summaries of the follow-up investigations are supplied to the Committee. These are available on the VRC website, for example, as Meeting Papers VRC/08/27, VRC/08/48 and VRC/09/02.

The results presented are mainly those for samples taken in the calendar year 2008. However, all of the results for follow-up samples taken as part of the 2007 GB programme have been included.

The results of the UK's surveillance for residues of veterinary medicines and other substances are sent to the European Commission. It examines the results of all Member States and publishes collated results for the European Union on its website: http://ec.europa.eu/food/food/chemicalsafety/residues/control_en.htm

Conclusion

Overall, the findings of the NSS indicated that the UK authorised uses of VMPs do not result in residues of human health concern. However, where the instructions for use are not followed, residues of health concern can result. For example, residues of phenylbutazone, which is not authorised for use in food-producing species, were detected.

Residues of potential health concern in UK produce

Four residues of possible health concern were detected in UK produce. These were:

- Phenylbutazone residues were detected in 1 of 41 cattle plasma samples tested, at a concentration of 0.13 µg/l.
- Phenylbutazone residues were detected in 2 of 26 horse kidney samples tested in a screen for NSAIDs, at concentrations of 30 and 130 µg/kg.
- Phenylbutazone residues were detected in 1 of 30 horse plasma samples tested in a screen for NSAIDs, at a concentration of 5 µg/l.

Phenylbutazone may not be used in animals that will enter the food chain. This is because, in rare cases, phenylbutazone may cause idiosyncratic aplastic anaemia, a rare but potentially fatal blood disorder. Animal studies indicate it is genotoxic and can cause cancer.

Phenylbutazone is authorised for use in horses that are not intended for human consumption and in dogs. It is used in these species to treat musculoskeletal disorders, such as rheumatoid and arthritic diseases.

Phenylbutazone residues in a cattle sample

A follow-up investigation on the farm of origin found that a second bovine had been treated with phenylbutazone, bought over-the-counter from a veterinary surgery. This animal was flagged for detention at slaughter and found non-compliant for phenylbutazone at a concentration of 2.2 µg/l. The carcase was excluded from the food chain.

The Divisional Veterinary Officer wrote to the veterinarian concerned and reminded them that phenylbutazone is not authorised for use in food-producing animals.

Phenylbutazone residues in horses

30 µg/kg – The investigation found the most likely cause was that the horse had been given phenylbutazone and was not signed out of the food chain. It was submitted for slaughter by a dealer, a few days after purchase. He did not keep written records of his horse purchases, nor medicine records for the horses he bought. The dealer appears to have issued a new passport and marked it that the horse was intended for human consumption. He has received guidance notes and been advised in writing of the need to keep medicine records.

130 µg/kg – The horse had been treated for lameness with phenylbutazone by a local vet. The owner reported that the vet did not request the horse's passport and claimed not to know that the use of phenylbutazone meant that it should not enter the food chain. Two other horses were on the premises and their passports were checked. They were marked as 'not for human consumption'.

5 µg/l – On administering phenylbutazone, the vet had not checked the horse passport to ensure it had been signed out of the food chain. The horse was submitted for slaughter by a dealer who only had it for a day and declared in the passport that the horse was fit for human consumption. The owner, dealer and vet have received written advice to complete/check passports in accordance with the Equine Identification Regulations.

Use of Phenylbutazone

Phenylbutazone is not authorised for use in food-producing animals for the reasons given above. To protect the welfare of companion horses, phenylbutazone is authorised in the UK to treat musculoskeletal disorders, such as rheumatoid and arthritic diseases. But once a horse has been treated, it must not then go into the food chain.

While horses are not regarded as a food-producing animal in the UK, horse meat is eaten on the Continent, primarily in Northern France and Belgium. Horse meat is exported from the UK to the Continent.

Each horse has a 'passport', where medicine use, such as phenylbutazone, should be recorded – barring it from the food chain. However, phenylbutazone residues were detected in samples from horses that entered the human food chain. This suggests that there is not sufficient awareness of the legislation in this area by horse owners and some vets. The passport system, as currently implemented, does not always prevent occasional consumer exposure.

The passport system is currently under review and new identity legislation will come into force in 2009. The VRC will support Defra's publicity campaign to raise awareness of the new identity regulations.

Summary for the Non-Statutory Surveillance Scheme

Background

The Non-Statutory Surveillance Scheme concentrates on imported and processed foods. This is to complement the National Surveillance Scheme, which tests domestic produce. The Non-Statutory Surveillance Scheme, as its name suggests, does not have a legal base. Therefore, the VRC has freedom to recommend whatever substances and foods it considers should be included. It is funded by Defra.

The Non-Statutory Scheme consists of two main elements. The first is a **rolling programme**, where certain commodities are collected across the year and tested for particular substances. The second is a **brand name survey**. In this, a particular commodity and substances are targeted and all of the details of the samples and how they were analysed are published in a discrete report. This year, the survey consisted of 100 samples of mainly imported poultry products, such as nuggets and burgers. These were analysed for residues of chloramphenicol, coccidiostats, nitroimidazoles and nitrofurans. This commodity was chosen, as such products are frequently eaten by children.

Where imported produce contained residues that are illegal in the UK, Defra's Chief Veterinary Officer wrote to his opposite number in the country of origin, where this was known. In these letters, he asked to be kept informed of any action that was taken to prevent such residues in future. The Food Standards Agency (FSA) was also informed of such results, so it could ensure product withdrawals were undertaken where appropriate and inform the European Commission, which can issue a Rapid Alert (RASFF) informing other EU Member States.

Results

In 2008, for the Rolling Programme, 1,320 samples were collected and 4,859 analyses completed. For the brand name survey of poultry products, 100 samples were collected and 300 analyses completed.

A total of 13 samples of imported produce from the rolling programme contained residues at concentrations above the relevant statutory or other limits (Reference Points). Six of the 13 non-compliant residues were of possible health concern.

The Non-Statutory Surveillance Scheme concentrates on imported and processed foods – which are not tested as part of the UK's National Surveillance Scheme.

A total of 13 samples from the rolling programme contained residues at concentrations above the relevant statutory or other limits. Six were of potential consumer health concern.

All 100 samples of poultry products tested as part of the brand name survey were compliant.

Residues of potential health concern in imported produce:

- Chloramphenicol residues were detected in 1 of 310 (0.32%) samples of warm-water crustaceans tested. These were at a concentration of 0.33 µg/kg.
- Nitrofurans residues were detected in 5 of 274 (1.8%) samples of warm-water crustaceans tested:
 - AOZ residues (3-amino-2-oxazolidone) were detected in 3 (1.1%) samples, at concentrations between 2.2 and 150 µg/kg
 - SEM residues (semicarbazide) were detected in 2 (0.7%) samples, at concentrations of 1.8 and 2.1 µg/kg.

Chloramphenicol residues in warm-water crustaceans

Chloramphenicol, an antibiotic, is banned in the EU for food-producing animals. This is on the basis of toxicological advice that indicates exposure at any concentration could result in adverse health effects in sensitive individuals. In rare cases, exposure might cause the serious blood disorder, aplastic anaemia.

The FSA was informed and a product recall requested. However, it was found that all of the prawns had already been supplied to the catering trade. The sample came from Indonesia and Defra's CVO wrote to his opposite number notifying them of the result and asking to be kept informed of the outcome of any action taken. The Indonesian authorities told him that the residues had been the result of chloramphenicol contamination on the skewers used. They said that they had recommended the business change supplier and to test future supplies of skewers for residues of chloramphenicol.

Nitrofurans residues in warm-water crustaceans

Nitrofurans were previously used as authorised veterinary medicines to treat some infections in farm animals. In 1995, they were banned in the EU and in foods imported into the EU. This was because of the likelihood 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 for their residues.

Three of the samples were of tiger prawns from India and two were of freshwater crustaceans from Bangladesh. Defra's CVO wrote to his opposite number in the countries of origin notifying them of the result and asking to be kept informed of the outcome of any action taken to prevent further residues.

In all cases, the FSA was informed and was able to request product withdrawals. It also informed the European Commission, which issued Rapid Alerts to all EU Member States.

Results in Detail



National Surveillance Scheme for domestic produce in 2008 – residues at or above the Reference Point (see page 54)

Sample	Analysed for	Number of samples analysed	Reference Point (µg/kg or µg/l)	Samples at or above the Reference Point	
				Number found	Concentration (µg/kg or µg/l)
Eggs – Free-Range	Antimicrobials	207			
	Sulphadiazine		50 (Action Level)	2	50, 60
	Enrofloxacin/ Ciprofloxacin		50 (Action Level)	1	610
Eggs – caged	Ionophores/nicarbazin	86			
	Nicarbazin		25 (Action Level)	2	60, 60
Wild Deer Muscle	Heavy metals	89			
	Lead		10,000	1	33500
Honey	Benzenoids	18			
	1-4, dichlorobenzene		100 (CCα)	1	210 ^a
	Naphthalene		100 (CCα)	1	170 ^a
Milk	Antimicrobials	443			
	Cephalonium		20 (MRL)	1	50
Broiler Liver	Ionophores/nicarbazin	598			
	Nicarbazin		200 (JECFA MRL)	53	230, 230, 240, 240, 250, 250, 260, 260, 270, 270, 270, 270, 270, 290, 290, 290, 310, 330, 330, 330, 340, 340, 350, 350, 360, 360, 360, 390, 450, 470, 500, 500, 570, 580, 680, 720, 740, 810, 850, 860, 890, 900, 940, 970, 1100, 1200, 1200, 1600, 2000, 2095, 2100, 3800, 4200
Broiler Muscle	Antimicrobials	1809			
	Chlortetracycline		100 (MRL)	1	284
Turkey Muscle	Antimicrobials	443			
	Chlortetracycline		100 (MRL)	1	220
Calf Kidney	Antimicrobials	77			
	Amoxicillin		50 (MRL)	1	80
	Sulphadiazine		100 (MRL)	1	270
Calf Kidney	Florfenicol	46	300 (MRL)	1	360
Cattle Kidney	Heavy metals	58			
	Cadmium		500 (MRL)	1	3200
Cattle Kidney	NSAIDs	545			
	Ibuprofen		8 (CCα)	1	30
Cattle Liver	Benzimidazoles/ levamisole	550			
	Oxfendazole		500 (MRL)	2	2090, 14300
Cattle Liver	Ivermectin	339	100 (MRL)	1	270

Eggs

- Antimicrobial residues were detected in 3 of 207 (1.5%) free-range egg samples tested in a screen:
 - Sulphadiazine residues were detected in 2 of 207 (0.97%) free-range egg samples tested, at concentrations of 50 and 60 µg/kg;
 - Enrofloxacin/Ciprofloxacin residues were detected in 1 of 207 (0.48%) free-range egg samples tested, at a concentration of 610 µg/kg.
- Nicarbazin residues were detected in 2 of 86 samples of caged eggs tested as part of an ionophore and nicarbazin screen. Both samples had concentrations of 60 µg/kg.

