Annual Report on Surveillance for Veterinary Residues in Food in the UK 2007

VETERINARY RESIDUES COMMITTEE

What is the role of the Veterinary Residues Committee?

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 intelligence 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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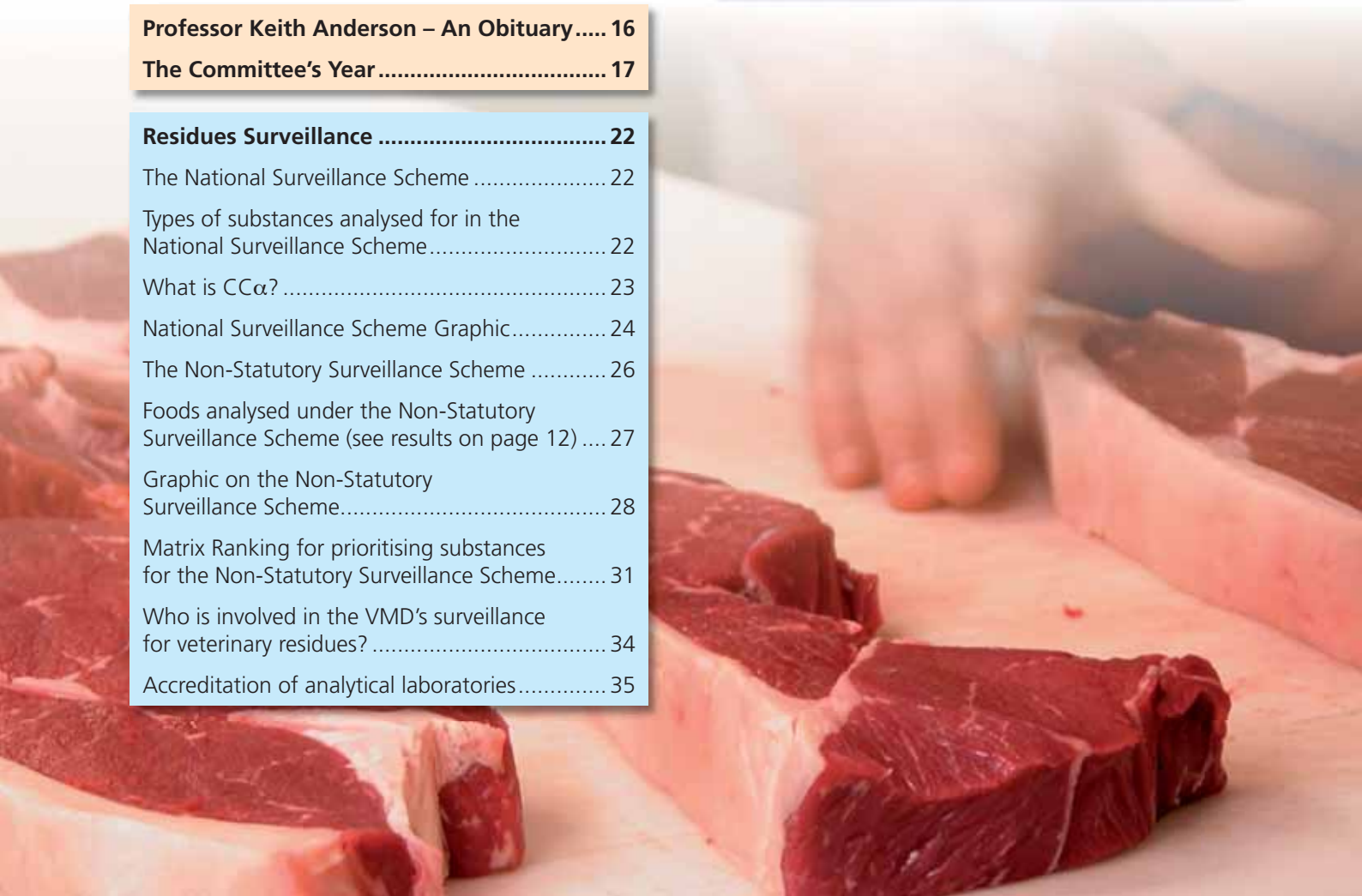


Chairman's Introduction

Dorothy Craig MBE, Chairman

The Committee was saddened to hear of the untimely death of Professor Keith Anderson in October 2007. Keith provided expertise on the food chain to the Committee, and was a valued member from its inception in 2001. His input is missed. There is an obituary to Keith on page 16.

Clear communication with stakeholders is one of the Committee priorities, so it was delighted to launch its new look website during the summer. We hope you will find it a valuable source of information. As always we welcome suggestions from readers.

On the domestic front, the Committee was again pleased to note the low number of non-compliant samples in the National Surveillance Scheme.

As analytical methods become more sensitive, it is inevitable that more samples will test non-compliant. There have been two examples of this during the year. In the first case, chloramphenicol was detected in duck muscle. The farm of origin was visited, and no evidence of the presence or use of illegal substances was detected. It emerged that the sampling officer in the abattoir was using eye-drops. The Meat Hygiene Service has updated and re-issued its guidance to staff on avoiding cross-contamination whilst sampling.

Secondly, the continued detection of hormonal substances – principally progesterone and nortestosterone in cattle – where follow-up investigations at the farms of origin found no evidence of abuse. This will increase the cost of the surveillance programme to a hard-pressed industry, and causes concern to those producers involved. It may also cause unnecessary consumer concern. The VRC is therefore very interested in the research being carried out into analytical methods to distinguish between naturally occurring hormones and abuse. This would reduce the number of follow-up investigations needed. The Committee will return to this issue in 2008.

The Committee held its Open Meeting away from London for the first time. We received a warm welcome in Belfast, where the Committee was delighted with the level of interest shown in its work. Encouraged by this, the 2008 meeting will be held in Glasgow, where we also hope to learn more about farming and consumer issues in Scotland.

Now I turn to the Non-Statutory Surveillance Programme, which looks largely at imports. The Committee this year consulted stakeholders over matrix/analyte combinations and this will become a regular feature of the Committee's work. It is clear from the responses that this programme concerns a wide range of stakeholders. This is particularly the case when substances prohibited from use in the EU are found in imports. In 2008, the Committee will continue to seek more funding for imports surveillance.

We look forward to seeing reduced non-compliances following the government/industry initiative on nicarbazin in poultry that was facilitated by the Food Standards Agency. In 2005, we completed the VRC's work to establish the reasons for unacceptably high levels of non-compliance and encouraged the industry to put its house in order, which the FSA has taken forward.

Regretfully, at the end of 2008, we say goodbye to those Members who have served eight years on the Committee. They have my sincere thanks, and those of fellow members, for their hard work and expertise in building up the Committee. As they look through this Report, they can be proud of their part in creating a genuinely independent body, providing expert advice on a wide range of residues issues to Government and explaining the implications to all our stakeholders.

Dorothy Craig MBE

Key Results and Actions Taken on Residues in 2007

Each sample in the National Surveillance Scheme is tested for a specific substance or a small 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/07/15, VRC/07/26 and VRC/07/40.

The results presented are mainly those for samples taken in the calendar year 2007. However, for completeness, the results for follow-up samples taken in 2006 have been included.

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

The residues of leucomalachite green in the farmed salmon did not arise as a result of a recent use of malachite green. The follow-up investigation found that the residues came from a previously contaminated filter bed (see page 9).

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.

Summary for the National Surveillance Scheme

In the National Surveillance Scheme (NSS), 33,493 samples were collected and 38,749 analyses were carried out. There were 109 residues in excess of statutory or other limits (see Reference Points on page 49). Of these, 49 residues were likely to have occurred from the use of veterinary medicinal products (VMPs). Comparative figures for 2003-2007 are in the table below.

