

**NOTE OF AN OPEN MEETING TO DISCUSS REVIEW OF EUROPEAN
LEGISLATION RELATING TO VETERINARY RESIDUES**

THURSDAY 10 JANUARY 2008

CONFERENCE ROOM, VETERINARY MEDICINES DIRECTORATE

Those present:

John FitzGerald	VMD (Chairman)
Eric Crutcher	VMD
Jack Kay	VMD
Noel Joseph	VMD
David Webb	VMD
Gillian Asbury	FSA
Ivan Bartolo	Seafish Industry Authority
Stephen Dawson	NOAH
Derek Findleton	R-Biopharm Rhone
John Foster	BVA
Jim Grant	Honey Association of the UK
Ester Heller	FSA
John Howat	Bee Farmers' Association of the UK
Susan Knox	Veterinary Residues Committee
John Lavery	Defra Legal
Peter Martin	Honey International Packers Association
Liz McIntosh	Bee Health, Defra
Catherine McLaughlin	National Farmers' Union
Keith Meldrum	International League for the Protection of Horses
John Newman	R-Biopharm Rhone
John Points	LGC Ltd
Phil Sketchley	NOAH

Apologies for absence:

Judy Brander	National Council of Women
Stuart Challenor	Tesco Stores
Keith Davenport	Ornamental Aquatic Trade Association
Dr Roger Dawson	Animal Medicines Training Regulatory Authority
Alistair Donaldson	Scottish Association of Meat Wholesalers
Lorraine Fearon	Royal Pharmaceutical Society (Vet Pharmacy Society)
Christianne Glossop	Welsh Assembly Government
Steve Hewitt	NPTC (part of City & Guilds Group Stoneleigh Park)
Peel Holroyd	Peel Holroyd and Associates
Glenn Kennedy	AFBI
Chris Laurence	Dogs Trust
Mark Williams	British Egg Industry Council

1. **Introduction, background to the review and current position presentation 2377/90 - (this presentation is on the VMD website¹)**

1.1 **EC** gave a presentation on the background to the review and the current position. He asked if there were other issues with the proposal that had not been included, which the meeting would like to discuss. Two points were raised:

- what was the EU decision process for the proposal, which was confirmed to be co-decision, by both the Council of Agriculture ministers and the EU Parliament; and
- the controls on the administration of unauthorised substances to live animals, which were then imported into the EU for later slaughter. This was thought particularly to be an issue with horses coming into Italy.

2. **Wider use of extrapolation to set MRLs (Article 5)**

2.1 **EC** explained that the proposal would give a legal base for making extrapolation a compulsory part of the assessment of an MRL application. In the short consultation VMD had carried out in September 2007, there had been general support for the wider use of extrapolation. The UK and other Member States were in favour, in principle, providing the scientific base for it was sound.

2.2 It was acknowledged that there was a lack of authorised medicines for bees but what consideration had there been to take account of bees? **EC** informed the meeting that the VMD was sponsoring research into identifying the correct marker residues for some medicines that had been used in bees abroad. Additionally, it also had a project that was modelling treatment with a veterinary medicine to help calculate withdrawal times.

2.3 **Susan Knox** asked if extrapolation would be automatic and how could one extrapolate from one species to another? **JF** confirmed that extrapolation was not automatic. The proposal would provide a legal base for scientists to make an assessment of whether extrapolation was scientifically sound, it did not make extrapolation automatic. He added that while extrapolation had been used in the past, there was to his knowledge little evidence of new products having come forward.

2.4 **Phil Sketchley** said that companies were working on widening the range of medicines available and stressed the importance of robust science to underpin extrapolation. Where data were available extrapolation had been agreed. Turning to Susan Knox's question on species to species, he reported that in some cases, such as from one ruminant species to another, extrapolation can be undertaken with good data to support it. This is because they would be similar animals. However, he acknowledged that extrapolation to bees would be more difficult.