Farmed Fish

- No residues were detected at concentrations at or above the relevant Reference Points.

Game

- Lead residues were detected in 1 of 89 samples of wild deer muscle tested. This was at a concentration of 33,500 µg/kg. This residue was believed to have occurred as a result of the deer having been shot.

Honey

- Residues of 1-4, dichlorobenzene and naphthalene were detected in 1 of 18 honey samples tested. These were at concentrations of 210 and 170 µg/l respectively.

This represents non-compliance with general food law. There was no honey left on the farm, but the FSA has arranged for the local authority to monitor the beekeeper's honey in 2009.

Milk

- Residues of cephalonium were detected in 1 of 443 (0.23%) milk samples tested in an antimicrobial screen. These were at a concentration of 50 µg/l.

Poultry

- Nicarbazin residues were detected in 53 of 598 (8.9%) broiler liver samples tested in a screen of ionophores and nicarbazin. These were at concentrations between 230 and 4,200 µg/kg.
- Chlortetracycline residues were detected in 1 of 1,809 (0.06%) broiler muscle samples tested in an antimicrobial screen. These were at a concentration of 284 µg/kg.
- Chlortetracycline residues were detected in 1 of 443 (0.23%) turkey muscle samples tested in an antimicrobial screen. These were at a concentration of 220 µg/kg.

Red Meat

- Antimicrobial residues were detected in 2 of 77 calf kidney samples tested in a screen:
 - Amoxicillin residues were detected in 1 of 77 samples tested. These were at a concentration of 80 µg/kg.
 - Sulphadiazine residues were detected in 1 of 77 samples tested. These were at a concentration of 270 µg/kg.

Percentages are only given where 100 or more samples were analysed.

Where residues above agreed limits are detected, a follow-up investigation is carried out on the farm of origin. The results of these investigations are published in papers to the Committee on its website www.vet-residues-committee.gov.uk. See VRC/08/27, VRC/08/48 and VRC/09/02.

Multi-residue methods (see page 28)

This year, the number of analyses of poultry liver for nicarbazin almost doubled from 301 in 2007 to 598 in 2008. It is, therefore, not surprising that the number of non-compliant results for nicarbazin also increased. However, there was also an increase in the proportion that tested non-compliant from 6.6% in 2007 to 8.9% in 2008.

The European Commission advice is that the presence of unconjugated alpha-boldenone or beta-boldenone is considered to be evidence of faecal contamination, which is more likely in samples collected on farm.

- Florfenicol residues were detected in 1 of 46 calf kidney samples tested. These were at a concentration of 360 µg/kg.
- Cadmium residues were detected in 1 of 58 cattle kidney samples tested in a screen for heavy metals. These were at a concentration of 3,200 µg/kg.
- Ibuprofen residues were detected in 1 of 545 (0.18%) samples of cattle kidney tested in a screen for NSAIDs. These were at a concentration of 30 µg/kg.

The follow-up investigation found no evidence of use of this substance on the farm. However, it is thought that the sampling officer was using an ibuprofen-based medication at the time. This is likely to have caused the contamination. This case will be used to highlight the issue of cross-contamination to sampling staff.

- Oxfendazole residues were detected in 2 of 550 (0.36%) cattle liver samples tested in a screen for benzimidazoles and levamisole. These were at concentrations of 2,090 and 14,300 µg/kg.

Toxicological advice is that while the residues above the MRL were undesirable, on a one-off basis, they were not of consumer health concern.

- Ivermectin residues were detected in 1 of 339 (0.29%) cattle liver samples tested. These were at a concentration of 270 µg/kg.
- Phenylbutazone residues were detected in 1 of 41 cattle plasma samples tested in a screen for NSAIDs. These were at a concentration of 0.13 µg/l. For details, see page 10.
- Progesterone residues were detected in 9 of 416 (2.2%) cattle serum samples tested. These were at concentrations between 0.5 and 7.0 µg/l.
- Testosterone residues were detected in 3 of 568 (0.53%) cattle serum samples tested. These were at concentrations between 0.6 and 7.0 µg/l.
- Boldenone and nortestosterone residues were detected in 21 of 2,795 (0.77%) cattle urine samples tested in a steroid screen:
 - Boldenone residues were detected in 10 of the 2,795 (0.36%) samples, at concentrations between 1.0 and 17 µg/l;
 - Nortestosterone residues were detected in 11 of the 2,795 (0.39%) samples, at concentrations between 0.5 and 30 µg/l.
- Zeranol residues were detected in 12 of 864 (1.4 %) samples of cattle urine tested in a stilbene and zeranol screen. These were at concentrations between 0.7 and 11 µg/l.

While zeranol can be used illegally to promote growth in cattle, there was no evidence found in the on-farm investigations to suggest this. Zeranol can be produced in feed that is contaminated with fusarium, a type of fungus. A statistical model was applied to results and this indicated that fungal contamination was the most likely cause of the residues.

- Cadmium residues were detected in 1 of 7 goat kidney samples tested in a screen for heavy metals. This was at a concentration of 1,050 µg/kg.
- Phenylbutazone residues were detected in 2 of 26 horse kidney samples detected in a screen for NSAIDs. These were at concentrations of 30 and 130 µg/kg. For details, see page 10.
- Phenylbutazone residues were detected in 1 of 30 horse plasma samples tested in a screen for NSAIDs. These were at a concentration of 5 µg/l. For details, see page 10.

- Chlortetracycline and oxytetracycline residues were detected in 5 of 1,666 (0.30%) pig kidney samples tested in an antimicrobial screen:
 - Chlortetracycline residues were detected in 4 of the 1,666 (0.26%) pig kidney samples, at concentrations between 1,040 and 2,700 µg/kg;
 - Oxytetracycline residues were detected in 1 of the 1,666 (0.06%) pig kidney samples, at a concentration of 910 µg/kg.
- Zeranol residues were detected in 1 of 268 (0.37%) pig urine samples tested in a stilbene and zeranol screen. These were at a concentration of 1.0 µg/l. A statistical model was applied to results and this indicated that fungal contamination was the most likely cause of the residues.
- Cadmium and lead residues were detected in 5 of 50 samples of sheep kidney samples tested in a heavy metal screen:
 - Cadmium residues were detected in 2 of the 50 sheep kidney samples, at concentrations of 1,350 and 1,940 µg/kg;
 - Lead residues were detected in 3 of the 50 sheep kidney samples, at concentrations between 550 and 5,940 µg/kg.
- DDT residues were detected in 1 of 1,278 (0.08%) samples of sheep kidney fat in a screen for organochlorines. These were at a concentration of 1,380 µg/kg.
- Triclabendazole residues were detected in 1 of 909 (0.11%) samples of sheep liver tested in a screen for benzimidazoles. These were at a concentration of 365 µg/kg.
- Boldenone and Nortestosterone residues were detected in 50 of 531 (9.4%) samples of sheep urine tested in a screen for steroids:
 - Boldenone residues were detected in 8 of the 531 (1.5%) samples, at concentrations between 1.0 and 3.0 µg/l;
 - Nortestosterone residues were detected in 42 of the 531 (7.9%) samples, at concentrations between 1.0 and 7.0 µg/l.

Why are hormone residues detected?

Hormones occur naturally in farm animals. That the NSS detects them is to be expected. This is because of the very sensitive analytical methods used. The VMD believe the hormonal substances detected in this year's programme are due to natural production within the cattle, pigs and sheep tested, or fungal contamination of feed (see above).

Follow-up samples taken as a result of investigations into residues detected by the National Surveillance Scheme in Great Britain

Follow-up samples taken as part of the 2008 programme in Great Britain

Sample	Analysed for	Number of samples analysed	Reference Point (µg/kg or µg/l)	Samples at or above the Reference Point	
				Number found	Concentration (µg/kg or µg/l)
Eggs – Free-range	Antimicrobial screen	4	50 (Action Level)	0	
Milk	Antimicrobials Cephalonium	5	20 (MRL)	0	
Broiler Feed	Ionophores/nicarbazin Nicarbazin	12	500 (CCα)	0	
Broiler Liver	Ionophores/nicarbazin Nicarbazin	2	200 (JECFA MRL)	0	
Hen Feed	Ionophores/nicarbazin nicarbazin	12	500 (CCα)	4	2000, 2100, 4500, 6100
Cattle Hair	Nortestosterone esters	15	1.64 - 6.59 (CCα)	0	
Cattle Plasma	Steroid screen	6	1.0 (CCα)	0	
Cattle Serum	Progesterone	38	0.5 (Action Level)	7	0.5, 0.6, 0.6, 0.7, 0.9, 0.9, 1.0
Cattle Serum	Testosterone	15	0.5 Action Level)	0	
Cattle Urine	Steroid screen Alpha boldenone	39	1.0 (CCα)	6	1.0, 2.0, 3.0, 3.0, 4.0, 4.0
Pig Kidney	Antimicrobials Tetracyclines	3	600 (MRL)	0	
Pig Urine	Stilbenes/zeranone Zeranone	4	0.32 (CCα)	0	
Sheep Urine	Nortestosterone	5	0.32 (CCα)	0	

Follow-up samples taken in both 2007 and 2008 as part of the 2007 programme in Great Britain

Sample	Analysed for	Number of samples analysed	Reference Point (µg/kg or µg/l)	Samples at or above the Reference Point	
				Number found	Concentration (µg/kg or µg/l)
Honey	Naphthalene	22	100 (LOQ)	7	43, 45, 62, 110, 300, 390, 980
Salmon Muscle	Malachite/ leucomalachite green Leucomalachite green	12	2 (MRPL)	12	2.0, 4.0, 4.0, 4.0, 4.0, 4.0, 4.0, 5.0, 5.0, 5.0, 6.0, 7.0
Trout Muscle	Malachite/ leucomalachite green Leucomalachite green	11	2 (MRPL)	10	2.0, 3.0, 4.0, 4.0, 4.0, 5.0, 10, 20, 20, 50
Broiler Feed	Ionophores	2	500 (CCα)	0	
Broiler Feed	Nicarbazin	2	500 (CCα)	0	
Duck Feed	Chloramphenicol	5	500 (CCα)	0	
Cattle Serum	Nortestosterone	9	0.5 / 5.0 (Action Level) ^d	1	4
Cattle Serum	Oestradiol	1	0.04 (CCα)	0	
Cattle Serum	Progesterone	24	0.5 (Action Level)	0	

d = 0.5 µg/l is the Action Level for female cattle and 5.0 µg/l for male cattle.