Analyses and non-compliant samples in the NSS from 2003-2007

Year	No of analyses	Samples at or above Reference Points	Those from veterinary medicinal products
2003	35,399	137	89
2004	39,475	137	75
2005	37,067	120	55
2006	38,257	101	50
2007	38,749	109	49

Usually, when residues were detected above the relevant Reference Point, a follow-up investigation was carried out on the farm of origin. These assessed the causes of the residues and gave advice 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.

Overall, the findings of the NSS indicated that the UK authorised uses of VMPs did not result in residues of human health concern.

However, residues of substances **not** authorised for use in food-producing animals were detected. Two samples were found to contain residues of phenylbutazone. Additionally, malachite green residues were detected in one sample of farmed trout and one of farmed salmon. While the incidence of such residues remains low, the Committee see any use of unauthorised substances in food-producing animals as unacceptable. The VRC endorses the strong action taken by the VMD to ensure destruction of the affected fish and will support continued vigilance against such use.

Summary for the Non-Statutory Surveillance Scheme

For the Non-Statutory Surveillance Scheme, a total of 1,485 samples were collected and 5,375 analyses completed in the rolling programme and a brand-name survey.

A total of 26 samples contained residues at concentrations above the relevant statutory or other limits (Reference Points).

Where imported produce was found to contain residues that are illegal in the UK, Defra's Chief Veterinary Officer wrote to her opposite number in the country of origin, where this was known. In these cases, she 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 recalls were undertaken where appropriate, and inform the European Commission, which can issue a Rapid Alert informing other Member States.

A total of 26 samples contained residues at concentrations above the relevant statutory or other limits.

Residues of possible health concern

Four residues of possible health concern were detected in UK produce, while 24 were detected in imported produce. These residues are listed below and more information is given in the detailed results sections.

UK Produce:

- leucomalachite green residues were detected in 1 of 129 farmed salmon samples tested (0.78%)
- leucomalachite green residues were detected in 1 of 108 farmed trout samples tested (0.93%)
- phenylbutazone residues were detected in 1 of 284 cattle plasma samples tested (0.35%)
- phenylbutazone residues were detected in 1 of 30 horse plasma samples tested.

Imported Produce:

- chloramphenicol residues were detected in 18 of 71 royal jelly samples tested in a brand-name survey
- crystal violet residues were detected in 1 of 300 samples of farmed fish tested under the rolling programme (0.33%)
- leucocrystal violet residues were detected in 1 of 300 samples of farmed fish tested under the rolling programme (0.33%)
- nitrofuran residues were detected in 2 of 300 samples of farmed fish tested under the rolling programme (0.67%)
- nitrofuran residues were detected in 2 of 136 warm-water crustaceans tested under the rolling programme (1.47%).

Results in Detail

National Surveillance Scheme 2007 – residues at or above the Reference Point (see inside rear cover)

Sample	Analysed for	Number of samples analysed	Reference Point (µg/kg)	Samples above the Reference Point	
				Number found	Concentration (µg/kg)
Eggs	Nicarbazin	234	25	2	40, 60
Salmon Muscle	**Malachite green/ leucomalachite green**	129	2 (MRPL sum of both substances)		
	Leucomalachite Green			1	10
Salmon Muscle	**Antimicrobials**	84			
	Oxytetracycline		100 (MRL)	2	1010, 1880
Salmon Muscle	**Tetracyclines**	84			
	Oxytetracycline		100 (MRL)	2	300, 530,
Tilapia Muscle	**Antimicrobials**	3			
	Oxytetracycline		100 (MRL)	1	390
Trout muscle	**Malachite green/ leucomalachite green**	108	2 (MRPL sum of both substances)		
	Leucomalachite Green			1	6
Honey	Naphthalene	10	10	2	88, 120
Broiler Liver	**Coccidiostats**	308			
	Nicarbazin		200 (JECFA MRL)	20	240, 250, 250, 260, 280, 290, 310, 320, 350, 430, 540, 560, 600, 760, 1200, 1300, 1400, 1400, 1800, 3000,
Broiler Liver	**Ionophores**	320			
	Lasalocid		100 (MRL)	1	740
Broiler Muscle	Nicarbazin	169	200 (JECFA MRL)	1	240
Broiler Muscle	**Antimicrobials**	1158			
	Sulphadiazine		100 (MRL)	1	350
Duck Muscle	Chloramphenicol	28	0.3 (MRPL)	1	0.4
Calf Kidney	**Antimicrobials**	136			
	Oxytetracycline		600 (MRL)	2	1430, 9800
	Dihydrostreptomycin		1000 (MRL)	3	20000, 20300, 31200
Calf Kidney	Florfenicol	92	300 (MRL)	2	390, 490

Sample	Analysed for	Number of samples analysed	Reference Point (µg/kg)	Samples above the Reference Point	
				Number found	Concentration (µg/kg)
Cattle Kidney	**Antimicrobials**	1290			
	Dihydrostreptomycin		1000 (MRL)	1	1900[a]
	Neomycin		5000 (MRL)	1	19000[a]
	Tylosin		100 (MRL)	1	870
Cattle Kidney	**Heavy Metals**	79	1000 (MRL)		
	Cadmium			9	1030, 1060, 1060, 1150, 1160, 1180, 1383, 1630, 2420,
	Lead		500 (MRL)	1	860
Cattle Muscle	Lead	11	100 (MRL)	1	110
Cattle Plasma	Phenylbutazone	284	5	1	6
Cattle Serum	Progesterone	237	0.5 (Action Level)	7	0.6, 0.6, 0.7, 0.7, 1, 1, 1.5
Cattle Urine	Boldenone	445	1 (Action Level)	2	2, 17
Cattle Urine	Nortestosterone	606	0.5/5.0[b] (Action Level)	14[c]	3, 6, 6, 8, 10, 12, 14, 17.1, 20, 20, 26, 30, 50, 80
Cattle Urine	Zeranol	330	0.3 (Action Level)	2	0.9, 2
Horse Plasma	Phenylbutazone	30	5	1	2[d]
Pig Kidney	**Antimicrobials**	791			
	Chlortetracycline		600 (MRL)	2	1780, 2100
Pig Kidney	**Sulphonamides**	790			
	Sulphadiazine		100 (MRL)	4	130, 330, 940, 2700
Sheep Kidney	**Heavy Metals**	51			
	Cadmium		1000 (MRL)	4	1730, 2040, 2530, 2990
	Lead		500 (MRL)	4	520, 1060, 1720, 2040
Sheep Liver	**Avermectins**	593			
	Doramectin		100 (MRL)	1	120
Sheep Urine	Nortestosterone	172	0.5/5.0[c] (Action Level)	11	0.7, 0.8, 1, 1, 1, 1, 1.1, 1.2, 2, 2, 4

a = One sample contained residues of both dihydrostreptomycin and neomycin
b = The Action Level for nortestosterone was 0.5 µg/kg for males and 5.0 µg/kg for females
c = Of the 14 samples listed for nortestosterone in Cattle Urine, 11 were female
d = Residue was confirmed below the Reference Point

Follow-up samples taken as a result of investigations into residues taken as part of the National Surveillance Scheme

Follow-up samples from the 2006 programme

Sample	Analysed for	Number of samples analysed	Reference Point (µg/kg)	Samples above the Reference Point	
				Number found	Concentration (µg/kg)
Egg	Antimicrobials	1	Various	0	
Egg	Ionophores	7	150 (MRL)	0	
Egg	Nicarbazin	2	25	0	
Salmon Muscle	**Malachite green/ leucomalachite green**	2	2 (MRPL sum of both substances)	0	
Trout Muscle	Cadmium	1	50 (MRL)	0	
Trout Muscle	**Malachite green/ leucomalachite green** Leucomalachite green	2	2 (MRPL sum of both substances)	2	100, 200
Milk	Aflatoxins	1	0.05	0	
Milk	Antimicrobials	2	Various	0	
Milk	Cephalosporins	1	Various (<70)	0	
Milk	Quinolones	1	Various (<50)	0	
Broiler Feed	Nicarbazin	1	10	0	
Hen Feed	**Ionophores** Lasalocid	8	50	1	300
Hen Feed	Nicarbazin	1	10	0	
Cattle serum	Progesterone	37	0.5 (Action Level)	7	0.5, 0.5, 0.5, 0.6, 0.8, 1.0, 1.4
Cattle serum	Oestradiol	11	0.04 (Action Level)	0	

