DRUG USE IN FARM ANIMALS

A report published by

FOOD ETHICS COUNCIL

THE INDEPENDENT COUNCIL FOR ETHICAL STANDARDS IN FOOD AND AGRICULTURE

GENERAL INTRODUCTION

Why a Food Ethics Council?

The food we eat is cause for concern. The rapid pace of change in the application of science, biotechnology and big business to systems of food production has brought with it an increase in public anxiety about such matters as factory farming, genetic engineering, and the widespread use of antibiotics and chemicals to control diseases of plants and animals. This concern embraces matters of food safety, animal welfare, conservation of the environment, the livelihood of farmers and, not least, effects on the less privileged in developing countries.

The UK Government has committed itself to establishing a Food Standards Agency, whose prime function will be to promote food safety. There are also several official international bodies (e.g. Codex Alimentarius Commission) which consider the quality, safety and efficacy of the application of biotechnology to food production. It is customary for these bodies, and the politicians who take advice from them, to state that they base their conclusions on 'the scientific evidence'. Public concern that a particular practice is somehow 'not right' tends to be dismissed because it is not 'scientific'. However, this approach fails to acknowledge that decisions for the public good cannot be based on science alone.

Following the Uruguay round of talks of the General Agreement on Tariffs and Trade (GATT), the European Parliament adopted a resolution[1] which emphasised:

"the need for the WTO (World Trade Organisation) to link trade issues to environmental, social and animal protection issues with the aim of accommodating conflicting interests and insists that WTO decisions must on no account be permitted to threaten existing international or EU standards."

This is a clear statement of intent to incorporate ethics into public decision making. It has, however, made little impact to date, mainly, we suggest, because few attempts have been made to proceed from this general expression of good intent, first to a rigorous analysis of the ethics of food production, and then to a series of practical recommendations for good practice. The Food Ethics Council has been established to address this need.

The Food Ethics Council: General Aims

In 1998, in response to an initiative from the Farm and Food Society, the Joseph Rowntree Charitable Trust made funds available to establish a Food Ethics Council, a group of independent individuals (see Box: Members of the Food Ethics Council) chosen to provide the range of expertise needed to address the following aims.

Our aims are to:

- *Review developments in food and agriculture within a sound framework of practical ethics which addresses the principles of wellbeing, autonomy and justice with respect to consumers, producers, farm animals (where relevant) and the living environment.*
- *Promote the incorporation of ethical thinking in decision-making in agriculture, food manufacturing and retailing.*
- *Produce authoritative, well-researched reports, which highlight ethical concerns and make recommendations for action.*

Members of the Food Ethics Council

Ms Helen Browning: Organic farmer; Chair of the Soil Association
Prof Ruth Chadwick: Professor of Moral Philosophy; Director of the Centre for Professional Ethics, University of Central Lancashire
Dr Paul Ekins: Director of Forum for the Future; Reader in the Department of Environmental Social Sciences, University of Keele
Prof Philip James: Director of the Rowett Research Institute, Aberdeen
Dr Vernon Jennings: Director of Sustainability Ltd, London
Ms Suzi Leather: (Vice Chair) Chair of a Community NHS trust; consumer affairs specialist
Dr Peter Lund: Senior Lecturer in the School of Biological Sciences, University of Birmingham
Dr Ben Mepham: (Executive Director) Director of the Centre for Applied Bioethics, University of Nottingham
Mr John Verrall: (Treasurer) Pharmaceutical chemist, Henley on Thames
Prof John Webster: (Chair) Professor of Animal Husbandry, University of Bristol Veterinary School

1 Official Journal of the European Communities (1994) C 18/165 European Parliament DGI – Legislative Planning Division – Resolution (no. 23) on the conclusion of the Uruguay Round and the future activities of the WTO (15.12.94)

Summary of Recommendations

A: Recommendations relating to the criteria on which regulatory decisions are made

1. A legal distinction should be drawn between the use of veterinary drugs to control disease and those used merely to increase productivity, effectively ensuring that the latter are subjected to more stringent approval criteria.

2. Regulatory authorities should make decisions on veterinary drug use with reference to a recognised ethical framework and not simply on the basis of scientific evidence.

3. Because current WTO rules prevent any distinction between food products based on methods of production (cf. Article III), except that according to Article XX, restrictions on international trade might be permissible:
- to protect 'public morals'
- 'to protect human, animal or plant life or health'
- 'relating to the natural conservation of exhaustible natural resources',

it is recommended that the full significance of these exemptions be explored by the EU in the interests of advancing animal welfare, consumer choice and environmental protection.

4. The Precautionary Principle, incorporating the nine elements defined in this report, should be established as a cornerstone of biotechnological decision-making in relation to agricultural and food systems, including those employing veterinary drugs.

B: Recommendations relating to the provision of scientific evidence on which regulatory decisions are made

5. Scientific data on which assessments of the safety, quality and efficacy of veterinary drugs are based should be provided by independent scientists, operating through a Government administered procedure, and on the principle of 'blind trials'. We recommend that responsibility for setting national standards and ensuring their effective control be vested with the new Food Standards Agency.

6. The legal provision by which manufacturers, under Section 118 of the UK Medicines Act (1968), may keep confidential information on the safety of veterinary products, should be repealed.

C: Recommendations relating to the composition of regulatory and advisory committees

7. UK Government Advisory Committees considering the application of biotechnology (including veterinary drugs) to food production and processing, should be reconstituted to include a broader range of perspectives, with less emphasis accorded to scientific expertise and rigorous application of the Nolan Principles.

8. In making appointments to the Joint Expert Committee on Food Additives, the Codex Alimentarius Commission, the World Trade Organisation and similar international regulatory committees, mechanisms should be introduced to ensure that advice given is not influenced by vested interests.

D: Specific recommendations on drug licensing, labelling and research

9. In view of the ethical analyses presented in this report (supported by the recent reports of the EU DG24 Scientific Committee on Animal Health and Animal Welfare and of Health Canada), we recommend that commercial licensing of BST in the EU to increase milk yield in dairy cattle should be prohibited indefinitely.