¹ <http://www.vmd.gov.uk/General/Residues/vrl.htm>

2.5 **Phil Sketchley** enquired about the views of other Member States. **EC** indicated that there was to the principle. The VMD did not know the views of the EU Parliament. It would be important to brief MEPs and a number of possibilities to engage with them were suggested. **Keith Meldrum** noted that the British Veterinary Association had appointed a lobbyist on veterinary public health issues. Avril Doyle (an Irish MEP) was the rapporteur for the Parliamentary Committee that was responsible for this legislation and the South West MEP, Neil Parrish was Chairman of the Environment Committee which was responsible for this dossier.

2.6 **JF** summarised that there was general support for extrapolation provided it was underpinned by good science.

3. **Third Country substances/adoption of Codex MRLs (Articles 9 and 13)**

3.1 **Third Country Substances**

3.1.1 **EC** reminded the meeting that Article 9 of the proposed legislation on widening MRLs included three scenarios. Member States or the Commission could request that the European Medicines Agency (EMA) provide an opinion on MRLs for any:

- substance in VMP in a 3C and no company has submitted an EU MRL application for that substance;
- substance is in a VMP intended to be used under Article 11 of Directive 2001/82 (“cascade”) but no company has submitted an EU MRL application;
- Biocidal products used in the EU that contain pharmacologically active substances.

3.1.2 The meeting noted that the proposal was very confusing. It was agreed that the VMD would seek clarification from the Commission. Once the proposal was clarified, VMD would issue a discussion paper to interested parties.

Action: VMD

3.1.3 Article 13 set out the classification system that would be used. It was very similar to the current system, in that it had annexes for substances:

- that require an MRL;
- for which an MRL has been provisionally set;
- do not need an MRL;
- are prohibited.

Once an MRL was set, it could be reviewed in the light of new evidence. The Commission had also proposed that the Annexes would be simple alphabetical lists, to make them easier to use.

3.2 Adoption of Codex MRLs

3.2.1 The new Regulation would make any new MRLs set by the Codex Alimentarius automatically EU MRLs, where the EU had not already set an MRL and also the EU had agreed the science. The EU was a member of the Codex Alimentarius and had the opportunity to examine the proposals twice during the Codex 8-point procedure.

3.2.2 **EC** stressed that the procedure would not apply to existing Codex MRLs, only to future ones. It was thought that the Commission should publish a summary opinion on a candidate substance that was to have an MRL set by Codex.

3.2.3 **JF** said that the UK was in favour of the proposal to allow Codex MRLs to be adopted without a further risk assessment, if the science supported it and that the proposal should apply to existing Codex MRLs. He asked the meeting if there were any objections. There were none.

4. Setting 'Reference Points for Action' for substances not authorised for use in the EU (Articles 15 and 16) (paper 08/03 on the VMD website)

4.1 The paper 08/03 summarised the proposal and arguments over setting Reference Points for Action (RPAs). **JF** asked the meeting if it agreed with RPAs and how should they be set?

4.2 **Keith Meldrum** insisted that, where residues of banned substances were detected, there should be a zero tolerance and the consignment should be destroyed. However, it was acknowledged that this approach might not be suitable for some substances, which while not authorised in the EU, were not actively banned on health grounds. **Ivan Bartolo** said RPAs for such substances would mean that 3C could use them, when EU produces could not – imports with low concentrations would continue to be allowed in.

4.3 **John Points** commented that for any control concentration, such as an RPA, there needed to be some measure of uncertainty. For example, if for a particular residue, an RPA of 1 µg/kg was set and two different consignments were analysed. If the results of the two analyses were: 0.9 µg/kg and 1.1 µg/kg, how could we take action, because there was essentially no measurable difference in the concentrations. It would be within the measure of uncertainty that accompanies such measurements.

4.4 **GA** said that if there was not a set limit it would give inconsistency between countries and allow importers to 'shop' between different ports. Also, if the scientifically set RPA was not a risk to consumers, we would have to marry this with the risk-management options given in Regulation 882/2004. There are options in that Member States can choose, but there was a need for consistency to benefit consumer health, for example, it could:

- redispach a consignment, usually to the country of origin; or
- destroy the consignment.