Follow-up Samples from the 2007 programme

Sample	Analysed for	Number of samples analysed	Reference Point (µg/kg)	Samples above the Reference Point	
				Number found	Concentration (µg/kg)
Honey	Naphthalene	22	10	7	43, 45, 62, 110, 300, 390, 980
Broiler Feed	Nicarbazin	2	10	0	
Broiler Feed	Ionophores	3	50	0	
Duck Feed	Chloramphenicol	5	500	0	
Cattle serum	Oestradiol	1	0.04 (Action Level)	0	
Cattle serum	Progesterone	24	0.5 (Action Level)	0	
Cattle urine	Nortestosterone	9	0.5/5[e]	1	4

e = 0.5ppb is the action level for male cattle and 5 is the action level for female cattle

Eggs

- Nicarbazin residues were detected in 2 of 234 egg samples tested (0.85%). These were at concentrations of 40 and 60 µg/kg.

Farmed Fish

- Leucomalachite green residues were detected in 1 of 129 salmon muscle samples tested (0.78%). This was at a concentration of 10 µg/kg.

Malachite green is not an authorised veterinary medicine and may not be used in food-producing animals. UK expert committees have concluded that both malachite green and leucomalachite green should be regarded as *in vivo* mutagens and that it would be prudent to regard leucomalachite green as a genotoxic carcinogen (http://www.advisorybodies.doh.gov.uk/com/malachit.htm). This conclusion was based on examination of long-term studies carried out in the USA.

Leucomalachite green is a metabolite of malachite green and can persist in the environment long after any use of malachite green has ceased.

The residues were thought to have come from two sand filters, which had become contaminated because of use of malachite green on the site in the past. These had been unused for some time, but recently recommissioned. Following the detection of the residues, they have been decommissioned and replaced. The affected fish were slaughtered and did not enter the food chain.

- Oxytetracycline residues were detected in 2 of 84 salmon muscle samples tested in an antimicrobial screen. These were at concentrations of 1,101 and 1,880 µg/kg.
- Oxytetracycline residues were detected in 2 of 84 salmon muscle samples tested in a screen for tetracyclines (these were additional to the samples detailed immediately above). These were at concentrations of 300 and 530 µg/kg.
- Oxytetracycline residues were detected in 1 of 3 tilapia muscle samples tested. This was at a concentration of 390 µg/kg.

All five residues of oxytetracycline listed above came from fish that were sampled in error. The fish were still under the Withdrawal Period for the treatments and should not have been sampled.

The five oxytetracycline residues detected came from fish that were sampled in error. The fish were still under the Withdrawal Period for the treatments and should not have been sampled at that time.

- Leucomalachite green residues were detected in 1 of 108 trout muscle samples tested (0.92%). This was at a concentration of 6 µg/kg.

Leucomalachite green residues should not be present in farmed fish, for the reasons given above. All fish on the site were placed under restriction to prevent them entering the food-chain and a follow-up investigation was undertaken.

Game

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

Honey

- Naphthalene residues were detected in 2 of 10 honey samples tested. These were at concentrations of 88 and 120 µg/kg.

Milk

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

Poultry

- Nicarbazin residues were detected in 20 of 308 broiler liver samples tested in a screen for coccidiostats (6.49%). These were at concentrations between 240 and 3000 µg/kg.

- Nicarbazin residues were detected in 1 of 169 broiler muscle samples tested (0.59%). This was at a concentration of 240 µg/kg.
- Lasalocid residues were detected in 1 of 320 broiler liver samples tested in a screen for ionophores (0.31%). This was at a concentration of 740 µg/kg.
- Sulphadiazine residues were detected in 1 of 1,158 broiler muscle samples tested in a screen for antimicrobials (0.09%). This was at a concentration of 350 µg/kg.
- Chloramphenicol residues were detected in 1 of 28 duck muscle samples tested. This was at a concentration of 0.4 µg/kg. This was above the EU MRPL of 0.3 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 can cause the serious blood disorder, aplastic anaemia.

Five further samples taken as part of the follow-up investigation were negative and the Animal Health Agency found no evidence of abuse of this substance. It was concluded that the chloramphenicol residue was likely to have resulted from contamination by the sampling officer.

Chloramphenicol is widely used in antibiotic eye-drops. The European Union requires that Member States are able to detect the very low concentration of chloramphenicol set as the MRPL. To do this very sensitive and specific analytical methods have been developed. This means they are very sensitive to the medicines used by the sampling officer. The Meat Hygiene Service has re-issued its guidance to staff on how to avoid cross-contamination from medicines they, their family or pets are taking.

Red Meat

- Antimicrobial residues were detected in 5 of 136 calf kidney samples tested in a screen for antimicrobial substances (3.67%):
  - Oxytetracycline residues were detected in 2 of 136 calf kidney samples tested (1.47%). These were at concentrations between 1,430 and 9,800 µg/kg.
  - Dihydrostreptomycin residues were detected in 3 of 136 calf kidney samples tested (2.21%). These were at concentrations between 20,000 and 31,200 µg/kg.
- Florfenicol residues were detected in 2 of 92 calf kidney samples tested. These were at concentrations of 390 and 490 µg/kg.
- Antimicrobial residues were detected in 3 of 1,290 cattle kidney samples tested in a screen for antimicrobial substances (0.23%):
  - Dihydrostreptomycin residues were detected in 1 of 1,290 cattle kidney samples tested (0.08%). This was at a concentration of 1,900 µg/kg.
  - Neomycin residues were detected in 1 of 1,290 cattle kidney samples tested (0.08%). This was at a concentration of 19,000 µg/kg.
  - Tylosin residues were detected in 1 of 1,290 cattle kidney samples tested (0.08%).This was at a concentration of 870 µg/kg.
- Heavy metal residues were detected in 10 of 79 cattle kidney samples tested in a screen for heavy metals:
  - Cadmium residues were detected in 9 of 79 cattle kidney samples tested. These were at concentrations between 1,030 and 2,420 µg/kg.
  - Lead residues were detected in 1 of 79 cattle kidney samples tested. This was at a concentration of 860 µg/kg.
- Lead residues were detected in 1 of 11 cattle muscle samples tested in a screen for heavy metals. This was at a concentration of 110 µg/kg.

- Phenylbutazone residues were detected in 1 of 284 cattle plasma samples tested (0.35%). This was at a concentration of 6 µg/l.

Phenylbutazone may not be used in cattle. This is because it can, in rare cases, cause serious blood disorders in humans, such as aplastic anaemia. 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.

The investigation established that cattle had not been fed with phenylbutazone treated feed. However, they had been held in a stable where a horse had previously been treated with phenylbutazone. It was therefore possible that the animal had eaten some straw contaminated with urine containing phenylbutazone. The farmer was advised on how to avoid such residues in the future.

- Progesterone residues were detected in 7 of 237 cattle serum samples tested (2.95%). These were at concentrations between 0.6 and 1.5 µg/l.
- Boldenone residues were detected in 2 of 445 cattle urine samples tested (0.45%). These were at concentrations of 2 and 17 µg/l.
- Nortestosterone residues were detected in 14 of 606 cattle urine samples tested (2.31%). These were at concentrations between 3 and 80 µg/l.
- Zeranol residues were detected in 2 of 330 cattle urine samples tested (0.61%). These were at concentrations of 0.9 and 2 µg/l.

Some strains of fusarium moulds can produce zeranol. Laboratory tests of the zeranol residues indicated that fungal contamination of cattle feed was the most likely source of the residues.

- Phenylbutazone residues were detected in 1 of 30 horse plasma samples tested. This was at a concentration of 2 µg/l.

