

Amendment of Directive 96/22/EC – the ‘EU Hormones ban’

What is Directive 96/22/EC?

This Directive controls the use of hormonal and thyrostatic substances and beta-agonists¹ in animals. It formalised the ban on the use growth-promoting hormones in animals.

Why are there controls?

The European Commission has based its view on hormonal substances on opinions from its Scientific Committee on Veterinary measures related to Public Health (SCVPH). It reported that the risks associated with the use of hormonal substances, particularly oestradiol, were greater than previously thought.

However, the UK, has taken advice from the independent Veterinary Products Committee (VPC). The VPC reported that while the data to draw definitive conclusions were not available; it found “*the weight of available evidence suggests that likely levels of human exposure to hormonally-active substances in meat from treated animals would not be sufficient to induce any measurable biological effect*”.

Why is 96/22 being amended?

The European Commission wants to tighten the restrictions on the use of oestradiol-related substances. It sponsored a report by Professor Dobson of Liverpool University on the availability of alternatives to oestradiol. This concluded that banning oestradiol definitively would not cause problems for member states.

The UK does accept that a scientific case has been made for the definitive ban. But, it welcomes some parts of the amendment, such as removing pet animals and leisure horses from parts of the legislation. This is because we believe could improve animal welfare, for those animals.

What is the current proposal?

The proposal has four main elements:

1. bans the remaining (therapeutic) uses of oestradiol (oestrogen)-related substances in farm animals
2. removes the restrictions on using certain hormonal substances in pet animals - this will also allow third countries that authorise these treatments in pet animals **only** to export food from animals not treated with hormones into the EU;
3. requires the Commission to gather additional information on other hormonally-active substances and bring forward any new proposals it thinks are necessary; and
4. removes horses from the restrictions on the use of beta-agonists to enable problems such as navicular disease (affecting the pedal bone in the hoof) and laminitis (which affects the hoof).

¹ Beta-agonists include substances, such as salbutamol, used in inhalers for asthma for humans. Other beta-agonists, such as, ractopamine, in much larger doses could be used to illegally promote growth in animals.

1. Banning therapeutic uses of oestradiol-related substances in farm animals

The use of hormonal substances to promote growth has been banned for since 1988. But oestradiol is still permitted to be authorised for certain therapeutic uses in individual cattle for conditions such as foetus mummification or pyometra were still allowed.

The current amendment would ban those remaining therapeutic uses of oestradiol-related substances in food-producing animals. There are currently no authorised veterinary medicines containing such substances in the UK.

The UK Government does not support this element. In therapeutic uses, only individual animals would be treated, and withdrawal periods could be set so that when a treated animal went for slaughter, no residues at concentrations above those naturally occurring would be present. So, the UK Government does not believe such use would constitute a risk (oestradiol is a naturally-occurring hormone. As such present in animals at differing concentrations, depending on their age and physiological state).

The UK government's view is based on a report by the independent Veterinary Products Committee (VPC)². It concluded that it was *“very unlikely that the presence of oestradiol-related substances in meat from treated animals would significantly increase the risk the risk of adverse effects in consumers. This was due to the very low concentrations resulting from treatment in comparison with those arising from endogenous production and from other dietary sources. Any increase in exposure would be likely to be small in the context of the entire food basket”*. Other committees have had similar views to the VPC.

2. Removing the ban on certain hormonal substances in pet animals

Directive 96/22/EC currently bans the use of certain hormonally-active substances and beta agonists in **all** animals, including pets. The concern was that products for pets might be used illegally for growth promotion in farm animals. The Commission has now concluded that this would **not** be economically viable, and has proposed that pets be removed from the legislation. This would allow companies to come forward with applications for products to treat a number of conditions, such as thyroid disorders in older pets.

The UK supports this element. It could increase the availability of veterinary medicines for pet animals and improve animal welfare. It is a welcome deregulatory measure.

The UK is not sure what the effect could be in imports from non-EU Member States.

² The report of the independent Veterinary Products Committee can be found in the 'Reports' section of its website www.vpc.gov.uk.

3. The Commission to gather additional information on other hormonally-active substances

The previous amendment to Directive 96/22/EC (Directive 2003/74) provisionally banned a number of other hormonal substances, apart from limited uses under veterinary supervision (those in Annex III of the Directive). The Commission is required by the current proposal to gather additional information and to come forward with any necessary proposals.

Both the VPC and the Food Standards Agency concluded that there is no scientific justification for a generic ban on all six hormonal substances for use in food-producing animals. However, if there was any prospect of that generic ban being lifted, the VPC has advised that there should be a full review of the science and the FSA would advocate a case-by-case EU risk assessment of each hormone.

The UK government can support gathering of evidence, as long it is not done partially. Any risk assessment should be done in line with internationally agreed standards.

4. The proposal has been amended to enable horses suffering from navicular disease and laminitis to be treated with beta-agonists.

This amendment was proposed by Ireland at Council Working Group and supported unanimously. Removing horses from the restrictions to enable treatment has the potential to improve their health and welfare. There is no information available on the impact this may have on the UK.

The UK supports this element. It sees allowing beta-agonists to be used for therapeutic purposes in horses as a helpful development which fits in with the UK's philosophy on animal welfare.

Where is the proposed amendment in the legislative process?

The proposal has been approved by the Council of Ministers (Hilary Benn for the UK). It will now go forward to be considered by the European Parliament. If accepted, it will become EU law. It won't come into force immediately, but only once transposed into domestic law.