10. In view of the ethical analyses presented in this report (supported by the recent report of the EU DG24 Scientific Committee on Veterinary Measures relating to Public Health), we recommend that the EC should maintain its position on banning the importation into the EU of beef from animals treated with anabolic hormones.

11. In view of the ethical analyses presented in this report (supported by evidence from several recent prestigious reports), we recommend that the use of antibiotic feed additives (ZFAs) as growth promotants should be phased out as soon as is practicable. All antibiotics administered to animals, for whatever purpose, should be classified as prescription only medicines/medicated feedingstuffs.

12. Any food product derived from animals treated with drugs designed solely to increase productivity (cf. Recommendation 1) should be labelled accordingly.

13. The UK Government should invest more resources in research on organic and similar systems of sustainable food production, which are based on good husbandry rather than dependent on the use of drugs.

1. INTRODUCTION

The main aim of this report is to examine the ethics of administering drugs to farm animals: firstly to control disease and, secondly, to increase productivity. We have chosen this as the subject of our first report because of its extreme importance and topicality. The two issues of major current concern are the use of antibiotics as 'growth promotants' in pig and poultry production and the use of hormones in milk and beef production.

At the time of writing, the European Union, under pressure from the WTO, is reviewing the moratoria it has imposed with respect to both these practices 'pending further scientific evidence'. We believe that these reviews must also be informed by the principles of practical ethics.

Our terms of reference were to:

• examine the ethical principles involved in the use of drugs for therapy, prophylaxis and productivity enhancement in food-producing animals

• *establish a procedure for regulation of* the use of these drugs based on both science and ethics, and achieved both through legislation and/or voluntary systems of quality control.

This involved a series of more defined objectives:

• to review the current use of drugs in animals used for food production, primarily in UK and European contexts but also with reference to the impacts of world trade, as subject to the legal provisions of the Codex Alimentarius Commission and the WTO.

• to consider the rationale for use of such drugs in terms of their effects *on animal health and welfare and claimed* economic advantages.

• to consider alternatives to the use of the drugs.

• in the light of the above considerations, to recommend practical measures (e.g. by the introduction of new legal *provisions and/or new codes of practice) whereby* sounder, ethically-validated procedures might be introduced concerning regulation of the use of drugs in food-producing animals.

Working methods

Topics for all reports are decided by the full Council. A working group, chaired by a member of Council, is set up to research and write each report. Each group includes non-Council members, invited to contribute their special skills. Reports are endorsed by the full Council.

Members of the working group for this report were: Prof. John Webster (chair: School of Veterinary Sciences, University of Bristol), Mr Mike Radford (School of Law, University of East Anglia), Mr John Verrall (pharmaceutical chemist, Henley on Thames) and Dr Ben Mepham (Centre for Applied Bioethics, University of Nottingham). This analysis of the ethics of drug use in farm animals has been based on Mepham's development (the Ethical Matrix) of principles originally formulated for use in the field of medical ethics.

The working group examined published scientific evidence, much of it already reviewed for governmental documents, and the legal regulations governing drug use in animals. There is not room here to make reference to all our source material but we do identify a number of key reviews which form a route of access to the relevant original publications.

A questionnaire (Appendix 1) was sent to 30 selected, informed individuals. Those responding, together with others from whom helpful advice was received, are listed in Appendix 2. The analyses in this report have been informed, inter alia, by these opinions.

2. DRUG USE IN FARM ANIMALS

Drugs given to farm animals (sometimes known as veterinary medicines) may be administered for the following three purposes:

2.1. *to treat disease* (therapeutic): drugs given when necessary to restore good health and alleviate the symptoms of disease in sick animals. These include drugs prescribed by a veterinary surgeon to control disease, e.g. antibiotics and anti-parasitic agents, and drugs designed to improve welfare, e.g. analgesics and anti-inflammatory agents.

2.2. to prevent disease (prophylactic): drugs administered to healthy animals with the intention of preventing disease. These include licensed drugs, such as vaccines and immunological preparations, and unlicensed products such as probiotics and

homeopathic preparations. This category also includes antibiotics and antiparasitic drugs administered to populations of healthy animals to protect them from challenge from the bacteria and parasites they are likely to encounter in the environment in which they are reared.

2.3. to increase productivity (productivity promotant): drugs administered to nominally 'healthy' animals to manipulate reproduction, increase milk yield, alter body composition or improve food conversion efficiency during growth. These are of two main types:

• **Hormones:** these substances alter the physiological state of animals. Examples include prostaglandins, used to synchronise mating; bovine somatotrophin (BST) to increase milk yield; and anabolic hormones, used to increase lean tissue growth rate and improve food conversion efficiency.

• **Zootechnical feed additives (ZFAs):** these products, incorporated into animal feed, include copper, antibiotics, and related compounds like monensin, which act primarily within the digestive tract to increase nutrient availability.

The expression 'veterinary drug' means 'a medicinal product which is manufactured, sold, supplied, imported or exported for the purpose of being administered to animals but not to human beings'. For the purposes of sale they are classified as shown (see Box 1).

The distinction between therapeutic, prophylactic and productivity promotant uses of veterinary drugs is not always clear cut. The use of hormones to manipulate growth or increase milk yield is clearly not therapeutic or prophylactic. The use of hormones to control fertility may be therapeutic or simply an aid to management. But the situation becomes more blurred when we consider the use of antibiotics, where the same substance may be used therapeutically, prophylactically or as a productivity promotant, as will be discussed below.

Consequently, legislation based on the notion that drug use can always be readily ascribed to one or other of the three categories described above is simplistic. Moreover, the full significance of veterinary drug use (for treated animals, livestock farmers, consumers and the living environment) is simply not encompassed by the established scientific assessment criteria. What is needed is a deeper form of analysis, which addresses the many other important questions, such as those concerning consumer safety, quality assurance, animal welfare and protection of the environment. In short, what is required is an ***ethical analysis*** - which should form the basis of a new, publicly acceptable, standard of assessment.