Non-Statutory Surveillance Scheme – residues at or above the Reference Point (see page 54)

Rolling programme of mainly imported produce

Sample	Analysed for	Number of samples analysed	Reference Point	Samples at or above the Reference Point	
			(µg/kg)	Number found	Concentration (µg/kg)
Farmed Warm-Water Crustaceans	Chloramphenicol	310	0.3 (MRPL)	1	0.33
	Nitrofurans	274	1 (MRPL)		
	AOZ			3	2.2, 8.9, 150
	SEM			2	1.8, 2.1
Imported Farmed Fish	Fluoroquinolones/quinolones	301			
	Enrofloxacin		100 (MRL)	2	130, 210
Imported Pâté ^e	Coccidiostats/nitroimidazoles	100			
	Nicarbazin		20 (Action Level)	4	24, 140, 210, 310
Imported Raw Poultry	Coccidiostats/nitroimidazoles	286			
	Nicarbazin		200 (JECFA MRL)	1	270

e = one sample was of UK origin
 AOZ = 3-amino-2-oxazolidone
 SEM = Semicarbazide

Rolling programme of mainly imported produce

Imported Raw Beef

- No residues were detected at concentrations at or above the relevant Reference Points.

Imported Farmed Warm-Water Crustaceans

- Chloramphenicol residues were detected in 1 of 310 (0.32%) samples tested. These were at a concentration of 0.33 µg/kg.

Chloramphenicol, an antibiotic, is banned in the EU for food-producing animals. This is on the basis of toxicological advice that indicates exposure at any concentration could result in adverse health effects in sensitive individuals. In rare cases, exposure might cause the serious blood disorder, aplastic anaemia.

For details see page 12.

- Nitrofurans were detected in 5 of 274 (1.8%) samples tested:
 - AOZ residues (3-amino-2-oxazolidone) were detected in 3 (1.1%) samples at concentrations between 2.2 and 150 µg/kg.
 - SEM residues (semicarbazide) were detected in 2 (0.73%) samples at concentrations of 1.8 and 2.1 µg/kg.

Nitrofurans were previously used as authorised veterinary medicines to treat some infections in farm animals. In 1995, they were banned in the EU and in foods imported into the EU. This was because of the likelihood 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 for their residues. For details see page 12.

Percentages are only given where 100 or more samples were analysed.

Chloramphenicol, an antibiotic, is banned in the EU for food-producing animals. This is on the basis of toxicological advice that indicates exposure at any concentration could result in adverse health effects in sensitive individuals.

Origin of SEM residues

SEM is a marker residue for the illegal use of the nitrofurans antibiotic, nitrofurazone. However, there are other reasons why it can occur in foods, for example, use of a prohibited type of jar seal has resulted in SEM residues in some foods. When SEM residues are detected, an assessment has to be made to decide how they arose.

Imported Farmed Fish

- Enrofloxacin residues were detected in 2 of 301 (0.66%) samples tested in a screen for fluoroquinolones and quinolones. These were at concentrations of 130 and 210 µg/kg.

Pâté

- Nicarbazin residues were detected in 4 of 100 (4.0%) samples tested in a screen for coccidiostats and nitroimidazoles. These were at concentrations between 24 and 310 µg/kg.

Imported Raw Poultry

- Nicarbazin residues were detected in 1 of 286 (0.35%) samples tested in a screen for coccidiostats and nitroimidazoles. These were at a concentration of 270 µg/kg.

Brand name survey of poultry products

A total of 100 samples of poultry products were analysed for residues of chloramphenicol, coccidiostats, nitroimidazoles and nitrofurans (94 samples of imported produce and 6 of domestic origin). The Committee recommended that poultry products such as nuggets and burgers should be tested for these substances as these foods are typically consumed by children.

- No residues of chloramphenicol, coccidiostats, nitroimidazoles and nitrofurans were detected at concentrations at or above the relevant Reference Points.

Industry results

The results submitted by industry are available in an Annex to the Annual Report on the VRC website: www.vet-residues-committee.gov.uk

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From 1 April 2007, the State Veterinary Service became part of Animal Health, another agency of Defra. The move brought together Defra's State Veterinary Service, the Dairy Hygiene and Egg Marketing Inspectorates and the Wildlife Licensing and Registration Service.

The Central Science Laboratory became part of the Food and Environment Research Agency (Fera) from 1 April 2009. Fera is an executive agency of Defra.

The Committee's Year

The full Committee held four meetings in 2008, including an Open Meeting in Scotland. As well as the VRC Members and the Secretariat, provided by the VMD, a number of advisors have attended the meetings. The advisors, while not members of the VRC, were able to help inform the Committee's discussions on a range of subjects. Organisations that provided advisors during the year were:

- Agri-Food and Biosciences Institute (AFBI) of Northern Ireland
- Animal Health (formerly the State Veterinary Service of Defra)
- Central Science Laboratory (CSL)
- Food Standards Agency (FSA)
- LGC Limited
- Veterinary Medicines Directorate (VMD)

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

- helping plan the National Surveillance Scheme (NSS) and the Non-Statutory Surveillance Scheme for 2009
- consulting stakeholders on the plan for the Non-Statutory Surveillance Scheme, which concentrates on imported foods
- reviewing the results of the VMD's surveillance schemes
- publishing a consumer factsheet on veterinary medicines residues
- considering residues of phenylbutazone detected in horses and cattle
- considering emerging risks and diseases
- horizon scanning and trend analysis of the EU's Rapid Alert System for Food and Feed
- reviewing the Matrix Ranking process
- considering the review of European veterinary residues legislation
- reviewing guidelines on the use of personal medicines by sampling officers
- recommending a brand name survey of poultry products
- research into analytical methods for hormone residues
- the joint government/industry initiative on nicarbazin residues
- holding its Fifth Open Meeting on 12 November 2008 in Glasgow
- statistically representative sampling.

Planning the Surveillance Schemes

VRC Members were actively involved in advising VMD on planning the surveillance programmes for 2009. In September 2008, two Members attended the National Surveillance Scheme planning meeting to help produce the draft 2009 plan. The full Committee later approved the plan. The NSS is described in detail on pages 27 and 30 and on the VRC's website (www.vet-residues-committee.gov.uk).

The VRC's Non-Statutory Planning Subgroup met in September 2008 to discuss a plan for 2009, drafted by the VMD. This had been based on a consultation of stakeholders (see below), the VRC's recommendations and the outcome of its Matrix Ranking assessments. The full Committee was then able to comment and make suggestions for the plan before it was finalised.



Consulting stakeholders on the plan for the Non-Statutory Surveillance Scheme, which concentrates on imported foods

Toward the end of August 2008, the VRC held a consultation exercise on its draft outline plans for surveillance under the VMD's Non-Statutory Surveillance Scheme for 2009. A consultation letter, with suggestions for the foods and substance groups that could be included, was sent to interested parties and placed on the VRC's website. The suggestions received were reviewed before the VRC finalised its recommendations for the Non-Statutory Scheme.

The VRC understands that this is a sensitive issue, where it has to balance the need to be open and transparent, with the need to have an effective programme. The issue was raised at our Open Meeting in Belfast in October 2007, so we could gather the views of stakeholders. These were generally supportive and the VRC felt it could carry out a consultation.

The Committee still retain the possibility of making changes during the year if these are considered necessary. Also, the Committee will review the outcome of its decision to consult on the plans.

Reviewing the results

At the four VRC meetings, the Committee reviewed the latest results of the VMD's surveillance schemes. It was able to ask detailed questions of the advisors, requesting extra information where necessary on the causes and follow-up investigations. The Committee then advised the VMD and the FSA on the actions they might wish to take.

Fact sheet for consumers on veterinary residues

The Committee see explaining the facts over veterinary residues as one of its key responsibilities. Using information from a survey of consumer attitudes to veterinary residues, the VRC published a fact sheet that explained that there is independent oversight of the UK's surveillance for residues of veterinary medicines in food. It also set out to explain that neither hormonal substances, nor antibiotics are allowed to be used for growth promotion in the EU.

The leaflet is available from the VRC website at: http://www.vet-residues-committee.gov.uk/surveillance/Consumer_Fact_Sheet.pdf

Residues of phenylbutazone in horses and cattle

The Committee noted that residues of phenylbutazone continue to be detected. This is of concern, because it has the potential to cause serious blood disorders (see page 11). Reports to the Committee have identified that the current system of horse passports, which should keep animals treated with this medicine out of the food chain, has not always prevented occasional consumer exposure.

The Committee has asked for updates on new equine identification legislation that should improve compliance. It will support initiatives from Defra and the VMD to publicise the responsibilities of horse owners and vets in relation to this important issue.

Considering emerging risks

Following a suggestion by one of the consumer members of the VRC, Defra's Deputy Chief Veterinary Officer, Alick Simmons gave a talk to the Committee. He explained Defra's system of surveillance for exotic diseases. He concluded that there would always be a risk from emerging diseases. For example, there had been some outbreaks of Avian Influenza and Bluetongue disease.

It is useful for the Committee to be aware of such emerging risks, as with different diseases, there could be a different pattern of medicines use, which would have to be reflected in the surveillance schemes.

The consultation letter can be found on the VRC's website at: http://www.vet-residues-committee.gov.uk/News/Consultation_letter_2008.pdf

The Matrix Ranking system is described in more detail on page X. A note of the Subgroup meeting, with the scores and rationale for a range of substances can be found in meeting paper VRC/08/29.

The VRC has received regular updates on the European Commission's proposals, which can be found in papers VRC/08/03, VRC/08/21, VRC/08/31 and VRC/08/43 on the VRC website: www.vet-residues-committee.gov.uk.

Chloramphenicol is an antibiotic used externally as eye drops to treat infections. Salbutamol is a common ingredient of inhalers used by asthmatics.