Phenylbutazone is authorised in the UK for use in horses to treat musculoskeletal disorders as mentioned above. But treated horses should not then enter the food chain. This is for the reasons given above.

The owner did not have medicines records since the farm was not producing animals for the food chain – only two horses were kept there. The slaughtered animal had not been actively treated with phenylbutazone, but it was thought likely that it could have had access to some treated feed intended for the other horse on the premises.

The owner was instructed to mark the other horse's passport to ensure it did not enter for food chain. Animal Health will carry out further checks on the farm in future to ensure the horse passport and medicines records are being kept correctly.

- Chlortetracycline residues were detected in 2 of 791 pig kidney samples tested in a screen for antimicrobials (0.25%). These were at concentrations of 1,780 and 2,100 µg/kg.
- Sulphadiazine residues were detected in 4 of 790 pig kidney samples tested in a screen for sulphonamides (0.51%). These were at concentrations between 130 and 2,700 µg/kg.
- Heavy metal residues were detected in 8 of 51 sheep kidney samples tested in a screen for heavy metals:
  - Cadmium residues were detected in 4 of 51 sheep kidney samples tested. These were at concentrations between 1,730 and 2,990 µg/kg.
  - Lead residues were detected in 4 of 51 sheep kidney samples tested. These were at concentrations between 520 and 2,040 µg/kg.
- Doramectin residues were detected in 1 of 593 sheep liver samples tested in a screen for avermectins (0.17%). This was at a concentration of 120 µg/kg.
- Nortestosterone residues were detected in 11 of 172 sheep urine samples tested (6.4%). These were at concentrations between 0.4 and 4 µg/l.

Why are hormone residues detected?

Hormones occur naturally in all of the farm animals that we test. That the NSS detects them is to be expected, because of the very sensitive analytical methods used. The VMD believe all of the hormonal substances detected in this year's programme were due to natural production within the cattle and sheep tested, or fungal contamination of feed.

Non-Statutory Surveillance Scheme – residues at or above the Reference Point (see inside rear cover)

Rolling Programme

Sample	Analysed for	Number of samples analysed	Reference Point (µg/kg)	Samples above the Reference Point	
				Number found	Concentration (µg/kg)
Farmed warm-water crustaceans	**Nitrofurans**	136	1 (MRPL)		
	AOZ			1	5.5[f]
	SEM			2	1.3[f], 2.6
Imported farmed fish	**Crystal violet/ leucocrystal violet**	300	0.5 (Action Level)		
	Crystal violet			1	0.9
	Leucocrystal violet			1	3.7
	Nitrofurans	300	1 (MRPL)		
	AMOZ			1	1.8
	SEM			1	1.2
Imported pâté	Nicarbazin	100	25 (Action Level)	1	36
Imported raw beef	**Avermectins**	305			
	Abamectin		10 (Action Level)	1	16

Brand-Name Survey

Sample	Analysed for	Number of samples analysed	Reference Point (µg/kg)	Samples above the Reference Point	
				Number found	Concentration (µg/kg)
Royal jelly	Chloramphenicol	71	0.3 (MRPL)	18	0.33, 0.93, 1, 1.2, 1.4, 1.4, 1.5, 1.5, 3, 3, 3.1, 3.2, 3.4, 5.4, 5.5, 7.5, 13, 21

AMOZ = 3-amino-5-morpholinomethyl-1,3-oxazolidin-2-one
AOZ = 3-amino-2-oxazolidinone
SEM = Semicarbazide
f = Both residues found in a single sample

Rolling programme

Imported farmed warm-water crustaceans

- Nitrofuran residues were detected in 2 of 136 samples tested (1.47%):
  - AOZ residues (3-amino-2-oxazolidinone) were detected in 1 sample at a concentration of 5.5 µg/kg (0.74%).
  - SEM residues (semicarbazide) were detected in 2 samples at concentrations of 1.3 and 2.6 µg/kg (1.47%).

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.

One sample was of tiger prawn from India and contained both AOZ and SEM. The Acting Chief Veterinary Officer wrote to his Indian counterpart and asked to be kept informed of any action taken. The FSA in Scotland dealt with the follow-up action on this sample. The importers had a certificate of analysis from India stating the product was free of residues.

A sample of soft-shelled crab from the USA contained residues of SEM. The FSA was informed, but a Rapid Alert was not issued, as the crab had been supplied to a cruise ship, which had left British waters, so was outside the FSA's jurisdiction. However, the Deputy Chief Veterinary Officer wrote to the USA asking to be kept informed of any action taken.

Imported farmed fish

- Crystal violet / leucocrystal violet residues were detected in 2 of 300 samples tested (0.67%):
  - Crystal violet residues were detected in 1 sample (0.33%) at a concentration of 0.9 µg/kg
  - Leucocrystal violet residues were detected in 1 sample (0.33%) at a concentration of 3.7 µg/kg.

Crystal violet is of the same family of dyes as malachite green. It is, therefore, possible it may pose similar risks as malachite green. UK expert committees have concluded that both malachite green and leucomalachite green should be regarded as *in vivo* mutagens and it would be prudent to regard leucomalachite green as a genotoxic carcinogen (http://www.advisorybodies.doh.gov.uk/com/malachit.htm). This conclusion was based on examination of long-term studies carried out in the USA.

Both samples were of tilapia, one from Jamaica and the other from the People's Republic of China. Defra's Chief Veterinary Officer wrote to her opposite numbers in the countries concerned to ask to be kept informed of any action taken. The results were passed to the FSA, which informed the European Commission and Rapid Alerts were issued.

- Nitrofuran residues were detected in 2 of 300 imported fish samples tested (0.67%):
  - AMOZ (3-amino-5-morpholinomethyl-1,3-oxazolidin-2-one) residues were detected in 1 sample at a concentration of 1.8 µg/kg (0.33%)
  - SEM residues were detected in 1 sample at a concentration of 1.2 µg/kg (0.33%).

As stated above, nitrofuran residues should not be present in foods exported to the EU.

Origin of SEM residues

SEM is a marker residue for the illegal use of nitrofuran antibiotics. However, there are other reasons why it can occur in foods. When SEM residues are detected, an assessment has to be made to decide on how they arose.

AMOZ residues, indicative of using the nitrofuran furaltadone, were detected in a sample of sea bass from Greece. The product was recalled and the FSA posted a Rapid Alert for information.

SEM residues were detected in a sample of seafood sticks from India. The FSA assessed that the residue, on the balance of probabilities, may not have been the result of illegal nitrofuran use. Therefore, the sample was released as compliant and no Rapid Alert was issued.

Defra's Acting CVO wrote to both countries asking to be kept informed of any actions taken to avoid such residues in the future.

Imported pâté

- Nicarbazin residues were detected in 1 of 100 samples tested (1 %). This was at a concentration of 36 µg/kg. The sample was from France. The French authorities have since advised that the liver in the pâté came from the Netherlands. The FSA informed the authorities in the Netherlands of the finding.

Imported raw beef

- Abamectin residues were detected in 1 of 305 samples tested (0.33%). This was at a concentration of 16 µg/kg. The sample was from Chile. Toxicological advice is that this was not of consumer health concern.

Brand-name survey of royal jelly

- Chloramphenicol residues were detected in 18 of 71 samples tested. These were at concentrations of between 0.33 and 21 µg/kg. These were above the EU Minimum Required Performance Limit (MRPL) of 0.3 µg/kg for chloramphenicol residues.

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 can cause the serious blood disorder, aplastic anaemia.

Samples for the survey were bought from both shops and internet sites. Some of the internet sites were based abroad. Where samples from these sites were found to be non-compliant, the VMD contacted the relevant authorities asking them to take further action.

Of the 11 samples purchased from within the UK and found to contain residues of chloramphenicol, ten were from internet sites and one from a shop.