BOX 1 – The classification of veterinary drugs and the legal regulation of their use

GENERAL SALE LIST (GSL) VETERINARY DRUGS, *which may (in effect) be sold through any retail outlet.*
PHARMACY ONLY VETERINARY DRUGS (P):
• **Prescription-only medicines (POM):** *veterinary drugs which may only be sold or supplied by retail in accordance with a prescription given by a veterinary surgeon or veterinary practitioner.*
• **Pharmacy and merchant list (PML):** *veterinary drugs which may be sold by pharmacies and registered agricultural merchants.*

A veterinarian may only prescribe **POM** *drugs to 'an animal or herd which is under his care'. (This applies also to PML drugs unless the veterinarian is a registered pharmacist). The ethical and professional criteria implicit in the term 'under his care' are laid down in the RCVS Guide to Professional Conduct.*

The **PML** *list covers drugs such as wormers, including those for pet dogs and horses. Zootechnical feed additives such as productivity promotants and coccidiostats were formerly classified as PML feed additives but are no longer considered as medicines under the Medicines Act and are controlled and authorised under EC legislation.*

Medicated feedingstuffs *are animal feeds with a prescribed (POM) veterinary medicinal product added to treat or prevent outbreaks of disease in livestock.*

Zootechnical Feed Additives *(ZFAs) are substances, e.g. antibiotics, trace elements, enzymes etc. which may be added to animal feeds to increase productivity: these were formerly classed as PMLs. In the UK their use is controlled by the Feedingstuffs (Zootechnical Products) Regulations 1998, which implements EC Directive 70/524/EEC*

Homeopathic preparations: *the authorisation of veterinary homeopathic medicines is controlled under EC Directive 92/74/EEC, which states that 'no homeopathic product may be marketed for therapeutic purposes unless it has a product licence or marketing authorisation'. In effect, this means that homeopathic products are subject to legislation which requires proof of their safety but not of their efficacy.*

Probiotics: *a probiotic may be defined as 'a live microbial preparation, used either as a food or animal feed, which can benefit the host through restoring its intestinal microbial balance'. The use of probiotics is not covered by the Medicines Act because no claims are made as to their medicinal efficacy.*

3. AN ETHICAL APPROACH TO BIOTECHNOLOGY ASSESSMENT

3.1 Background

Currently, prospective technologies are routinely subjected to assessment procedures to ensure that they deliver the claimed benefits reliably and without significant risks (essentially, covered by the criteria 'safety, quality and efficacy'). Once these criteria have been satisfied, market forces tend to be regarded as the appropriate means for addressing other issues of public concern. While in theory (e.g. in a society where there was a high level of public awareness and trust) the free market might be a satisfactory way of ensuring consumer choice and protection, many aspects of modern-day food production present a profound challenge to this assumption. Questions relating to the origins of our food, its means of production, dependence on problematical technologies, and impacts on the welfare of consumers, animals and the environment, cannot be assessed simply on the basis of economics and technology, not least because animals and the environment cannot express their interests as 'stakeholders'. A satisfactory form of ethical assessment needs to take account of all these issues.

A sound starting point for deliberation is to outline principles of the common morality or 'common-sense ethics', which most reasonable people share. One problem with such a claim is that it depends rather critically on how you define 'reasonable'. Different cultures might see things differently (human autonomy, women's rights, animal rights) yet still be considered rational, if not reasonable. Nevertheless, despite multiculturalism and pluralism, the pursuit of democracy, which few in our culture would challenge, makes certain assumptions that conform to the idea of the common morality.

These assumptions have been described by the American medical ethicists, Tom Beauchamp and James Childress, who identify four principles, namely *prima facie* respect for ***beneficence, nonmaleficence, autonomy*** and ***justice***.[2]
In a medical context:
Beneficence refers to 'doing good'; i.e. the duty to help the patient by effecting a cure or relieving suffering.
Nonmaleficence refers to 'doing no harm' (the ancient Hippocratic Oath) and this applies, for example, to avoiding procedures which might be undertaken primarily to advance knowledge or skills, rather than for the good of the patient.
Autonomy concerns respect for the patient as a person, and not just as a 'case'.
Justice is interpreted as 'fairness', e.g. showing no favouritism or sexual, racial or age preference.

This, so-called, 'principled approach' to medical ethics seeks to assist doctors and nurses in addressing many of the dilemmas with which they are constantly faced. The use of the principles does not determine the outcome but it does ensure that attention is paid to a range of ethically relevant issues, that there is a consistency of approach towards patients, and that the decisions made are explicit and can be verified (or challenged). The principles are based on established ethical theories (even though most people are not aware of them) which commonly feature in perceptions of 'right action' (see Box 2).

In adapting this approach to agricultural and food biotechnologies, Mepham[3] noted that the following are valuable with respect both to medicine and food production:

- the assumption of a common morality
- a principled approach which is based on established ethical theory
- the characteristics of rationality, transparency and consistency.

There are, however, several important differences between medical ethics and food ethics. Thus, for the latter:

- there are more 'interest groups' (e.g. animals, consumers, farmers and the living environment), some of which (animals and the environment) cannot express opinions
- the ethical analysis needs to impact on public policy decisions (not simply *ad hominem* as in the surgery)
- to be of use in democratic, publicly-accessible policy making, the terminology needs to be as simple and user-friendly as possible (or, at least, comprehensible to the committed non-expert).

3.2 The Ethical Matrix

In this report, we propose to analyse the issues raised by applying the ethical principles described above to the interests of four groups, viz:

- **Treated Organisms:** in this case, the animals whose products are used for human food
- **Producers:** in this case, livestock farmers
- **Consumers:** in this case, those who consume animal products (meat, eggs, milk)
- **The Biota:** i.e. the living environment.

Respect for these four groups is considered in relation to the principles of ethics described, namely autonomy, justice and, here, wellbeing (the latter combining, for simplicity, the principles of beneficence and nonmaleficence – which are often closely and reciprocally interrelated).