Horizon scanning and trend analysis of the EU's Rapid Alert System for Food and Feed (RASFF)

http://ec.europa.eu/food/food/rapidalert/index_en.htm

The EU has the RASFF to allow all Member States to share information when risks to food and feed safety are detected. This means that if residues, for example, of unauthorised substances, are detected in any Member State, all other Member States are alerted. The Committee considered an analysis of all of the veterinary medicine related RASFFs for 2004-2007 and also analyses of the parallel systems operated by the USA and by Canada, which the FSA had produced.

The intelligence and trend data provided by such information is very helpful in ensuring that the UK's surveillance schemes are targeted in the right areas. The Committee will continue to monitor these data.

Matrix Ranking

Matrix Ranking is a system developed by the Committee to prioritise which substances should be included in the VMD's Non-Statutory Surveillance Scheme. It is important to the Committee that decisions should be evidence-based and understood by interested parties.

The Matrix Ranking Subgroup met on 11 March 2008. As well as assessing a range of substances, the Subgroup recommended two changes to the scoring system. One was to add 'non-genotoxic carcinogen' as an adverse effect in the 'Nature of the Hazard' category with a score of 4. The other was to increase all of the scores for detectable residues by one point. Previously if no residues had been detected in surveillance for a particular substance, the overall score would have been zero and a low position in the table would result. The Subgroup thought that if there were higher scores in other categories this should be reflected in the overall score and place in the Matrix Ranking table, to reflect the potential risk.

Review of European veterinary residues legislation

The EU is reviewing major pieces of legislation that affect the VMD's National Surveillance Scheme. The Commission state that while the current legislation has resulted in a high degree of consumer protection, it has had the effect of reducing the availability of veterinary medicines. This could adversely affect animal welfare and in some cases there are no medicines to treat particular conditions or diseases. This is particularly a problem for minor species, such as bees. Changes to the legislation could result in different medicines being available, so the review is of great interest to the VRC in planning the surveillance.

Guidelines on medicines by use staff by sampling officers

Members asked to see the guidance issued to Meat Hygiene Service (MHS) staff on taking medication. This warned officers of possible cross-contamination of samples taken for residues surveillance. The guidance was re-issued following cross-contamination of a sample of duck muscle with chloramphenicol and two earlier samples containing residues of salbutamol.

Chloramphenicol and salbutamol are banned from food-producing animals. Avoiding such residues is important for the integrity of the programme and the Committee asked the LGC Limited and AFBI, which had similar guidance, to review the MHS document. This is reported in VRC/08/23 and VRC/08/25.

This issue was raised again by the residue of ibuprofen detected in a sample of cattle kidney in 2008. This was also thought to be due to cross-contamination.

Recommending a brand name survey

The VRC previously decided that it could recommend one brand name survey each year, where this was thought necessary.

In late 2008, the Committee recommended a survey of poultry products for chloramphenicol, coccidiostats, nitroimidazoles and nitrofurans. The plan was to collect 100 samples: 75 from shops and wholesalers, and 25 from the Border Inspection Posts. The 'shoppers' collecting samples from shops and wholesalers were asked to obtain products that might typically be eaten by children. This would include: chicken nuggets, goujons and burgers etc. The survey was carried out in late 2008 and in 2009. The results are presented on page 21 and in a report on the VRC website – www.vet-residues-committee.gov.uk.

Research into analytical methods for hormone residues

We expect to find hormone residues in samples tested under the National Surveillance Scheme. This is because hormones occur naturally in farm animals and the sensitive analytical techniques now available can detect down to below one part per billion. Where follow-up investigations are held, these nearly always find no evidence of hormone abuse on the farm of origin.

Researchers have been looking for some time for methods to differentiate between hormone residues that have occurred naturally, and those that have occurred as a result of administration by the farmer or other person. If this could be done, it would reduce the resources used in unnecessary follow-up investigations and also enable appropriate action to be taken where administration is confirmed.

Supporting the joint government/industry initiative on nicarbazin residues

Since the Committee's inception, it has taken a keen interest in residues of coccidiostats in poultry products. To identify the reason for the residues, it set up its own Subgroup. This identified problems in the manufacture and handling of animal feed as the prime causes of the residues detected. These account for about half of all residues of veterinary medicinal products detected in the UK's National Surveillance Scheme. Significant reductions in the number of non-compliant samples were recorded between 1998 and 2003, however, in recent years progress appeared to have stalled.

The VRC supported the FSA in facilitating a government/industry initiative to further reduce the incidence and concentrations of nicarbazin residues in poultry. The Committee considered the report of this initiative at its June meeting.

Details of the initiative and a leaflet on avoiding nicarbazin residues can be found in meeting paper VRC/08/32 and on the FSA website at:

<http://www.food.gov.uk/news/newsarchive/2008/may/nicarbazin0508>

<http://www.food.gov.uk/multimedia/pdfs/publication/nicarbazin0209.pdf>.

A note of the Glasgow meeting is available as VRC/08/47 on the VRC's website: <http://www.vet-residues-committee.gov.uk/Minutes/Minutes08/minutes121108.pdf>. Dr Webster's presentation is also available as: http://www.vet-residues-committee.gov.uk/Papers/Papers08/VMR_issues.pdf.

Open Meeting in Glasgow

The Committee held its 5th Open Meeting on 12 November 2008 in Glasgow. The Open Meeting gave the VRC the opportunity to hear the views of stakeholders. This is the second time the Open Meeting has been held outside London and is part of the Committee's commitment to openness and giving the widest cross-section of people in the UK a chance to attend.

The Committee discussed some of its normal business and heard a presentation from Dr John Webster, the Technical Director of the Scottish Salmon Producers' Organisation on the issues and challenges that the industry faced.

There were also sessions to allow attendees to give their own views and ask questions of the Committee. Among the issues raised were:

- how importers would find it useful if the results of the VMD's Non-Statutory Surveillance Scheme were available more quickly after samples had been taken
- the possibility of 'naming and shaming' suppliers of non-compliant consignments
- malachite green contamination of fish by the green paper towels that had been used to wrap them
- the number of samples collected in the UK, compared to other countries in the EU
- the use of the new multi-residue methods developed by the LGC Limited.

Statistically representative sampling

The FSA presented a paper on this subject. For a number of surveys, the Committee has recommended 300 samples be collected, based on statistical probability tables. The Committee discussed the possibility of cutting the number of samples taken, without reducing the likelihood of detecting non-compliant samples to an unacceptable extent. This can be possible where there is a known violation rate. If this was possible, the other samples could be allocated to other foods or substances, so widening the scope of the Non-Statutory Scheme.

The Committee asked the FSA and VMD to discuss the possible ways this approach could be implemented in practice.

Residues Surveillance – Explanation of the Schemes



The National Surveillance Scheme

All EU Member States must carry out surveillance to check that any residues in their home-produced foods of animal origin are within statutory limits and that unauthorised substances are not being used. In the UK, the National Surveillance Scheme (NSS) covers: red meat, poultry, wild and farmed game, farmed fish, milk, honey and eggs. Annexes to the European legislation set down the number of samples that Member States must take, based on forecast production. The legislation also lays down broad parameters on the groups of substances to be surveyed.

Overleaf is a flowchart of how the NSS works. There is a more detailed explanation on our website, www.vet-residues-committee.gov.uk.

The National Surveillance Scheme (NSS) covers: home-produced red meat, poultry, wild and farmed game, farmed fish, milk, honey and eggs.

Types of substances analysed for in the National Surveillance Scheme

EU legislation, Council Directive 96/23/EC, sets the criteria for operating the National Surveillance Scheme. It does not require all substance types to be 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 summarising the types of substances that were sought in the different sectors. For details of all of the substances sought, please see the annex to this report on the VRC website (www.vet-residues-committee.gov.uk), which contains all of the results of the surveillance.

Type of substance	Product types						
	Eggs	Farmed fish	Game	Honey	Milk	Poultry	Red meat
Hormones			X			X	X
Gestagens							X
β-agonists			X			X	X
Annex IV substances ^f	X	X	X	X	X	X	X
Antimicrobials ^g	X	X	X	X	X	X	X
Anthelmintics	X	X	X		X	X	X
Non Steroidal Anti-Inflammatory Drugs (NSAIDS)					X		X
Coccidiostats	X		X			X	X
Thyrostats							X
Dexamethasone/Betamethasone							X
Carbadox ^h							X
Sedatives			X				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					

f = Annex IV substances are ones for which no safe concentration can be set for any residues and are, therefore, banned from use in food-producing animals.

g = A general screening method can be supplemented by specific tests for sulphonamides, tetracyclines etc., dependant on the product type.

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

Development of multi-residue methods of analysis

Up until recently, separate methods were needed for many substances in the National Surveillance Scheme (NSS). This is because the substances used as veterinary medicines often have quite different structures from each other. These different structures have not always lent themselves to the type of multi-residue methods often used for multi-classes of pesticides. Also, the EU veterinary residues legislation is written on the basis that, generally, one sample is tested for only one class of residues.

However, the LGC Limited has now validated multi-residue methods to confirm a wider range of substances. These methods include:

- ionophore coccidiostats and nicarbazin
- organochlorine, pyrethroid and organophosphorus insecticides and polychlorinated biphenyls (PCBs)
- steroids
- stilbenes and zeranol.

This has allowed all of the samples that would have been analysed separately to be pooled. For example, in previous years, the NSS would have analysed some 300 samples of broiler liver for ionophore coccidiostats (such as lasalocid) and a separate 300 samples for nicarbazin. This year, 598 samples were simultaneously analysed both for the ionophores and nicarbazin.

What is the effect of this?

With nearly twice as many tests, we found more non-compliant samples. For example in the case of nicarbazin, the number of non-compliant results more than doubled from 2007 to 2008, from 20 to 53. While the proportion did increase slightly, this is likely to have accounted for about 13 of the extra non-compliant samples. The other 20 extra non-compliant samples were likely to have been due to testing so many more samples.

Results for nicarbazin in broiler liver from 2004-2008

Year	Samples analysed for nicarbazin	Number non-compliant	Percentage non-compliant
2004	277	36	13.0
2005	306	27	8.8
2006	305	26	8.5
2007	301	20	6.6
2008	598	53	8.9

What is $CC\alpha$?