The concentrations detected were between 0.93 and 21 µg/kg. The country of origin of the sample bought from a shop is not known. There was no product left and the retailer agreed to display a point of sale notice. Of the remaining ten samples:

- three were from USA
- five were from China, but three of these were duplicates, with the same batch numbers
- one was from Turkey
- the country of origin of one sample is not known.

The Acting CVO has written to the authorities in the USA regarding their three samples and to the authorities in China regarding three of their five samples asking to be kept informed of the outcome of any action that is taken.

The FSA, working with local authorities, ensured that the remaining stock for eight of the samples was withdrawn and for six of these, the customers were notified. For the remaining two samples, one was dealt with by the States of Guernsey and for the other the company was no longer trading from the advertised address and all efforts to contact them have failed.

Rapid Alerts were issued for six samples. Three of these originated from the USA, one from China, one from Turkey and one sample where the country of origin is unknown.

Rapid Alerts were not issued for the other non-compliant samples where information on the supplier of the product is lacking**.** Three samples came from China, but the retailer was unsure who had been the supplier. The UK supplier of the last sample had ceased trading. The European Commission was sent a copy of the brand-name report.

Industry results

The VRC was pleased to receive five sets of results from retailers and other bodies. This is more than in previous years, but it would like to encourage others to send in their results. It could help reassure the public to be able to show that there is other testing going on, additional to the schemes the VRC has direct oversight of.

Overall, the results of industry testing are similar to those of the schemes overseen by the VRC. In general, few residues of concern detected, but one or two areas of concern remain. Residues of phenylbutazone were detected in one sample of cattle plasma. Also, another retailer reported residues of a nitrofuran antibiotic in two samples of imported prawns; however, these were at concentrations below the EU MRPL of 1 µg/kg.

A full report on the brand-name survey is available on the VRC website – www.vet-residues-committee.gov.uk.

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

Professor Keith Anderson – An Obituary

Professor Keith Anderson

It is with regret that we inform our readers that Professor Keith Anderson died on 16 October 2007. Keith had been a member of the Committee since its inception in 2001 and was a valuable and loyal member.

Keith was a freelance consultant in a number of areas, including food legislation and food technology. He was Principal Consultant to Ventress Technical Services Ltd of Cambridge and a visiting professor at London University. Prior to this, he had a long career with Unilever/Brooke Bond Foods providing technical management expertise in the UK and Holland.

Keith was a Director and Council Member of the Institute of Food Science and Technology, and he was Editor of the Food and Drink Industry Bulletin for ten years. He edited the "Practical Approaches to Food Control and Food Quality" book series published by Springer, and was involved with the Food Industries' manual. He was a Council Member of the European Food Law Association.

Keith had a particular interest in Good Manufacturing Practice in the food industry. He was an active member of the Institute of Biology. He was chairman of the Campden and Chorleywood Food Research Association's Meat and Poultry Forum. He wrote and edited widely in the field of food science and technology, and upheld ethical standards of animal husbandry.

The Committee's Year

The full Committee held four meetings in 2007, including an Open Meeting. 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 Ltd
- 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 2008
- reviewing the results of the VMD's surveillance schemes
- holding its Fourth Open Meeting on 31 October 2007 at the AFBI headquarters in Belfast
- attending the UK's preparatory meeting for the Codex Alimentarius
- building on its links with its sister committee, the Pesticides Residues Committee
- launching a revised VRC website
- giving a presentation on the Committee's work at the NOAH conference (NOAH is the animal health industry's representative body)
- assessing antibiotic residues detected in young male calves detained following inspection by the Meat Hygiene Service
- considering nortestosterone residues detected in the urine of male cattle which had been submitted to abattoirs after emergency on-farm slaughter
- recommending tests on imported beef for hormonal substances
- considering the regulatory status of coccidiostats and histomonostats
- considering the EU's review of veterinary residues legislation
- recommending a survey of royal jelly for chloramphenicol
- consulting stakeholders on the plan for the Non-Statutory Surveillance Scheme, which concentrates on imported foods.

Planning the Surveillance Schemes

VRC Members were actively involved in advising VMD on planning the surveillance programmes for 2008. In September 2007, two Members attended the National Surveillance Scheme planning meeting to help produce the draft 2008 plan. The full Committee later approved the plan. The NSS is described in detail on page 22 and on the VRC's website (www.vet-residues-committee.gov.uk).

The VRC's Non-Statutory Planning Subgroup met in September 2007 to discuss a plan for 2008, drafted by the VMD. This had been based on the VRC's recommendations and the outcome of its Matrix Ranking assessments. The VRC was then able to comment and make suggestions for the plan before it was finalised.

The Agri-Food & Biosciences Institute (AFBI) was created on 1 April 2006 as an amalgamation of the Department of Agriculture and Rural Development (DARD) Science Service and the Agricultural Research Institute of Northern Ireland (ARINI). AFBI is a DARD Non-Departmental Public Body (NDPB).

LGC Ltd was previously the Laboratory of the Government Chemist.

From 1 April 2007, the State Veterinary Service became part of Animal Health, an 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.

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 causes and follow-up actions. The Committee then advised the VMD and the FSA on the actions they might wish to take.

A note of the Belfast Open Meeting is available on the VRC's website: http://www.vet-residues-committee.gov.uk/Minutes/Minutes07/minutes311007.pdf.

Open Meeting in Belfast

The Committee held its 4th Open Meeting on 31 October at the Agri-Food and Biosciences Institute headquarters in Belfast. The Open Meeting gave the VRC an opportunity to hear the views of stakeholders, and is part of the Committee's commitment to openness.

In the previous three years, the VRC had held its Open Meetings in London. Some representations had been received that while London was convenient to many, it was difficult for some interested parties to get to. The Committee agreed and decided that in future, some of its Open Meetings will be held outside of London.

The Committee discussed its normal business, such as assessing the results of the surveillance schemes. It also consulted attendees on:

- whether it should consult on the surveillance plans for imported foods
- VRC Annual Report
- redrafting of European legislation on veterinary residues
- regulation of coccidiostats and histomonostats.

At the end of both the morning and afternoon sessions, there were opportunities for stakeholders to ask questions and give their views. Among the issues raised were:

- why foods such as fish and prawns were included in the imports surveillance, rather than beef, which is a more important component of the diet
- why milk tanker drivers had been authorised to take samples for the National Surveillance Scheme
- a request for a level playing field for testing imported and domestically produced poultry for nicarbazin residues and in the cattle sector
- information on why lambs entered an abattoir in Wales while still under statutory Withdrawal Periods
- the committee should communicate that authorised uses of veterinary medicines had not resulted in residues of potential health concern.

Withdrawal Period

The Withdrawal Period is the length of time after the end of treatment with a veterinary medicine that must pass before an animal can go for slaughter or milk or eggs can be taken for human consumption. Any residue present would then not be of consumer health concern.

Building on its links with its sister committee, the Pesticides Residues Committee

The VRC has been keen to build up links with similar committees. So, it was pleased to invite the Secretariat of the Pesticides Residues Committee (PRC) to its January meeting. The PRC Secretariat gave a presentation on the issues facing it. The Chairman of the VRC made a presentation at the January PRC meeting. The VRC also sent representatives to the PRC's Open Meeting in York on 9 May.

The VRC is keen to maintain its links with the PRC. This is because some of the issues the committees face are very similar. For example, budgets for surveillance are under pressure and the committees look at some of the same foods and sometimes the same substances. It makes sense to co-operate where we can and share information.

Relaunching the revised VRC website

The VRC decided to have its own website when the Committee was formed in 2001. However, feedback from stakeholders was that some years on, it was not as helpful or clear as the VRC's Annual Report. So, over the last year, the VRC has been involved in redesigning its website, which was launched in the summer of 2007. We would value the views on how people find it.

UK's preparatory meeting for the Codex Alimentarius

Susan Knox, one of the VRC's members with consumer expertise, attended the UK's preparatory meeting for the Codex Alimentarius. She was able to feed in her views and report to the Committee on the meeting.