2 Beauchamp T L and Childress J F (1994) Principles of Biomedical Ethics, 4th edition. New York and Oxford: Oxford University Press
3 Mepham Ben (1996) Ethical analysis of food biotechnologies: an evaluative framework. In 'Food Ethics' ed. Ben Mepham. London: Routledge pp. 101-119

Respect for	WELLBEING (Health & Welfare)	AUTONOMY (Freedom/choice)	JUSTICE (Fairness)
TREATED ORGANISMS	Animal welfare	Behavioural freedom	Telos*
PRODUCERS	Adequate income & working conditions	Freedom to adopt or not to adopt	Fair treatment in trade and law
CONSUMERS	Availability of safe food	Respect for consumer choice (labelling)	Universal affordability of food
THE BIOTA*	Conservation of the biota	Maintenance of biodiversity	Sustainability of biotic populations

Table 1

The Ethical Matrix showing, in twelve individual cells, the interpretation of respect for the three principles of wellbeing, autonomy and justice in terms *appropriate to the* interests of (in this instance) farm animals, livestock farmers, consumers, and the biota (animal and plant life of the natural environment). *These, rather unfamiliar, terms are explained briefly in the text.

Because the three principles and four interest groups interact, the twelve resulting ethical impacts can be represented in the form of a table (the Ethical Matrix),[4] which aims to facilitate analysis by imposing a rational structure (see Table 1). But it would be a mistake to imagine that the Matrix can resolve complex ethical issues simply by consigning their elements to the separate 'cells'.

In the Matrix, the way in which the three principles impact on the interests of the various groups affected by agricultural and food technologies is expressed in terms which are intended to be familiar but are at the same time authentic from an ethical perspective; e.g. respect for consumer autonomy (effectively 'choice') may translate into a requirement for food labelling, that for the wellbeing of animals as 'animal welfare'. The 'biota' are defined as 'animal and plant life', i.e. the wildlife which constitute the living environment: (it is assumed that geological formations *per se* are not ethically relevant, although effects on them may well be ethically relevant for humans). Somewhat more problematically, justice for animals is defined as 'telos' - the ancient Greek word meaning 'ultimate end or goal'. Here, it refers to the concept that justice for an animal corresponds to respect for its intrinsic worth (which philosopher Immanuel Kant considered was possessed by every person) i.e. this can be seen as the basis of the view that animals have certain 'rights' analogous, if not commensurate, with human rights.

At its simplest, the Matrix is merely a check-list of concerns, which happen to be based on ethical theory. But it can be much more e.g. by serving as a means of promoting public education and as a stimulus to ethical deliberation. It is, of course, impossible to discuss the full significance of this approach here, any more than it would be possible to give a satisfactory account of, say, biochemistry, in a couple of pages. Since the Matrix *per se* has no substantive output, its value can only be measured in terms of its 'usefulness'.

However, it is important to note that :

- the Matrix is not prescriptive: even if one were to assign scores to different 'cells' (e.g. a food technology might improve food safety and thus score +3 in that cell, but reduce animal welfare, leading to a score of -2 in that cell), the fact that individuals *weigh* the cells differently precludes a definitive decision on ethical acceptability.

- it is probable that no form of biotechnology or system of food production could afford equal respect to all the ethical principles, and hence some may need to be overridden by others or respect for some only partially discharged.

- the Matrix can only compare two situations (usually, conditions with and without a proposed technology) but if the conditions without the proposed technology represent the *status quo*, this might unduly limit the options for ethical action: alternative scenarios need to be included within the analysis.

- the Matrix is designed to facilitate decision-making by making explicit the relevant ethical concerns, encouraging ethical reflection and discussion.

4 See note 3

BOX 2 – Background Ethical Theory

According to the approach adopted here, respect for ***wellbeing*** *corresponds to issues prominent in utilitarian theory, which characteristically employs a form of cost/benefit analysis to decide on 'right action'. Most famously articulated in the eighteenth and nineteenth centuries by Jeremy Bentham and John Stuart Mill, it can be epitomised as 'The greatest good for the greatest number'. While this might seem a worthy objective, naive forms of utilitarianism suffer from several defects e.g.:*

- *it depends on predictions of outcome (which might be wrong) and (fallible) assessments of who or what counts in the cost/benefit analyses*
- *it can be held to justify gross inequality (as long as the majority 'are happy') or even crime (stolen money distributed to the needy)*
- *goods and harms are often incommensurable (how can we weigh the safety of a hair shampoo against the suffering of animals used to test it?)*

Respect for ***autonomy*** *corresponds to the notion of 'rights' advanced in the eighteenth century by Immanuel Kant, which appeals to our responsibilities and duties to 'treat others as ends in themselves': in essence, the Golden Rule: 'Do as you would be done by'. For Kant, ethics was about respecting others as individuals, not calculating costs and benefits (i.e. in contrast to utilitarianism, irrespective of outcome).*

- *A major defect of this approach taken in isolation is that there is no rule by which to decide how to prioritise duties, e.g. the duties to protect others from harm and to tell the truth - if, as may happen, telling the truth is a cause of harm.*

Respect for ***justice*** *corresponds to Rawls' notion of 'justice as fairness'. For Rawls (a contemporary US philosopher): "Justice is the first virtue of social institutions, as truth is of systems of thought. A theory, however elegant and economical, must be rejected or revised if it is untrue; likewise laws and institutions, no matter how efficient or well arranged, must be reformed or abolished if they are unjust".**

- *However, there is a problem in defining what fairness means: e.g. does it mean that goods should be distributed according to need, or ability, or effort?*

In practice, all these theories are likely to contribute, to varying degrees, to people's attitudes on what should be done in specific circumstances. It seems unlikely that anyone could consistently act as an out-and-out utilitarian; or as an out-and-out Kantian. Instead, each of us blends these theories (consciously or unconsciously) with intuitive responses and cultural influences to achieve what has been termed a 'reflective equilibrium'.

* Rawls J (1972) A Theory of Justice. Oxford: Oxford University Press

3.3 Application of the Ethical Matrix to Veterinary Drugs

The aim in the following sections is to examine three types of veterinary drug (BST, growth promoting hormones and zootechnical feed additives) used, or proposed for use, as productivity promotants, in the light of the principles defined in the Ethical Matrix. In theory, the consequences of such drugs could respect, infringe or have no impact on each of the ethical principles. Our approach is to report ethical impacts on the separate interest groups (animals, consumers etc) as objectively as possible.