In previous EU legislation, where analysis indicated that a sample contained a concentration above the relevant MRL or Action Level, it was considered non-compliant and enforcement action could be taken. However, new legislation on analysis (Decision 2002/657/EC) requires regulators to take account of the possible error or inaccuracy that occurs whenever you measure something.

For example, if you measure 100 g of flour on your kitchen scales, we know it is likely to be close to 100 g, but unlikely to weigh exactly 100 g. It may vary slightly each time you weigh this amount. Extracting a residue from a food and analysing it are complex procedures and each step could introduce some variability. So analytical laboratories are now required to build in a measure of the variation or uncertainty associated with their analytical results.

This means that a sample is only considered non-compliant if the measured concentration is greater than the Reference Point (normally the MRL) plus the measure of uncertainty or variation. This measure is called the $CC\alpha$. This uncertainty is calculated in a prescribed manner, and is dependent upon both the specific analytical method and the precision observed by the laboratory at the time of validation.

Definitions

$CC\alpha$, the **Decision Limit**, is the concentration of a drug residue in a sample at which it is decided that the sample is non-compliant with a pre-defined statistical certainty.

Commission Decision

2002/657/EC established criteria and procedures for the validation of analytical methods to ensure the quality and comparability of analytical results generated by official laboratories.

Who attends the September planning meeting?

As well as two members of the VRC, a number of organisations are represented:

- Veterinary Medicines Directorate
- Food Standards Agency
- Animal Health
- Department for Environment Food and Rural Affairs
- Agri-Food and Biosciences Institute
- Meat Hygiene Service
- LGC Limited
- Central Science Laboratory

1 Representatives of the VRC and others meet each September to discuss the plan for the following year. The draft plan is then examined and approved by the VRC. The plan is also submitted to Brussels to ensure it conforms to the relevant EU law.

Planning the Programme

5 Taking account of toxicological advice received and other information, the VRC can give its view on the significance of particular residues and the actions that might be taken, for example to identify the cause of the residue.

The results of the surveillance are fed into the planning process for next year.

Advice Given

4 The VRC sees all of the results of the surveillance. The Committee can consult the FSA and VMD to give a scientific opinion on the significance of any residues for human health.

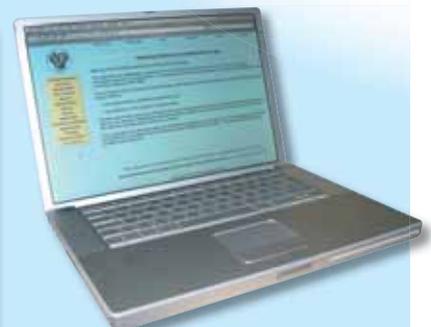
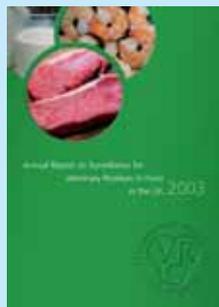
Results Assessed

Follow-up Investigation

Results Published

All of the results are published

As well as this report, all of the results are published in papers to the VRC on our website. The VMD also publish the results in its quarterly newsletter 'MAVIS', which is available on its website. The website addresses are:
www.vet-residues-committee.gov.uk
www.vmd.gov.uk



Surveillance Scheme Works



2 Samples are collected and secured with a tamper-proof seal. This allows any sample to be traced back to its farm of origin.



What happens in Brussels?

Officials from the European Commission and all of the EU Member States examine the plans. This is to ensure that **all** Member States' plans conform to the relevant EU law (Council Directive 96/23/EC).

Samples Collected

Samples Analysed

Initial Assessment of Results

3 Follow-up investigations are carried out into the causes of all residues above the relevant MRL or Action Level. The farmer will also be given advice on how to avoid residues in the future.



The Non-Statutory Surveillance Scheme

The Non-Statutory Surveillance Scheme concentrates on imported and processed foods. This is to complement the National Surveillance Scheme, which tests domestic produce. The Non-Statutory Surveillance Scheme, as its name suggests, does not have a legal base. Therefore, the VRC has great freedom to recommend the substances and foods which should be included. The scheme is funded by Defra.

The Non-Statutory Surveillance Scheme consists of two main elements:

- a **rolling programme**, where certain commodities are collected across the year and tested for particular substances; and
- **brand name surveys**. In these surveys, samples are collected from shops and wholesalers and Border Inspection Posts. All of the details of the samples, such as where they were bought and how they were analysed are included in a draft report. The owners of the brands are given an opportunity to comment on any non-compliant results that involve their produce. The VRC can use brand name surveys where it has particular concerns or wishes to highlight an issue.

The Committee recommend that, with the limited funds available, the scheme should target areas where it considers that residues of concern are most likely to occur. Imported raw produce was identified as the primary target for investigation.

One key difference between the schemes is that the National Surveillance Scheme can select the best tissue in which to detect residues. For example, kidney or urine can be collected, depending on the substance being sought. However, the Non-Statutory Surveillance Scheme can only collect and test the tissue imported, usually muscle.

The VRC is aware that there are other areas where it would be valuable to have surveillance. Therefore, the Committee has developed its own system to ensure that the funds are used to best effect, by prioritising the substances of greatest concern. This system – Matrix Ranking – is explained on pages 37 to 39.

Overleaf is a representation of how the Non-Statutory Surveillance Scheme operates. A fuller explanation is on the VRC's website at: www.vet-residues-committee.gov.uk.

Foods analysed under the Non-Statutory Surveillance Scheme (see results on page 20)

Rolling programme

The foods selected for analysis under the 2008 rolling programme were:

- raw beef – imported
- farmed warm-water crustaceans – imported
- farmed fish – imported
- poultry liver pâté (99 imported and one domestic sample)
- raw poultry – imported

Not all foods were analysed for all the substances in the scheme. Based on current intelligence and previous results, the analyses carried out on a particular food were prioritised. Samples were collected mainly from shops, wholesalers and Border Inspection Posts. Generally, the samples were of foods from countries outside the EU.

Brand name survey

A total of 100 samples of poultry products were analysed for residues of chloramphenicol, coccidiostats, nitroimidazoles and nitrofurans. Ninety four of the samples were imported and six were of domestic origin. The Committee recommended that poultry products, such as nuggets and burgers should be tested for these substances because they wished to focus on foods that were typically consumed by children.

The full details of the substances tested for each of these foods is given in the Annex to this report, which is available on the VRC website: www.vet-residues-committee.gov.uk.

The full report of the brand name survey of poultry products can be found in the 'Reports' section of the VRC website: www.vet-residues-committee.gov.uk.

How the Non-Statutory S

1 A number of factors, such as toxicity and previous evidence of residues can be fed into the VRC's Matrix Ranking system to give a prioritised list of substances.

6 The FSA can:

- alert consumers
- ask local authorities to investigate
- request and oversee product withdrawals
- alert the European Commission and so other EU Member States of residues problems.

5 The VMD can:

- alert the FSA, who can take the actions listed above
- inform the retailer or importer to get details of the product
- ask Defra's Chief Veterinary Officer to write to the country of origin requesting to be kept informed of any action taken to prevent such residues in future.

Planning the Programme

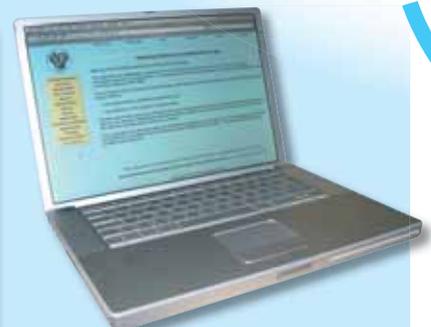
Action

Advice Given

Results Assessed

All of the results are published

As well as this report, all of the results are published in papers to the VRC on our website. The VMD also publish the results in its quarterly newsletter 'MAVIS', which is available on its website. The website addresses are:
www.vet-residues-committee.gov.uk
www.vmd.gov.uk



Surveillance Scheme Works



2 The budget for the year can be applied to the list to see which analyses can be afforded for the final plan in any particular year.

3 Samples are collected from shops, wholesalers and Border Inspection Posts.

Budgeted Plan Produced

Samples Collected

Samples Analysed at CSL

4 The VRC sees all of the results of the surveillance. This allows members to comment and ask questions on the results and assess their significance for consumers.



More detail on operating the Scheme

A fuller explanation of how the Non-Statutory Surveillance Scheme operates is available on the VRC website in the Surveillance Information section.

The Veterinary Residues Committee works to ensure that use of veterinary medicines does not result in residues of health concern for the consumer



Matrix Ranking for prioritising substances for the Non-Statutory Surveillance Scheme

The Committee developed Matrix Ranking to help prioritise the substances it recommends for surveillance. With the limited funds available for the Non-Statutory Surveillance Scheme, not all substances or foods can be included each year. The Committee hopes that in adopting a system where each substance can be assessed transparently against published criteria and weightings, people will understand why particular choices have been made. It would also allow stakeholders to challenge the choices made, or make further suggestions.

The Committee's Matrix Ranking Subgroup met on 11 March 2008. It made two small changes to the assessment system:

- in the 'Hazard' category, a non-genotoxic carcinogen would be scored as '4'
- all scores for 'Evidence of Detectable Residues' were increased by one point.