The Codex Alimentarius Commission is an international body that sets standards in food to help international trade. As part of this, it can set MRLs for veterinary medicines. EU Member States and the European Commission are members of Codex Alimentarius and can scrutinise the proposals it is considering.

Antibiotic/oxytetracycline residues detected in young male calves

The Committee was alerted to an emerging issue towards the end of 2005. A number of young male calves had been detained at abattoirs and sampled as 'suspects'. Meat Hygiene Service inspectors carry out ante-mortem inspections to look for signs of ill health. They also conduct post-mortem inspections where injection sites can become more obvious. Where inspectors detect something unusual, they can detain the carcase as a 'suspect'.

Analyses have detected residues of oxytetracycline and dihydrostreptomycin at concentrations above the MRL. The residues were not of immediate concern for consumer health, but there was the possibility that a sensitive individual consuming meat from such an animal, could suffer a mild stomach disturbance. Also, tetracyclines can cause some discolouration of developing teeth in children.

The majority of the calves were taken to livestock sales by farmers and then sold to dealers. They in turn took the animals to slaughterhouses or delivered them the next day. All claimed not to have treated the animals with veterinary medicines.

The Committee are concerned when animals sold for further fattening are taken from sales to slaughter, as the residues status of those animals may not be clear. All parts of the supply chain have a responsibility to ensure that animals with unacceptable residues do not enter the food chain.

Nortestosterone residues detected in the urine of male cattle submitted to abattoirs after emergency on-farm slaughter

Last year, the Committee reported that testing by the Agri-Food and Biosciences Institute had revealed nortestosterone residues in male cattle. This phenomenon had occurred in animals submitted to abattoirs in Northern Ireland after emergency slaughter on farms. On-farm slaughter is used where an animal has been injured and moving it would cause distress.

This was the first time this substance had been found in male cattle and the possibility of illegal use had to be investigated. Over 1000 male cattle were sampled on the farms of origin. None were found to contain nortestosterone. DARD commissioned a report from Professor Wall of University College Dublin. He concluded that the NI procedures had been sound and that testing had found the same phenomenon in some other EU countries.

A risk assessment to consumers eating beef from casualty animals containing nortestosterone residues was carried out. The risk was thought to be small. However, as nortestosterone has never been assessed to be a veterinary medicine, the data were incomplete. But, nortestosterone is already consumed

What is 'Suspect' sampling?

In addition to the normal sampling for the NSS, animals or carcases that arouse the suspicions of authorised officers can be sampled as 'suspects'.

Animals are subject to both ante and post-mortem inspection at abattoirs. If for any reason, the meat inspector believes an animal has residues of a medicine at a concentration above the statutory limits, or that the Withdrawal Period has not been completed, the inspector can detain it at the abattoir. The carcase can be sampled and analyses carried out. If the analyses detect residues of an unauthorised substance, or residues of an authorised substance at a concentration above the relevant Maximum Residue Limit, then the carcase does not enter the food chain and is destroyed.

through eating other animals, which are known to naturally produce this substance.

In 2007, there was no test for differentiating between naturally occurring and illegally administered nortestosterone. However, a test has now been developed at the Agri-Food and Biosciences Institute in NI. The Committee hope that this test will soon be validated for use in Great Britain. Once this is done, the VRC has recommended some testing of casualty animals should be undertaken in GB.

Testing imported beef for hormonal residues

Samples of imported beef had previously been tested for potential hormonal growth promoters under VMD's Non-Statutory Surveillance Scheme. However, no non-compliant samples had been detected. So, in 2005 and 2006, the VRC recommended that imported beef be dropped temporarily from the programme, to allow other commodities to be included.

For 2007, the VRC thought it was time to look again at imported beef. Some 300 samples were tested for residues of trenbolone and zeranol, two synthetic hormonal substances that could be used for growth promotion. However, no evidence of any residues was detected. Normally, urine or blood samples would be taken to test for hormonal residues, but this is not possible with imported beef, as only muscle is imported. Therefore, it is more difficult to detect any residues of hormonal substances.

Regulatory status of coccidiostats and histomonostats

What are coccidiostats and histomonostats?

Coccidiosis and histomoniasis are protozoal diseases that particularly affect the intestinal tract of poultry. Coccidiostats and histomonostats are medicinal substances that are used to control and treat these diseases.

Coccidiostats and histomonostats are currently regulated as feed additives. This is done by a specialist panel of the European Food Safety Authority. However, the European Commission is reviewing whether these substances should now be regulated as veterinary medicines.

VMD initially consulted the independent Veterinary Products Committee, which recommended they should be regulated as veterinary medicines. However, when VMD consulted more widely, arguments were put forward to keep coccidiostats and histomonostats as feed additives.

VMD also consulted the VRC. This was because the Committee had taken a keen interest in coccidiostats and has expertise in such substances. The VRC tabled the issue for discussion at its Open Meeting in Belfast.

The Committee concluded that there would be few benefits from regulating these substances as veterinary medicines. They are closely regulated by EFSA and MRLs are being set to aid enforcement action. If regulated as veterinary medicines, certain technical changes in the products would be required. These could result in the loss of valuable products to the UK livestock industry. Overseas competitors would still have access to these products, so could gain a competitive advantage.

The VRC supported maintaining the status quo. The Committee will continue to monitor the review of these substances.

The EU's review of veterinary residues legislation

The VMD has a dedicated part of its website that explains the EU's proposals and the latest developments on residues legislation – www.vmd.gov.uk.

The EU is reviewing the 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 has effects on animal welfare and in some cases there are no medicines to treat particular conditions or diseases.

The VRC has received regular updates on the proposals.

Brand-name survey

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

For 2007, the Committee recommended a survey of royal jelly for chloramphenicol. Chloramphenicol is banned for use in food-producing animals. This is because if it is eaten, it can cause a serious blood disorder. While royal jelly is not a major part of the UK diet, those people who do eat it, eat it regularly, so could be at risk if residues of chloramphenicol were present.

Consulting on outline plans for the Non-Statutory Surveillance Scheme

Soon after it was formed, the Committee recommended that the VMD should not publish its surveillance plans. The VRC made this recommendation to avoid the possibility of some producers changing the substances they used to avoid residues being detected.

More recently, the Committee has reviewed this approach. The Pesticides Residues Committee produces draft plans for its surveillance. The plans are not detailed, but lay out the types of commodities and groups of substances it may include in the following year's surveillance. These outline plans are then released for public consultation. Suggestions received can be assessed before final decisions are taken.

The VRC understands that this is a sensitive issue, balancing 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, so we could gather the views of stakeholders. These were generally supportive and the VRC held a consultation on the draft plans for 2008.

The Committee still retain the possibility of making changes during the year if it thinks it is necessary.

The reports on all of the brand-name surveys recommended by the VRC, including the full results, are available on the VRC website – www.vet-residues-committee.gov.uk:

1. **malachite green in farmed fish**
2. **chloramphenicol, nitrofurans and streptomycin in honey**
3. **nitrofurans in imported crustaceans**
4. **chloramphenicol in royal jelly.**

Residues Surveillance

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

The National Surveillance Scheme

All EU Member States must carry out surveillance to check that their home-produced foods of animal origin are safe. 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.

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 of 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
ß-agonists			X			X	X
Annex IV substances[g]	X	X	X	X	X	X	X
Antimicrobials[h]	X	X	X	X	X	X	X
Anthelmintics	X	X	X		X	X	X
Non Steroidal Anti-Inflammatory Drugs (NSAIDS)			X		X		X
Coccidiostats	X		X			X	X
Thyrostats							X
Dexamethasone/Betamethasone							X
Carbadox[i]							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					

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

What is CCα?

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 variation 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 associated with their analytical results.

This measure will mean 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 variation. This concentration is called the Decision Limit, or CCα.

Definition of CCα

CCα, 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.