4.5 **EC** suggested that the Commission should be very clear with 3Cs. In line with Decision 2005/34, if residues of banned substances were repeatedly found at concentrations below the RPA, the Commission should take action. This stronger line would help underline that use of such substances was not acceptable.

4.6 **Keith Meldrum** noted that some of the banned substances had not been banned because they caused concern at all concentrations. As analytical techniques had improved so much, was there a case for reviewing the substances in the current Annex IV of the current Regulation 2377/90? There were substances that if they could be shown to be safe at the lower concentrations that could now be detected, could form medicines, which would help animal welfare.

4.7 **JF** said that the paper the meeting had received had been sent to the Slovenian Presidency. As such, he was happy for it to be circulated more widely to allow others to comment to the VMD.

5. **MRLs for pharmacological ingredients of biocides used in animal husbandry (Articles 1 and 9) Paper 08/04 on the VMD website**

5.1 **JF** introduced this item, the background to which is summarised in Paper 08/04. The Commission had said that some 60 pharmacologically active substances would need to be assessed. But it thought only 15-20 might require further examination to set MRLs. **JF** asked the meeting for comments.

5.2 **Keith Meldrum** asked how this might affect the excellent Defra approved disinfectant scheme. These biocides were crucial in the combating of notifiable disease. He had not seen any problem with the current arrangements and cautioned against setting up extra burdens, which could result in the loss of valuable products.

5.3 **Catharine McLaughlin** indicated she was concerned. She said farmers needed such products. There were already extra burdens the farming industry was being asked to pick up, such as the cost and responsibility sharing initiative. The first step should be to identify if there was a problem.

5.4 **EC** reported that the Commission was now starting to give the detail on this area. There was to be another Council Working Group on Monday 14 January and biocides were on the agenda. It should be decided whether biocides be included in the proposed Regulation.

6. **An update on the amendment of the EU 'hormones ban' (Directive 96/22/EC)**

6.1 **EC** summarised the proposal. This small amendment would:

- ban the remaining therapeutic uses of oestradiol and related substances;
- take pet animals out of the legislation banning the use of hormonal substances and beta-agonists;
- allow horses to be treated with beta-agonists (this had been an amendment suggested by the Irish representative).

Taking pet animals out of the legislation could benefit animal welfare, in particular, if medicines became available to treat hyperthyroidism in cats.

6.2 The amendment had been approved by the Council of Agriculture Ministers and would now be discussed in plenary in the European Parliament. It seemed very likely to be passed. The meeting did not express any reservations.

7. **An update on the proposal to rewrite the EU legislation of surveillance for veterinary residues in food (Directive 96/23/EC)**

7.1 **EC** explained this legislation required Member States to carry out surveillance for veterinary medicinal products and banned substances. At the time the Directive had been written, it had adopted a blanket approach and allowed little leeway for Member states to tailor their surveillance to local needs. He hoped that when a proposal was received from the Commission, it would adopt a risk-based approach. Also, it would be helpful to have better links to the Community Reference Laboratories to disseminate analytical methods for the banned substances.

8. **Next Steps**

8.1 **What will VMD need from you?**

8.1.1 As the proposals developed, the VMD would have to make a judgement on the effect they would have on the UK. VMD would need the help of stakeholders to identify any costs and benefits that might come from the proposals.

8.2 **Formal consultation**

8.2.1 **JF** assured the meeting that this would not be the last opportunity to comment. If stakeholders wanted another meeting, he encouraged them to contact the VMD. He also said that there would be a formal 12-week consultation on the proposals when they had been properly clarified. There was now an area on the VMD website where documents relating to this proposal would now be posted:

<http://www.vmd.gov.uk/General/Residues/vrl.htm>.

9. **Summary and close**

9.1 **JF** thanked everyone for their attendance and participation.