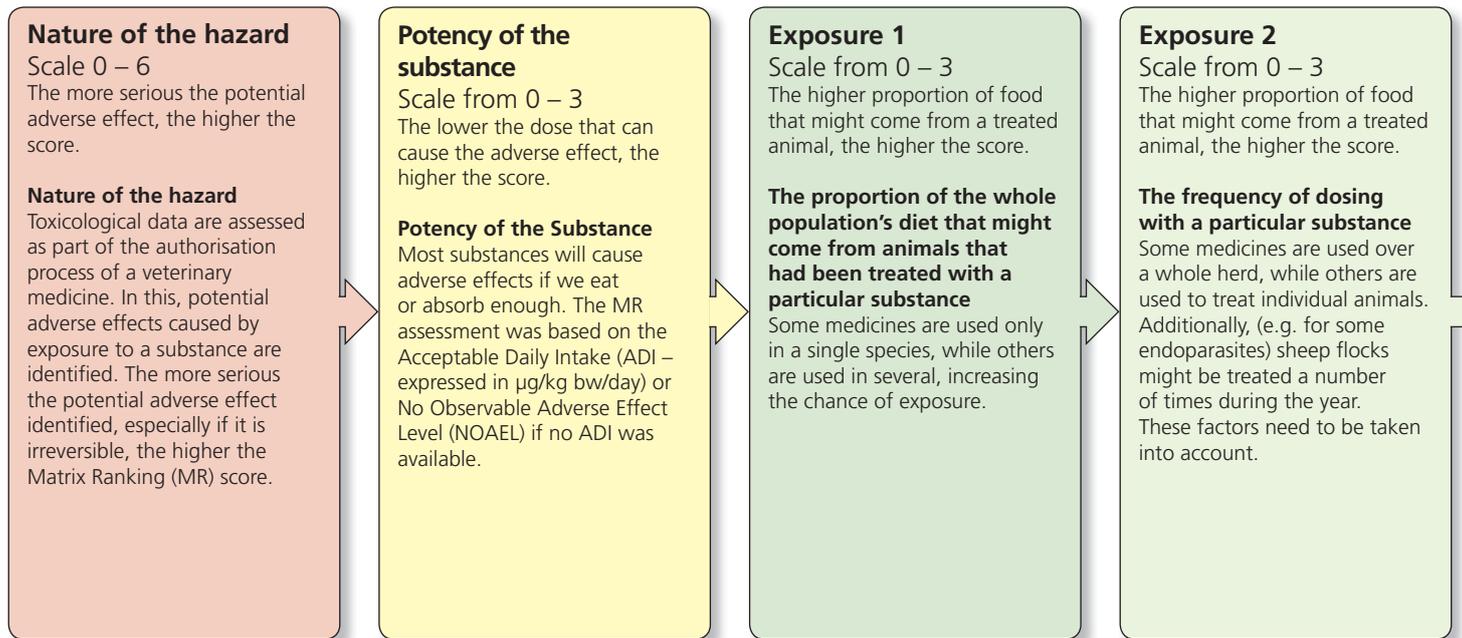
In the system used up to that time, a '0' was allocated where there was evidence of no detectable residues. As the system multiplies the score for detectable residues by the other scores, this resulted in a zero score overall. So, it did not differentiate between substances where the potential risk was higher.

By moving all scores up one point, this ensures that a positive score is usually recorded. This means that substances where there is no evidence of detectable residues would still rank lowly in the table. However, there is now a differentiation between those of low potential risk to consumers and those where the potential risk would be higher, if residues were later detected.

A full report on the meeting can be found as paper VRC/08/29 on the VRC's website: www.vet-residues-committee.gov.uk.

Matrix Ranking for Prioritising Substances

Criteria (A) + (B) × (C) + (D) +



Weighting system

Nature of the hazard

Score	Definition
0	No reported adverse effects.
1	Reversible adverse pharmacological effects (e.g. increased blood pressure or heart rate). Microbiological effects (e.g. disturbance of gut flora).
2	Reversible organ toxicity (e.g. kidney or liver damage).
3	Irritants. Evidence of allergic reactions in animals.
4	Carcinogenic by mechanisms not relevant to humans. Irreversible organ toxicity. Foetotoxicity/embryotoxicity. Immunotoxicological effects (e.g. sensitisation). Non-genotoxic carcinogen.
5	Irreversible neurotoxic effects. Irreversible reproductive effects (e.g. teratogenicity). Evidence of mutagenicity.
6	Evidence of carcinogenicity in humans. Carcinogenic by mechanisms relevant to humans.

Potency of the substance

Score	Based on the ADI (µg/kg bw/day)
0	>10
1	>0.10 – 10
2	>0.001 – 0.10
3	<0.001

Exposure 1

Score	Definition
0	<2.5%
1	2.5 – <20%
2	20% – <50%
3	50% – 100%

Exposure 2

Score	Definition
0	<2.5%
1	2.5 – <20%
2	20% – <50%
3	50% – 100%

for the Non-Statutory Surveillance Scheme

E) × F = Substance total score

High exposure groups

Scale from 0 – 3

Where there are consumer groups who might be at particular risk and not covered in dietary surveys, a higher score is allocated.

Evidence of high exposure groups

Some groups might ingest a higher amount of a particular residue because of their diet. It is also possible that they are not adequately covered by dietary surveys. Where there is evidence for such groups or if there are little data on which to make an assessment, a higher score is allocated.

Evidence for detectable residues

Scale from 1 – 4

Where residues above legal or other limits have been detected, a higher score is allocated.

Evidence of detectable residues

The higher the concentration detected, in comparison to the MRL/MRPL for the particular substance, the higher the score allocated. The highest score can be allocated when:

- a residue has been confirmed for a substance for which no safe concentration has been identified; or
- no residue testing has been carried out.

To give the overall substance score

$$(A + B) \times (C + D + E) \times F = \text{Overall Substance Score}$$

1. scores for Hazard (A) and Potency (B) are added up
 2. the scores are also added up for:
 - Proportion of the diet coming from treated animals (C)
 - Frequency of dosing with a particular substance (D)
 - Evidence of high exposure groups (E)
 3. is the score for the Evidence of detectable residues (F).
- The totals for 1, 2 and 3 are multiplied together to get an overall score.

High exposure groups

Score	Definition
0	Knowledge that there are no high exposure groups.
1	Unlikely to be high exposure groups.
2	Likely to be high exposure groups.
3	Knowledge that there are high exposure groups or no data on which to make a judgement.

Evidence of detectable residues

Score	Definition
1	No evidence of detectable residues for a substance/ food combination included in last year's surveillance.
2	Residues detected in previous year at concentrations below the MRL/MRPL.
3	Residues detected at the MRL/MRPL in previous year, or intelligence from RASFFs or other sources that a particular substance is being detected.
4	Residues detected at concentrations ten or more times the MRL/MRPL in previous year. Residues where no limit has been set, or no previous tests carried out, but there is some intelligence of possible presence in food.

Matrix Ranking Principles

In 'Matrix Ranking', specific criteria and weightings were developed, against which candidate substances were assessed. The Committee hopes stakeholders see this as an open and transparent system for prioritising the sampling under the VMD's Non-Statutory Surveillance Scheme.

Results for all of the substances so far assessed and a fuller explanation is on the VRC website.

From April 2008, the State Veterinary Service, Defra's Egg Marketing Inspectorate and Dairy Hygiene Inspectorate were brought together to form a new Defra agency, Animal Health.

The Central Science Laboratory became part of the Food and Environment Research Agency (Fera) from 1 April 2009. Fera is an executive agency of Defra.

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

- Animal Health (previously the State Veterinary Service) of Defra – collects statutory samples from livestock farms in Great Britain, and carries out follow-up investigations on farms in Great Britain.
- Border Inspection Posts (BIPs) – Port Health Officers at the BIPs collect samples of imported foods for the Non-Statutory Surveillance 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.
- In Northern Ireland, the Department of Agriculture and Rural Development (DARD) collects samples for the National Surveillance Scheme (NSS) on behalf of the VMD. DARD also carries out follow-up investigations.
- Egg Marketing Inspectorates (EMI) of Animal Health and the Scottish Government, Rural Payments & Inspections Directorate – collect statutory samples of eggs from packing stations.
- Fisheries Research Services (FRS) collects statutory samples and carries out follow-up investigations on fish farms in Scotland.
- Meat Hygiene Service (MHS) of the Food Standards Agency (FSA) – collects statutory samples from abattoirs; it also has powers to detain animals suspected of containing residues above the Maximum Residue Limit or of having been treated with unauthorised substances.
- Mintel International Group Limited, a market research company, buys samples of foods from shops and wholesalers for the Non-Statutory Surveillance Scheme.

Analysing samples

- Central Science Laboratory (CSL) – analyses samples collected under the Non-Statutory Surveillance Scheme and samples of honey for the NSS.
- Agri-Food and Biosciences Agency analyses samples for the NSS in Northern Ireland.
- LGC limited, analyses samples collected under the NSS in Great Britain, apart from honey.

Investigating non-compliant samples

- AH, Cefas, DARD and FRS investigate the reasons for non-compliant samples in their respective areas (see collecting samples, above).
- Food Standards Agency (FSA) has a responsibility for food safety and protecting consumers' interests in relation to food. It co-ordinates some food safety incidents. It also organises food withdrawals and recalls on non-compliant domestic and imported produce.
- The Investigations Branch of the Rural Payments Agency carries out investigations where the circumstances mean a prosecution may result.
- Legal Department of Defra – prepare the national legislation in Great Britain covering the NSS and assess evidence to see if prosecutions should be brought.
- Animal Medicines Inspectorate of the VMD – inspects feed mills that produce medicated feed.



Overseeing the surveillance

- Veterinary Residues Committee (VRC) examines the plans and makes recommendations about the surveillance and also scrutinises the results.
- European Commission – in conjunction with the other Member States, examines and approves the National Surveillance Plans. It also issues the Rapid Alerts, to tell all Member States when residues of potential health concern are detected in the Community.
- FSA – acts as UK contact for the EU's Rapid Alert system.
- AFBI, AH, FSA, CSL and LGC Limited attend VRC meetings as advisors.

Accreditation of analytical laboratories

What standards do the analytical laboratories work to?

All analytical methods used in the surveillance schemes are accredited to ISO 17025. This is the international standard that ensures that the analytical methods are fit for purpose. In addition, the methods for substances listed in Annex I, Group A of Council Directive 96/23/EC must also comply with the requirements of Commission Decision 2002/657/EC. This specifies method performance characteristics, to give confidence in the identification and quantification of residues.

What checks are there?

Laboratories are subject to a range of audits:

- United Kingdom Accreditation Service (UKAS) audits annually against ISO 17025
- EC Food and Veterinary Office (FVO) inspects every 3-5 years to check compliance with Decision 2002/657/EC and other Community legislation
- VMD audits LGC Limited twice each year to ensure compliance with Community legislation and contractual specifications
- US Department of Agriculture audit LGC Limited and the Agri-Food and Biosciences Institute annually to ensure that analyses meet the requirements of US legislation
- British Standards Institute (BSI) audits against the quality standard ISO 9001.

The laboratories also take part in proficiency test schemes such as the Food Analysis Performance Assessment Scheme (FAPAS). These allow laboratories to compare their individual results with a 'consensus mean' after each has tested the same sample using their own methods.

The VMD sometimes requests that unusual or potentially contentious results obtained at one laboratory are repeated at another accredited laboratory. Such second laboratory analyses have confirmed the original result.