Within the space available, it is only possible to perform summary analyses; a process which is, however, facilitated by the recent publication of several authoritative reports on the subjects to be discussed. It should be appreciated that the authenticity of the analyses is dependent on a rigour that cannot be demonstrated here: readers wishing to examine the primary data are referred to the bibliographies of the reports cited. Reference to principles described in the Matrix is denoted by use of bold italics, e.g. ***autonomy***.

We then conclude each analysis with an ethical evaluation, which forms the basis of a number of our subsequent recommendations. This evaluation represents the outcome of our 'weighing' of the impacts of the cells of the Matrix, coupled with appeal to the Precautionary Principle (see Section 7.3 of this report) when the available evidence reveals significant uncertainties. We believe that our assessment of the evidence, in the manner presented in the Matrix, will find general support, although few people will have considered the issues in the terms used here. But even if there is disagreement over the ethical evaluations the proposed framework may nevertheless facilitate fruitful dialogue.

4. BOVINE SOMATOTROPHIN (BST)

4.1 Background

This genetically engineered protein hormone is used in the USA and several other countries to increase milk yield in dairy cattle. Responses to fortnightly subcutaneous injection of BST (at the tail head or behind the shoulder) are claimed to increase yield by 10-15% (2 - 7 litres of milk per day).[5]

First licensed in the USA as 'Posilac' in 1994, it is claimed by the manufacturers, the Monsanto company, that, by 1998, over 100 million doses of this BST product had been sold, with 30% of the 9 million cows being in herds to which BST was administered. In the USA a veterinary prescription is not required either to purchase or to administer BST. Arguments for the use of BST are primarily economic - fewer cows being required to produce a given quantity of milk, but this is also claimed to have beneficial environmental impacts since cows have certain undesirable products, such as manure and methane gas.

The first application for marketing authorisation in the EU was made by the Monsanto Company in 1987. In April 1990, the Council of Ministers prohibited marketing and use of BST, other than in authorised research studies, until the end of 1991, and this ban was subsequently extended to allow time to collate relevant research studies. Following several other developments, such as the FDA approval of BST for use in the USA in 1993, the EU Council of Ministers announced a decision in December 1994 to extend the existing moratorium on the sale or use of BST until 31 December, 1999. A decision on the continuation or termination of this ban after January 2000 is to be announced this year.

4.2 ETHICAL ANALYSIS

Application of the Ethical Matrix to BST focuses mainly on issues affecting the treated dairy cattle and consumers of dairy products, but also identifies other concerns related to dairy farmers, the environment and the economic impacts on national economies.

4.2.1 Treated Cattle

BST was first proposed as a dairy biotechnology as long ago as the mid-1980s. Consequently, the scientific literature on BST, and its physiological mode of action, is extensive. Despite this, the number of studies which have specifically addressed the impacts of BST on animal welfare is small by comparison with those which explore its effects on productivity.

For current purposes, the recent report of the EU Consumer Policy and Health Protection Directorate (Report on Animal Welfare Aspects of the Use of Bovine Somatotrophin, published 10th March 1999)[6] provides a useful summary. The report expressed the opinion that *"animal welfare does not appear to have been an issue in the decision making process on BST in the USA"* i.e. as performed by the Food and Drug Administration. Indeed, the EU report concluded that an adequately wide range of studies on welfare indicators in animals receiving BST had not been performed, making accurate assessment of risks impossible. Despite this, the report drew the following conclusions:

- BST use increases the risk of clinical mastitis, which is a painful disease resulting from inflammation of the udder. The magnitude of the increase in incidence of this condition following BST use has been variously recorded as: 15-45%; 23%; 25%; 42%; and 79%. The duration of treatment for mastitis was longer in cows receiving injections of BST.

- An increased incidence of foot and leg disorders associated with long term administration of BST has been described, e.g. in the largest scale study the number of multiparous cows (several calvings) with foot disorders and the number of days affected were both more than doubled. Lameness has been identified by the UK Farm Animal Welfare Council as the major source of pain and suffering in dairy cows.

- Adverse injection site reactions occur in BST-treated animals, with studies showing severe reactions in at least 4% of cows. It has been reported that injections made at the tail head cause less swelling than those behind the shoulder; but because there is less subcutaneous space here to accommodate inflammation, pressure and pain at the injection site may be greater.

- Reproductive capability is adversely affected by BST, with studies showing that the pregnancy rate (i.e. the number of inseminated animals which become pregnant) fell from 90% to 63% in primiparous cows (first calving) and from 82% to 73% in multiparous cows. Rates of multiple births, which may reduce welfare, were substantially increased by BST.

- BST-treated cows have reduced 'body condition' at the end of the lactation period and experience increased periods of being 'off feed'. This is due to increased demands on both the energy reserves of the body and the digestive capacity of the gut.

- Several other conditions are associated with BST use e.g. increased incidences of bloat, indigestion and diarrhoea; reduced ability to cope with raised environmental temperatures; and a higher culling rate in multiparous cows.

5 European Union DG XXIV (1999) Scientific Committee on Animal Health and Animal Welfare 'Report on Animal Welfare Aspects of the use of Bovine Somatotrophin' (10.3.99) Brussels: European Commission
6 See note 5

Such conditions clearly reduce ***animal welfare*** (i.e. they impair fitness and cause suffering). ***Behavioural freedom*** is also adversely affected because lameness affects mobility, while the need to supply the cows with greater amounts of concentrate feed (to fully exploit the effect of BST) tends to favour regimes in which cows are kept indoors and deprived of opportunities to graze.

The concept of 'respect for animal ***telos***' implies that animals should receive fair treatment according to their intrinsic worth. In such terms, the enforced alteration of physiological and behavioural norms (reflected, for example, in reduced reproductive fertility) may be seen as an infringement of the standards of treatment to which animals 'under human care' are entitled.

Thus, according to the evidence presented in the EU expert report, BST use infringes all the identified ethical principles as they apply to animals. (A recent report from Health Canada[7] provided essentially similar data, and led to a recommendation that BST should not be used in dairying in that country.)