How the National Surv

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

– State Veterinary Service

– Department for Environment Food and Rural Affairs

– Agri-Food and Biosciences Institute (see page 34)

– Meat Hygiene Service

– LGC (formerly the Laboratory of the Government Chemist)

– 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

eillance 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.

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.

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).

The Non-Statutory Surveillance Scheme

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. As such, the scheme continues to complement the National Surveillance Scheme (NSS), which looks at UK produce.

One key difference is the NSS 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 are very 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 31-33.

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 12)

Rolling programme

The foods selected for analysis under the 2007 rolling programme were:

- raw beef – imported
- honey – imported
- poultry liver pâté
- raw poultry – imported
- farmed fish – imported
- farmed warm-water crustaceans – 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 and Border Inspection Posts. However, this year, 100 were collected from wholesalers. Most of the samples were of foods from countries outside the EU.

Brand-name survey of royal jelly

The VRC recommended that the VMD carry out a brand-name survey of royal jelly for residues of chloramphenicol. Chloramphenicol may not be used as a veterinary medicine in the EU. This is because of the increased risk of serious blood disorders in sensitive individuals. The VRC recognises royal jelly is not a major constituent of the average diet. But, those people who eat it, often do so regularly.

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 royal jelly can be found at: http://www.vet-residues-committee.gov.uk/Reports/Brand_naming_report_2007.pdf.

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.

Planning the Programme

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.

Action

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.

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

urveillance 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.

Budgeted Plan Produced

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

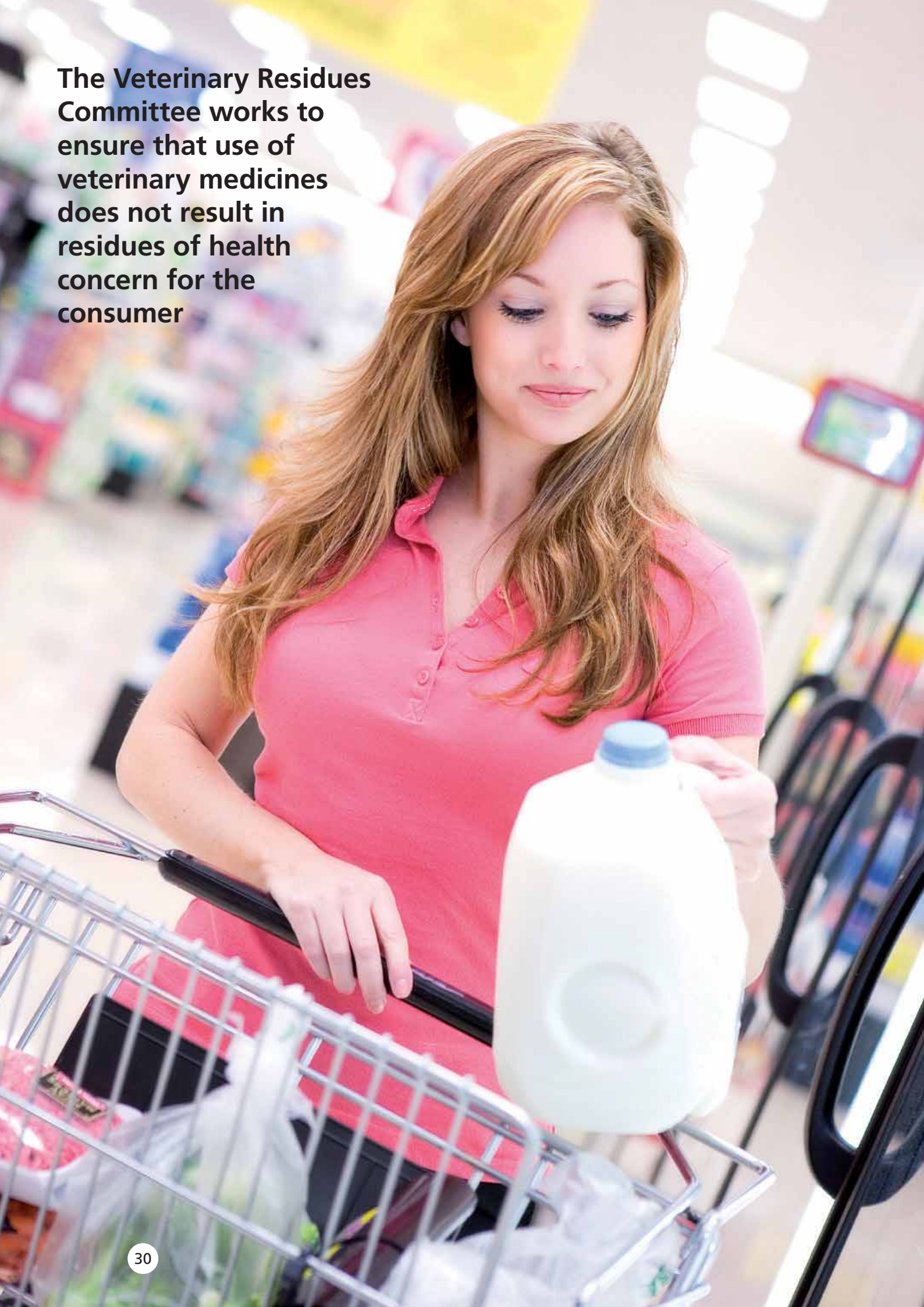
Samples Collected

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.

To calculate the overall score the individual scores were place into three groups. These were derived by:

1. adding the scores for Hazard (A) and Potency (B)
2. adding the scores for:
    - proportion of the diet coming from treated animals (C)
    - frequency of dosing with a particular substance (D)
    - evidence of high consumer exposure groups (E)
3. taking the score for the Evidence of Detectable Residues (F).

The totals for 1, 2 and 3 were multiplied together to get an overall score.

(A + B) × (C + D + E) × F = Overall Substance Score

Overleaf is a graphic that explains the process of assessing a substance. The amended results for the substances assessed using the new scoring method are on page 48.

A full report on the meeting can be found as paper VRC/07/05 on the VRC's website: www.vet-residues-committee.gov.uk.

Matrix Ranking for Prioritising Substances

Criteria (A + B) × (C + D +

Nature of the hazard
Scale 0 – 6
The more serious the potential adverse effect, the higher the score.

Nature of the hazard
Toxicological data are assessed as part of the authorisation process of a veterinary medicine. In this, potential adverse effects caused by exposure to a substance are identified. The more serious the potential adverse effect identified, especially if it is irreversible, the higher the Matrix Ranking (MR) score.

Potency of the substance
Scale from 0 – 3
The lower the dose that can cause the adverse effect, the higher the score.

Potency of the Substance
Most substances will cause adverse effects if we eat or absorb enough. The MR assessment was based on the Acceptable Daily Intake (ADI – expressed in µg/kg bw/day) or No Observable Adverse Effect Level (NOAEL) if no ADI was available.

Exposure 1
Scale from 0 – 3
The higher proportion of food that might come from a treated animal, the higher the score.

The proportion of the whole population's diet that might come from animals that had been treated with a particular substance
Some medicines are used only in a single species, while others are used in several, increasing the chance of exposure.

Exposure 2
Scale from 0 – 3
The higher proportion of food that might come from a treated animal, the higher the score.

The frequency of dosing with a particular substance
Some medicines are used over a whole herd, while others are used to treat individual animals. Additionally, (e.g. for some endoparasites) sheep flocks might be treated a number of times during the year. These factors need to be taken into account.

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).
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 0 – 3
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) × (C + D + E) × F = 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
0	No evidence of detectable residues for a substance/ food combination included in last year's surveillance.
1	Residues detected in previous year at concentrations below the MRL/MRPL.
2	Residues detected at the MRL/MRPL in previous year, or intelligence from RASFFs or other sources that a particular substance is being detected.
3	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 are on page 48 and a fuller explanation is on the VRC website.