The substances listed in Annex I, Group A of Council Directive 96/23/EC include: hormonal substances that might be used for growth promotion, beta-agonists and also substances for which no safe limit can be set for their residues. More information can be found in Annex I of Council Directive 96/23/EC and Annex IV of Council Regulation 2377/90.

Details of UKAS, FAPAS, FVO and BSI are available from their websites.

www.ukas.com

www.fapas.com

http://ec.europa.eu/food/fvo/index_en.htm

www.bsi-global.com/

Explanation of the Significance of Veterinary Residues

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

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

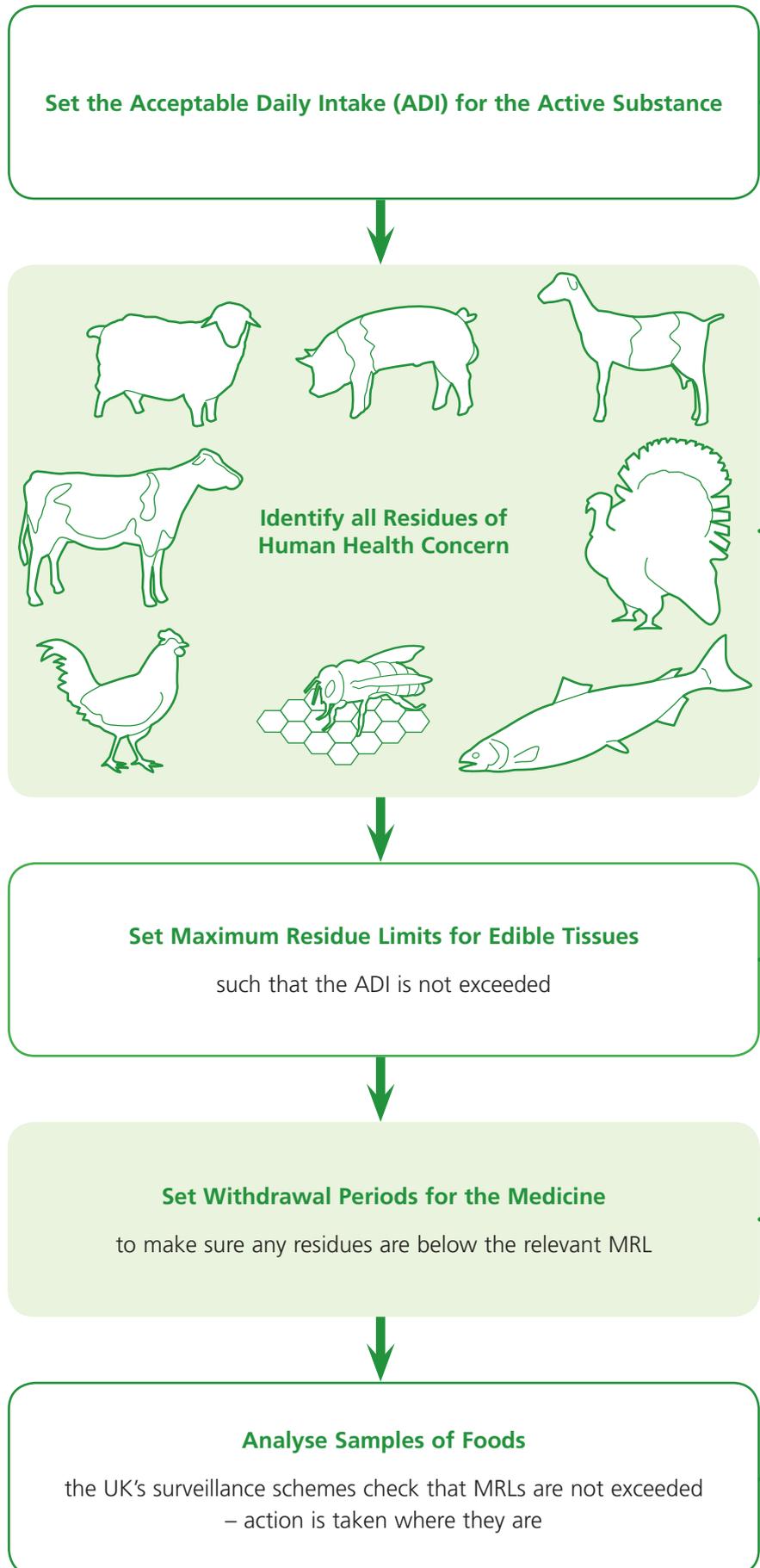
Understanding the regulatory process for veterinary medicines can help put the results of surveillance in context. Central to the process is an assurance that the use of veterinary medicines should not result in any consumer exceeding the Acceptable Daily Intake, or ADI.

Who Sets Maximum Residue Limits?

International committees of scientific experts set MRLs.

In the European Union, the Committee for Medicinal Products for Veterinary Use (CVMP) assess safety data to set MRLs. The CVMP is part of the European Medicines Evaluation Agency. Additionally, the European Food Safety Authority sets MRLs for certain feed additives, such as coccidiostats.

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.



Setting the Acceptable Daily Intake

International regulatory bodies assess data from a wide range of short and long-term studies. From these, they identify the quantity that had no adverse effect in any of the studies – the ‘No Observable Adverse Effect Level’ or NOAEL. This quantity is then divided by an uncertainty factor, typically 100-1000, to allow for possible differences between species and individuals and compensate for other uncertainties in the data.

This quantity 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. Treated animals may convert the active substance in the medicine to other substances, called metabolites, which can themselves be pharmacologically active. The regulatory process takes account of this.

Setting Maximum Residue Limits (MRLs)

The ADI is divided among all the edible tissues where a substance is authorised (including honey and milk), 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 and so also below the ADI.

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 risk to the consumer.

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 Observable Adverse Effect Level or NOAEL

– is the greatest concentration or amount of a substance, found by experiment or observation, that causes no detectable adverse alteration of morphology, functional capacity, growth, development, or life span of the target organism under defined conditions of exposure.

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 each day (based on a 60 kg person) are:

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

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

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

In the National Surveillance Scheme, a Veterinary Officer (VO), Fish Health Officer (FHO), or Bee Health Officer (BHO) visits the farm of origin to investigate the cause. They may also give the farmer advice on how to avoid such residues. Among the things the VO, FHO or BHO can examine in detail are:

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

What happens when a residue of an unauthorised substance or major exceedence of an MRL is found?

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 assessed later by Defra's lawyers to see if there is sufficient to warrant a prosecution. On the initial visit to a farm, a VO, FHO or BHO may accompany the IO to give technical advice.

What actions do they undertake?

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 the Police and Criminal Evidence Act, 1984 (PACE)
- examine the medicines records
- take further samples from the farm to confirm the previous finding.
- The follow-up samples would usually be analysed at the LGC Limited (see page 40).

Further sampling

If the follow-up sample or samples were non-compliant, the VO, FHO or BHO 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 bought-in livestock are suspected as the source of the residue. In this case, the feed mill or the breeding farm supplying the original farm could be visited and inspected.

Continued surveillance

If the further sampling described above finds more non-compliant samples, more visits may be made to the farm and more samples taken. Restriction notices on the farm may also be maintained.



Slaughter

Where follow-up sampling on a farm reveals residues of unauthorised substances, the VMD can require by law*, that the affected animals are slaughtered and do not enter the food chain.

Conclusion

At the end of the enquiry, the information is submitted to the lawyers in Defra's Legal Branch. They would decide if there was sufficient evidence for a successful prosecution and assess if a prosecution was in the public interest. Restriction notices could be kept in place until it can be demonstrated there are no more unacceptable residues. The farm could also be targeted for intensive sampling in the future.

Follow-up actions in the Non-Statutory Surveillance Scheme

The VMD tells the retailer of any samples bought from their stores with residues above the relevant MRL, MRPL or Action Level. The VMD also informs the Food Standards Agency (FSA). If the food concerned is imported, the Chief Veterinary Officer of Defra is informed. He writes to his opposite number in the country concerned and asks them to report the outcome of any action that is taken to avoid recurrence.

The FSA can decide to ask local authorities to investigate if a legal breach or residues of health concern are detected – for example, of banned substances. The FSA can also request and oversee product withdrawals and redispach or re-export to a third country where this is appropriate.

The FSA also operates 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. The Commission can also decide if further steps should be taken with regard to particular foods of animal origin entering the EU from a specific country.

* The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997 as amended.

The risk assessment process

We report residues found above the MRL or the relevant Action Level. What does this mean in terms of any risk to consumers? Whenever such residues are found, their health significance to consumers is assessed. This is often done by comparing the amount a consumer might have eaten with the Acceptable Daily Intake, or ADI.

The ADI is the amount of a residue that is considered safe to consume daily over a lifetime. It might be that single or limited exceedences of the ADI may not be of health concern. However, for some substances a single exceedence would be of concern. So, the seriousness of any exceedence has to be judged case-by-case, depending on what basis the ADI was originally set.

Risk Assessment consists of four stages:

- 1. Hazard identification** – identifying the toxicological, pharmacological and microbiological properties of medicine 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' (NOAEL) 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. The uncertainty factors normally reduce the amount to between 1/100 to 1/1000 of the NOAEL.

- 3. Exposure assessment** – the surveillance schemes measure the concentrations of any residues of veterinary medicinal products (VMPs) 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 to which consumers might be exposed is calculated.
- 4. Risk characterisation** – by comparing the exposure and hazard information generated in stages 1 to 3, the likelihood of adverse effects occurring and their severity in consumers exposed to the residue can be estimated.

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. This may involve a review of any new data, and 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.

Glossary



ACCEPTABLE DAILY INTAKE – 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 risk to the consumer.

ACTION LEVEL – where there is no MRL for a particular substance, usually any confirmed residue above the CC α or LOQ will trigger a follow-up investigation. However, if there are no health concerns associated with particular residues, a higher concentration can be set – the Action Level. This is to prioritise the limited resources for investigations.

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 Council Regulation 2377/90/EC's annexes. Annex IV indicates that on safety grounds no MRL can be set. Substances in Annex IV may not be administered to food-producing animals.

ANTHELMINTICS – are used to control internal parasites, such as tapeworms and roundworms in farm animals.

ANTIMICROBIALS – compounds that, at low concentrations, exert an action against micro-organisms 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, micro-organisms (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 micro-organisms.

BORDER INSPECTION POST – foods of animal origin imported from countries outside of the European Union must arrive at designated Border Inspection Posts, such as at Tilbury docks. Here documentation and other checks can be made, including taking samples for residues analysis.