4.2.2 Producers

Ethical impacts on farmers centre on their ***freedom to adopt, or not to adopt***, this new technology. Compulsion to use BST through economic necessity would offend the ethical principle of ***autonomy***. This type of situation is not uncommon, since most farmers have long been compelled, through economic necessity, to join the 'technological treadmill'. However, each new imposition of a 'technological advance' both limits freedom of choice and leaves the industry more dependent on external inputs and the commercial imperatives of multinational biotechnology companies. A recent survey of dairy farmers in the UK showed that 79% did not consider BST 'ethically acceptable'.[8] But if their economic survival required them to use BST, most farmers would probably see it as the lesser of two evils.

It is claimed that the effectiveness of BST use depends on 'a high level of management skills', which are, however, defined (in inevitable self-fulfilment) by the scale of the milk yield response observed. In practice, there is considerable variation in responses to BST injection (and in some cases no significant yield increase is observed), so that its economic use might depend on sufficiently large herds (to allow for poor responders), adequate feed (which is crucial to sustain the response) and recourse to veterinary treatment to manage increased illness. Such conditions are unlikely to apply for most livestock farmers in less developed countries, whose ***wellbeing*** might thus be adversely affected by failure to compete with (probably imported) dairy products produced using BST. The principle of ***fairness*** is thus likely to have international implications.

4.2.3 Consumers

Relevant ethical concerns here refer to ***food safety, consumer choice*** and impacts on ***affordability***. Again, a recent report of the EU Consumer Policy and Health Protection Directorate provides a useful summary. Their 'Report on Public Health Aspects of the Use of Bovine Somatotrophin', which was published on 16th March 1999,[9] forms the basis of the following remarks.

- While BST, itself, is unlikely to exert any adverse biological effects in humans, effects of cleavage products of BST (i.e. molecular fragments) have not been investigated in detail.

- However, BST administration increases the concentration in milk of a substance with undisputed biological activity in humans (viz. insulin-like growth factor-1, also known as IGF-1).

- According to the report of the Joint (FAO/WHO) Expert Committee on Feed Additives (JECFA),[10] *"rbST can be used without any appreciable health risks to consumers"* because *inter alia* IGF-1 is degraded in the gut. However, in contrast, according to the EU report: *"clear evidence is provided that orally ingested IGF-1 reaches the receptor sites in the gut in its biologically active form"*. Moreover, *"The diverse biological effects attributable to the intrinsic activity of IGF-1, exerting a broad variety of metabolic responses through endocrine, paracrine and autocrine mechanisms, make the definition of an in vivo quantitative dose-effect relationship virtually impossible"*.

- The EU report cites the need to evaluate *"the possible contribution of life span exposure to IGF-1 and related proteins, present in milk from BST treated cows, to gut pathophysiology particularly of infants, and to gut associated cancers"* and draws attention to *"an association between circulating IGF-1 levels and an increased risk of breast and prostate cancer"*.

- Data on the amount of IGF-1 and of a more active form (so-called 'truncated IGF-1') in milk of BST-treated cows were described as *'incomplete'*.

- Increased use of antimicrobial substances (to treat BST-associated mastitis, see 4.2.1) might lead to the selection of resistant bacteria.

Such unquantified risks may fail to respect consumer ***wellbeing***. Moreover, in a recent UK survey, 65.4% considered that the use of BST was not 'ethically acceptable.'[11] Respect for their ***autonomy*** would allow consumers to choose whether or not to purchase the dairy products that result from BST use by requiring such products to be labelled. (This was indeed a recommendation of the EU Group of Advisers on the Ethical Implications of Biotechnology, chaired by Baroness Warnock.[12])

7 Health Canada (1998) Report of the Canadian Veterinary Medical Association Expert panel on rBST.
8 Millar K M *et al* (1999) Ethical attitudes of consumers and farmers to the use of two dairy technologies: Bovine Somatotrophin and Automated Milking Systems. Proceedings of the British Association of Animal Science, Scarborough
9 European Union DG XXIV (1999) Scientific Committee on Animal Health and Animal Welfare 'Report on Public Health Aspects of the Use of Bovine Somatotrophin (15.3.99) Brussels: European Commission
10 Joint FAO/WHO Expert Committee on Food Additives (1998) Rome. WHO Food Additive Series 41, 125-146
11 See note 8
12 European Commission Group of Advisers on the Ethical Implications of Biotechnology (1993) 'The ethical implications of the use of performance enhancers in agriculture and fisheries '(Rapporteurs: M Warnock and M Siniscalco). Brussels

But, this is not currently the case with dairy products or other products containing milk constituents, which are imported from the USA.

Indeed, an adequate labelling policy might present formidable practical difficulties. All milk contains some natural BST, so that separation of the milk produced with the genetically engineered form of BST from milk containing only the natural BST would entail the following:

- separate collection systems (possibly from the same farm if some cows were BST-treated and some not)
- a monitoring programme based on accurate diagnostic tests (which exist but have not been developed for large scale use) and
- informative and comprehensible labelling
- Moreover, if consumers were to be given a genuine choice, retail outlets would have to sell both types of dairy product.

Results of a survey indicate that in the EU milk consumption would decline if BST use were to be legalised[13]. This raises a different type of public health concern, in that milk is an important source of dietary nutrients (particularly calcium) and any significant reduction in its consumption might have adverse effects on public health. For example, inadequate calcium intake increases the risk of osteoporosis (brittle bones, predisposing to fractures).

With respect to the principle of ***affordability***, there appears to be no evidence that BST use in USA has benefited consumers through reduced prices.

4.2.4 The Biota

The living environment is represented in the Ethical Matrix as the biota (i.e. undomesticated animal and plant life). The ethical principles are translated as respect for ***conservation*** of the living environment, ***biodiversity*** and ***sustainability***. It is valid to argue that because BST increases yield per cow, the total number of cows needed to supply milk requirements will be reduced, and this could free up land for more environmentally friendly purposes.

Reducing cow numbers could also reduce some of the pollutive effects on the environment which accompany dairy farming, e.g. on a global scale fewer dairy cows would produce less methane (a greenhouse gas). But this neglects the adverse consequences of increased intensification, which often leads to more point-source pollution, e.g. from slurry and silage effluents. Moreover, methane production from anaerobic degradation of slurry is far greater than from aerobic degradation of faeces dropped in the field.