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 (AH) (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 VMD. DARD also carries out follow-up investigations in Northern Ireland.
- 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 fish 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 plc, 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 National Surveillance Scheme.
- Agri-Food and Biosciences Institute analyse samples for the National Surveillance Scheme in Northern Ireland.
- LGC Ltd, analyses samples collected under the National Surveillance Scheme 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).
- The Investigations Branch of the Rural Payments Agency – carry 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.

The Veterinary Sciences Division and Food Science Division laboratories of DARD became part of the Agri-Food and Biosciences Institute in April 2006.

From April 2007, the State Veterinary Service, Defra's Egg Marketing Inspectorate and Dairy Hygiene Inspectorate were brought together to form a new Defra agency, Animal Health.

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.
- Food Standards Agency – has a responsibility for food safety and protecting consumers' interests in relation to food. The FSA co-ordinates investigations into food safety incidents and acts as UK contact for the EU's Rapid Alert system. Its officials also attend VRC meetings as advisors.
- AFBI, AH, CSL and LGC Ltd 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 Ltd twice each year to ensure compliance with Community legislation and contractual specifications
- US Department of Agriculture audits LGC Ltd 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 request that unusual or potentially contentious results obtained at one laboratory are repeated at another accredited laboratory. Such 2nd 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/

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.

Explanation of the Significance of Veterinary Residues

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

Identify all Residues of Human Health Concern

Set Maximum Residue Limits for Edible Tissues

such that the ADI is not exceeded

Set Withdrawal Periods for the Medicine

to make sure any residues are below the relevant MRL

Analyse Samples of Foods

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

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.

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 µg/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 highest concentration of an active substance found to have had no adverse effect in a safety test.

Veterinary Hypothetical Diet – in setting MRLs, the amounts of particular foods in our diet are taken into account. The upper quantities of foods that we are assumed to eat 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 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 officers might look at 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
- whether the Withdrawal Periods were observed
- if administered by feed, where this was mixed
- 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 Ltd (see page 34).

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 reveals more non-compliant samples, further 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 would be 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 (or her deputies). She writes to her 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 residues of health concern are detected – for example, of banned substances. The FSA can also request and oversee product withdrawals where this is appropriate.

The FSA 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 specified country.

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

   Most effects have a threshold level and exposure to doses below this will not result in adverse effects. Using the most relevant 'No Observable Adverse Effect Level' (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 used are typically 100 to 1000 times.
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 CCα 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. 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.

CCα – 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.

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 for controlling oestrus in farm animals.

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

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 page 31).

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 i.e. leucomalachite green.

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.

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.

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.

NON-COMPLIANT – for licensed veterinary medicines, a non-compliant sample is a sample, which on confirmatory analysis, was shown to contain a residue above the MRL or (in the case of a small number of coccidiostats, where MRLs have not yet been set) above the Action Level, with at least 95% certainty ($\geq CC\alpha$). For prohibited and unauthorised substances, a non-compliant sample is a sample, which on confirmatory analysis, was shown to contain a residue with at least 99% certainty ($\geq CC\alpha$).

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 Ministers[1] (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 medicines[2] in samples collected under the VMD's surveillance programmes, with particular reference to food safety and observance of withdrawal periods for veterinary medicines;[3]
- 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; and
- to set up subgroups as necessary to further the work and objectives of the VRC.

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 2007

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 are:

Dorothy Craig MBE,
Chairman

John Ambrose
Local Authority

Professor Keith Anderson
Food Industry

Dr Paul Brantom[j]
Toxicology/Food Safety

Sarah Buckley
Consumer

Mr Neil Cutler OBE
Farming

Susan Knox
Consumer

Stephen Lister
Veterinary

Dr W John McCaughey
Analytical Chemistry

Stephen Spice
Retail

Dr Brian Vernon
Feed Industry

Dr Keith Lawrence[k]
Pharmaceutical Industry

Dr Shirley Price[k]
Toxicology

j = Dr Brantom was nominated by the Food Standards Agency to advise on food safety and risk assessment.
k = No photograph was available

* 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 VRC Members are on the VRC website: www.vet-residues-committee.gov.uk

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	
Mr Stephen Lister	

The Non-Statutory Surveillance Subgroup members were:

Mrs Dorothy Craig	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	

Contact addresses

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Matrix Ranking scores and overall rankings (see page 31)

Substance	Nature of the hazard (A)	Potency of the substance (B)	Diet (C)	Usage (D)	High exposure groups (E)	Evidence of detectable residues (F)	Total (A+B) × (C+D+E) × F	Ranking
Nitrofurans	6	3	3	1	1	3	135	**1**
Zeranol	6	3	3	1	1	3	135	**1**
Chloramphenicol	6	3	2	0	2	3	108	**3**
Metronidazole	6	3	1	1	2	3	108	**3**
Phenylbutazone	6	3	1	3	2	2	108	**3**
Malachite Green	6	3	2	1	1	3	108	**3**
Albendazole	6	2	2	2	2	2	96	**7**
Fipronil	3	2	1	2	3	3	90	**8**
Naphthalene	3	3	1	1	2	3	72	**9**
Lasalocid	2	2	3	2	2	2	56	**10**
Bromopropylate	3	0	1	2	3	3	54	**11**
Florfenicol	3	1	2	1	1	3	48	**12**
Tetracyclines	2	2	3	2	1	2	48	**12**
Oxyclozanide	3	0	2	2	1	3	45	**14**
Tylosin	2	1	3	2	0	3	45	**14**
Nitroxynil	3	1	1	1	1	3	36	**16**
Sulphonamides	1	1	2	2	1	3	30	**17**
Nicarbazin	1	1	3	2	2	2	28	**18**
Diazinon	2	2	2	2	2	1	24	**19**
Cypermethrin	2	2	2	2	2	1	24	**19**
Enrofloxacin/ Ciprofloxacin	3	1	3	0	0	2	24	**19**
Salinomycin	3	1	2	1	2	1	20	**22**
Ivermectin	3	2	1	1	1	1	15	**23**
Clenbuterol	3	2	3	0	0	1	15	**24**
Streptomycin	1	0	3	1	2	2	12	**25**
17ß-oestradiol	6	3	3	0	0	0	0	**26**
Levamisole	4	1	2	2	1	0	0	**26**
Dimetridazole	5	2	0	0	0	0	0	**26**
Dexamethasone	2	2	3	1	1	0	0	**26**
Oxolinic acid	3	1	0	0	0	3	0	**26**

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. In the case of licensed veterinary medicinal products, these are based on the Maximum Residue Limits (MRLs), which are legal limits. However in the case of certain licensed compounds (some coccidiostats, where MRLs have not yet been set) and all prohibited and unauthorised substances, different criteria apply:

- **Any confirmed residue** – for substances without an MRL any confirmed residue above CCα will usually trigger a follow-up investigation
- **Action Level** – where there is currently no MRL, usually any confirmed residue above the CCα will 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. Action Levels are currently applied to naturally occurring hormones in animals and to nicarbazin in broiler liver.
- **Minimum Required Performance Limit (MRPL)** – for some prohibited and unauthorised substances, the EU has set MRPLs. Originally established to harmonise analytical capability, these are now the concentrations at or above which the EU requires enforcement action to be taken. However, all findings of prohibited and unauthorised substances (above CCα of the analytical method) are considered to be non-compliant and are reported as such.

The MRPLs relevant to veterinary surveillance are:

Substance	Concentration (µg/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 = 3-amino-5-morpholinomethyl-1,3-oxazolidin-2-one
AOZ = 3-amino-2-oxazolidinone
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 at concentrations above CCα should be reported as non-compliant. "Non-compliant" reports, therefore, 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.

Action Levels applied to hormones – With the sensitive analytical equipment used, it is inevitable that hormonal substances, which occur naturally in all species will be detected. Action Levels have been set at concentrations that are very likely to be naturally occurring, rather than the result of illegal administration.

CCα, the Decision Limit, is the measured 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 23).

How Maximum Residue Limits are set and what happens if a concentration above one of the Reference Points is exceeded is explained on pages 38 and 39.

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