BRAND NAMING SURVEY – a one-off survey where information, such as the brand on the packet and name of the shop where it was bought, is published.

CC α – the Decision Limit. This is the concentration of a drug residue in a sample at which it is decided that the sample is non-compliant with a pre-defined statistical certainty.

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.

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

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

Fera – the Food and Environment Research Agency, an agency of Defra, which incorporated the former Central Science laboratory.

GENOTOXIN – a substance that damages DNA. A genotoxin can cause mutations in DNA (and so be a mutagen), it can trigger cancer (and so be a carcinogen), or it can cause a birth defect (and so be a teratogen).

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 analysed for in the National Surveillance Scheme.

HORMONES – Hormones are substances 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. There are also synthetic, hormonally-active substances, such as STILBENES, GESTAGENS and THYROSTATS. Administering any hormonally-active substances to increase growth rate in food-producing animals is banned in the EU. Some hormonal substances have legal therapeutic uses and may also be used for controlling oestrus in farm animals.

INVESTIGATION OFFICER – a member of the Rural Payments Agency of the Department for Environment, Food and Rural Affairs. Usually these are ex-police officers and are trained in taking statements.

LIMIT OF QUANTIFICATION (LOQ) – the smallest analyte concentration for which a method has been validated with specified accuracy and precision.

MATRIX – The sample of, for example, eggs, liver, kidney, milk, muscle or animal feed, analysed for the presence of a residue. (This use of matrix is different from Matrix Ranking for prioritising substances to be included in the Non-Statutory Surveillance Scheme, as described on pages 37 to 39).

MAXIMUM RESIDUE LIMIT – is the maximum concentration of a residue that is legally permitted or acceptable in or on a food. It is expressed in µg/kg of that food. When determining MRLs, the ADI must not be exceeded after considering intake from all sources.

METABOLITE – substances entering the body are usually converted into other chemicals, which are known as metabolites. Some of these metabolites can pose a risk to consumers e.g. leucomalachite green

MRPL – Minimum Required Performance Limit: the European Commission set concentrations for residues of some Annex IV and certain other banned substances that all Member States must be able to detect (See inside back cover).

MYCOTOXINS – are 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.

NITROFURANS – were previously authorised as veterinary medicines 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.

NON-COMPLIANT – a non-compliant sample is a sample which on confirmatory analysis is shown to have a concentration of an authorised substance above the MRL, MRPL or Action Level. Where these have not been set for the substance or the matrix concerned, the measured concentration of a non-compliant sample will be equal to or above the CC α .

NON-STATUTORY SURVEILLANCE SCHEME – this scheme, funded by Defra, currently concentrates on imported and processed foods. As such, it complements the statutory National Surveillance Scheme, which tests domestic produce.

NSAIDS – are non-steroidal anti-inflammatory drugs. Carprofen 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 may be used as veterinary medicines, such as sheep dips, to control ticks and mites. They are also widely used as insecticides.

RAPID ALERT SYSTEM FOR FEED AND FOOD, 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.

TERATOGEN – is a substance that can cause birth defects. Teratogenicity is the ability of a chemical to cause birth defects. Teratogenicity results from a harmful effect to the embryo or the fetus/foetus.

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

The Veterinary Residues Committee

The Veterinary Residues Committee (VRC) is an independent advisory committee, established in January 2001. It is part of the Government's commitment to make all advisory committees more open and independent.

All members are appointed in line with the code of practice of the Commissioner for Public Appointments. The code of practice sets out the regulatory framework for the public appointments process and is based on the seven 'Nolan' Principles of Public Life.

Terms of Reference

The VRC was established in January 2001 to:

- advise Ministers¹ (where appropriate) and the Chief Executives of the Veterinary Medicines Directorate (VMD) and the Food Standards Agency (FSA) on the incidence and concentrations of residues of veterinary medicines² in samples collected under the VMD's surveillance programmes, with particular reference to food safety and observance of withdrawal periods for veterinary medicines³;
- to assess and advise on the scope and operation of the VMD statutory surveillance programme within the requirements of European Community legislation;
- to formulate an annual non-statutory surveillance programme, advise on the scope and results of relevant FSA surveys and consider the need for further analytical surveys;
- to set up subgroups as necessary to further the work and objectives of the VRC; and
- to publish an Annual Report on Veterinary Residues Surveillance, and to communicate the VRC's findings and recommendations to Government and stakeholders in a comprehensive, understandable and timely way.

1 The Ministers referred to are: The Secretary of State for Environment, Food and Rural Affairs, Ministers of the Scottish Executive, the National Assembly for Wales and the Minister for Agriculture and Rural Development Northern Ireland.

2 In addition to veterinary medicines, surveillance also covers banned substances, heavy metals (lead and cadmium), malachite green, organochlorines (OCs), organophosphates (OPs), and polychlorinated biphenyls (PCBs).

3 A 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 Maximum Residue Limit (MRL).

Membership of the Veterinary Residues Committee in 2008

All of the Members were appointed in line with the code of practice of the Commissioner for Public Appointments*. Members were chosen to give the Committee a wide range of expertise in areas relevant to residues surveillance and consumer matters. The members were:



Dorothy Craig MBE,
Chairman



John Ambrose ⁱ
Local Authority



Dr Paul Brantom ^{ij}
Toxicology/Food Safety



Sarah Buckley
Consumer



Mr Neil Cutler OBE ⁱ
Farming



Susan Knox
Consumer



Stephen Lister
Veterinary



Dr W John McCaughey
Analytical Chemistry



Stephen Spice ⁱ
Retail



Dr Brian Vernon ⁱ
Feed Industry



Dr Keith Lawrence ^{ik}
Pharmaceutical Industry



Dr Shirley Price ^k
Toxicology



* The code of practice sets out the regulatory framework for the public appointments process and is based on the seven 'Nolan' Principles of Public Life.

Short biographies of the current VRC Members are on the VRC website: www.vet-residues-committee.gov.uk

i = This member retired from the Committee in 2008, see overleaf for the names of new members that were appointed for 2009.

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

k = No photograph was available.

Membership of the Subgroups

To further its work, the Committee has three subgroups. These specialise in: communicating the work of the Committee; planning the VMD's Non-Statutory Surveillance Scheme; and developing the Committee's Matrix Ranking system of prioritising surveillance.

The Communications Subgroup members were:

Dr Paul Brantom Chairman
Mrs Sarah Buckley
Mr Neil Cutler OBE
Mr Stephen Lister

The Non-Statutory Surveillance Subgroup members were:

Mrs Dorothy Craig MBE Chairman
Mr John Ambrose
Dr Paul Brantom
Mrs Susan Knox
Dr W John McCaughey
Mr Stephen Spice

Matrix Ranking Subgroup members were:

Dr Paul Brantom Chairman
Dr W John McCaughey
Dr Shirley Price

New Members appointed to the VRC for 2009

Mr Jon Avern Local Authority
Mr Tim Brigstocke Farming
Dr Gill Clare ¹ Toxicology/Risk Assessment
Mr Andrew Grant Fish Farming
Mr Declan O'Rourke Pharmaceutical Industry
Mr David Ralph Feed Industry
Mr Mark Ranson Retail Sector
Professor Mike Roberts CBE Food Industry

¹ = Dr Gill Clare was nominated by the Food Standards Agency to advise on food safety and risk assessment.



Contact addresses

The Veterinary Residues Committee

Mrs Dorothy Craig MBE, Chairman
Veterinary Residues Committee
Woodham Lane
New Haw
Addlestone
Surrey
KT15 3LS

Website: www.vet-residues-committee.gov.uk

The VRC Secretariat

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

Tel: 01932 336911

E-mail: vrcsecretariat@vmd.defra.gsi.gov.uk

Website: www.vmd.gov.uk

Food Standards Agency

Food Standards Agency
Pesticides, Veterinary Medicines and Biocides Branch
Aviation House
125 Kingsway
London
WC2B 6NH

Tel: 0207 276 8829

E-mail: helpline@foodstandards.gsi.gov.uk

Website: www.food.gov.uk

Reference Points – the concentrations that trigger follow-up actions

The Reference Points act as trigger concentrations for a follow-up investigation on the farm of origin of the animal product to find the cause of the residue, or for a sample to be flagged as a 'non-compliant' sample. Usually these are the Maximum Residue Limits (MRLs), which are legal limits, but where there is no MRL other points are used:

- **Action Level** – where there is no MRL for a particular substance, usually any confirmed residue above the CC α or LOQ will normally trigger a follow-up investigation. However, if there are no health concerns associated with particular residues, the VRC can recommend that a higher concentration is set – the Action Level. This is to prioritise the limited resources for investigations.
- **Limit of Quantification (LOQ)** – the smallest analyte concentration for which a method has been validated with specified accuracy and precision.
- **CC α** – The 'Decision Limit, or CC α , is the concentration of a drug residue in a sample at which it is decided that the sample is non-compliant with a pre-defined statistical certainty. (See page 29. For substances without any statutory concentrations, CC α replaces LOQ.)
- **Minimum Required Performance Limit (MRPL)** – for some banned substances, the EU has set MRPLs. Originally to harmonise analytical capability, these are the concentrations at or above which the EU requires enforcement action in imported produce.

The MRPLs relevant to veterinary surveillance are:

Substance	Concentration ($\mu\text{g}/\text{kg}$)
Chloramphenicol	0.3
Malachite green	2 (Sum of malachite green and its metabolite, leucomalachite green)
Medroxyprogesterone acetate	1
Nitrofurans	1 (Sum of the metabolites, AHD, AMOZ, AOZ and SEM,)

AHD = 1-aminohydantoin idinone
 AMOZ = 5 methylmorpholino-3-2-oxazolol
 AOZ = 3-amino-2-oxazolidone
 SEM = semicarbazide

The Veterinary Residues Committee understands why the EU has set MRPLs. But, the Committee recommends **all** confirmed residues of unauthorised or banned substances should be reported to them. Such samples do not necessarily imply health concerns, but it is for the relevant authority, such as the Food Standards Agency or Veterinary Medicines Directorate to decide what actions were appropriate to manage any risk.

How Maximum Residue Limits are set and what happens if a concentration above one of the Reference Points is exceeded is explained on pages 42 and 43.



The Veterinary Residues Committee,
Woodham Lane, New Haw, Addlestone, Surrey KT15 3LS
vrsecretariat@vet-residues-committee.gov.uk