4.3 An ethical evaluation of BST use

The recent reports cited above suggest that use of BST in milk production:

- **Substantially increases the risk of pain and disease in dairy cows (4.2.1)**
- **Compromises the autonomy of farmers (in Europe and globally) (4.2.2)**
- **Compromises consumer autonomy because milk products from BST-treated cattle are not labelled (4.2.3).**
- **Presents undefined risks to consumers from increased intake of IGF-1 in milk (4.2.3)**
- **Might put public health at risk if there is widespread rejection of dairy products following the licensing of BST in the EU (4.2.3)**
- **Might increase local pollution as a consequence of intensification, while possibly marginally reducing methane emissions (4.2.4).**
- **From a limited utilitarian perspective, it might benefit the manufacturers of BST, the economies of countries in which it is manufactured and certain capital-intensive farms where the returns more than offset the (economic) costs of impaired fitness in the cows.**

A precautionary approach, which took account of the ethical impacts on the range of interest groups identified in this analysis, would suggest that the existing moratorium on BST use in the EU should be extended indefinitely – or at least until known adverse effects were to be eliminated and hazards shown to be insignificant.

Should the WTO attempt to overrule a continued EU moratorium on BST use in the EU it would need to be recognised that the labelling of milk and dairy products would present formidable technical and procedural difficulties.

13 Commission of the European Communities: Economic and Social Committee (1994) Own-initiative Opinion on the use of Bovine Somatotropin in the EU (CES 023/94) Brussels

5. HORMONAL GROWTH PROMOTERS

5.1 Background

In both humans and animals, sex hormones such as oestradiol, progesterone and testosterone are involved in the physiological regulation of growth and development. This has led to attempts to increase the weight gain and feed conversion efficiency of animals reared for meat by supplementing their normal (endogenous) hormones with extra amounts, either of these steroid hormones or similar synthetic compounds. In the USA, Canada and certain other countries, six anabolic hormones (steroids and steroid analogues) are used as growth promoters in beef cattle. Three of these are naturally occurring steroid hormones (17ß-oestradiol; testosterone and progesterone) and three are synthetic compounds (zeranol; trenbolone; and melengestrol acetate - MGA). Most are administered as subcutaneous implants (e.g. behind the ear) or by injection, although MGA is supplied as a feed additive. The effect of these anabolic steroids is to increase lean tissue growth. Fat deposition is reduced and since fat is so energy dense, food conversion efficiency is increased. By these criteria alone, a healthier product is produced at less cost.

In 1981 the European Commission set up an investigation to establish whether the six hormones presented any effects which would harm human health. This ('Lamming') committee and a subsequent working group reported that the concentrations of the substances and their metabolites found in edible tissue were not harmful, providing that the drugs were administered 'under appropriate conditions'.[14]

However, since 1988, the use of hormonal growth promoters has been prohibited in the EU, and a 'third country' is required to guarantee that meat imported into the EU is from animals in which such substances have not been used. Recently, the EU decision has been challenged by the USA and other countries through the WTO, and in March 1999 the USA threatened to instigate a trade war over the issue. The current UK Government position, represented by Mr Nick Brown, the Agriculture Minister, is that 'the EU ban is not justified by the science'.[15]

Other hormones which have the potential to manipulate growth for economic gain include PST (porcine somatotrophin) and clenbuterol (an adrenalin-like ß-agonist). In pigs, PST has an effect similar to that of the anabolic steroids (though the physiological processes involved are different). Lean tissue growth is increased, carcasses are less fat and food conversion efficiency is improved. However, currently, PST is not licensed for commercial use.

Clenbuterol does not increase lean tissue growth but reduces fat deposition. So, again, the meat is leaner and food conversion efficiency is increased. However the adrenalin-like effects of clenbuterol can cause serious cardiac and respiratory problems in both treated animals and humans consuming meat from them.[16] This substance is also currently banned for use as a growth promotant and it is likely that the ban will persist. Indeed, this should be facilitated by the fact that there is now a simple and effective method of testing, based on analysis of hair clippings.

5.2 ETHICAL ANALYSIS

An ethical analysis of growth promoting hormones, with reference to the Ethical Matrix, focuses on impacts on the treated animals, producers and consumers.

5.2.1 Treated Cattle

Data from growing cattle treated with anabolic steroids do not reveal evidence of increased incidence of production-related diseases, as is the case with BST, probably because growth is a much less metabolically demanding process than milk production.

However, these compounds are (or act like) sex hormones and this can have significant adverse effects. There have been reports of abnormalities in the reproductive tracts of both male and female cattle treated with anabolic steriods,[17] and of *"a very obvious and significant dose-related decrease in thymus weight of young calves administered ... a combination of estradiol and trenbolone acetate"*.[18] Such effects may be considered infringements of both animal ***welfare*** and ***telos***. Furthermore, treated animals are more sexually active. When they are confined at a high stocking density in single-sex groups this leads to an increased level of sexual aggression (infringing ***behavioural freedom***) and thus increased risk of injury. Implantation of the hormone pellet may also be seen as an instrumental use of a living being, offending its ***telos***, while ***welfare*** is jeopardised by the small, but significant, risk of infection at the implantation site. Thus, in terms of the Ethical Matrix, there are threats to all three ethical principles as they apply to animals.

5.2.2 Producers

There are certain physical hazards to which farmers may be exposed through use of hormonal growth promoters, perhaps most obviously in the case of the feed additive MGA, which might have adverse effects (cf. respect for ***wellbeing***) through inhalation of dust.

14 Commission of the European Communities. (1984) Report of the Scientific Veterinary Committee, the Scientific Committee for Animal Nutrition and the Scientific Committee for Food on the basis of the report of the scientific group on anabolic steroids in animal production. Brussels
15 MAFF News Release (22.3.99) 'Proposed US restrictions on imports of agricultural products from the EU'
16 For example, Martinez-Navarro J F (1990) Food poisoning related to consumption of illicit ß-agonist in liver. Lancet 336, 1311
17 World Trade Organization (1997) EC Measures Concerning Meat and Meat products (Hormones): complaint by the United States: Report of the Disputes Panel (Dr André)
18 Dr Margaret Haydon, an assessor at Health Canada, in evidence to the Standing Senate Committee on Agriculture and Forestry, Ottawa on 3.5.99. It should be noted that, at the time of writing, the Committee has not yet reported its findings

Commercial pressures to adopt these practices in those countries in which the hormones are licensed have led to their widespread use and, in a global market, there is no reason to assume that this would not also apply in the EU were they to be licensed here (cf. ***autonomy***).

Many beef farmers in UK are now taking advantage of participation in quality-assurance schemes, especially those such as RSCPA Freedom Foods, which demand extremely high standards of animal welfare. This expression of increased ***autonomy*** by producers (which reflects an equivalent desire for increased autonomy by consumers) would be threatened by a removal of the current ban on the importation of hormone-treated beef, particularly if it was not labelled as such.

5.2.3 Consumers

Several standard assumptions about anabolic hormones imply that they constitute a ***food safety hazard***. Thus:

- the specification of 'withdrawal periods', which must elapse before such meat can be sold for human consumption, acknowledges that the hormones are a food hazard
- the withdrawal periods are designed to ensure that hormone levels have returned to the 'normal range'
- it is assumed that there is a threshold below which there is no risk.

However, previous risk assessments (e.g. in the Lamming Report), based on these assumptions, are now believed to be untenable. For example:

- A formal risk assessment of the natural hormones, oestradiol, progesterone and testosterone, was thought unnecessary because they are produced in the human body and there is substantial variation in observed levels. However, in 1999, ADI (acceptable daily intakes) figures were defined.
- Epidemiological evidence for the association between exposure to these hormones and the occurrence of cancer of the breast, prostate and testis was attributed to their hormonal activity – and it was assumed that cancer could only be due to higher intake levels than those needed for physiological action.

But according to the recent report of the EU Scientific Committee on Veterinary Measures relating to Public Health (SCVPH),[19] there is now growing scientific evidence for several important factors which were previously not acknowledged:

- Adverse effects of hormones may be mediated not only by processes involving hormone receptors but also via formation of hormone metabolites, which may have genotoxic effects, especially in the case of oestradiol.
- There is increasing awareness of the sensitive hormone balance which exists at different developmental stages in humans,

making it imperative to distinguish between age and sex in assessing safe hormone exposure levels: prepubertal children may be particularly at risk to elevated levels.

- The increase in hormone-associated diseases (such as breast and prostatic cancer) in many countries suggests a need to re-evaluate the possible contribution of residues of growth promoting agents in meat to the total load of hormones and hormone-like substances in the diet.

The Report concluded that:

- a risk to consumers has been identified, with different degrees of conclusive evidence, for all six hormones
- *"In the case of 17β-oestradiol ... a substantial body of recent evidence (suggests) that it has to be considered as a complete carcinogen, as it exerts both tumour initiating and tumour promoting effects"*
- the current state of knowledge does not allow a quantitative estimate of risks due to the other five hormones
- for all six hormones, "*endocrine, developmental, neurobiological, immunotoxic, genotoxic and carcinogenic effects be could be envisaged*" (with pre-pubertal children being the group of greatest concern).
- no threshold levels could be defined for any of the six substances (i.e. below which there would be *no* effects).

In addition, there have been concerns about abuses of the hormones and difficulties in controlling their use, for example:[20]

- misplacement of approved implants (e.g. injected into neck muscles, which have a rich blood supply, rather than the ear), increasing risks to consumers if the implanted material is not excluded from the food chain and/or if hormone levels are substantially increased
- use of multiple implants simultaneously, e.g. when oestradiol and trenbolone are administered together there is a pronounced synergism.

19 European Union DG XXIV (1999) Scientific Committee on Veterinary Measures Relating to Public Health: Assessment of potential risks to human health from hormone residues in bovine meat and meat products (30.4.99) Brussels

20 European Commission Spokesman's Service (1999) Abusive use and difficulties of controls of growth hormones increase risks (3.5.99) Brussels

Moreover,

• *"Within the framework of the US National Residue Program no residue examinations have ever been performed ... for trenbolone acetate. No residue tests have been performed for zeranol since 1989 and for MGA since 1990".*[21]

The main risks to human **wellbeing** are therefore likely to be due to the intrinsic hazards of such substances, coupled with abuses, inadequate monitoring and/or loopholes in the law. In practice, there are five major problems.

• The recent evidence from the EC SCVPH report [22] suggests that exposure to any concentration of residues in hormone-treated meat presents some degree of risk to consumer health – i.e. there is no threshold level.

• It is difficult (though not impossible) to police the use of the 'natural' steroids, (17β-oestradiol, testosterone and progesterone) by testing for residues in meat (and in cattle sent for slaughter). However, there is now a very sensitive test for residues of clenbuterol in meat (and other tissues such as hair) which makes it possible to police its illegal use.[23]

• A ban on the use of (allegedly 'safe') substances such as trenbolone may increase the black market for more dangerous compounds such as stilboestrol. Indeed, the original EU ban on testosterone, trenbolone etc. was imposed following evidence of abnormal mammary development in babies fed products containing veal from calves implanted with stilboestrol, which had already been banned.

• Whether the use of certain anabolic hormones is legalised or not, there is a real risk of residues in meat arising from their illegal use (administration of illegal substances or administration of legal substances at an illegal time). This implies that there is a potential risk to humans that which can only be controlled by diligent and widespread monitoring of residues.

• Safety information may not be disclosed because of legal provisions. Thus, in evidence to the Appellate Body of the WTO *"Canada and the United States stated that they had conducted risk assessments and had authorised MGA for growth promotion, but refused to provide scientific evidence and information claiming that their studies were proprietary and confidential in nature".*[24]

In conclusion, it should be noted that consumer confidence in the safety of beef has been severely undermined by the recent BSE and E Coli scares. Anything which aggravates that situation fails to respect **consumer wellbeing** in its widest sense.

5.2.4 The Biota

Environmental impacts of anabolic hormones (on conservation, biodiversity and sustainability) are less easy to discern in the short-term. However, recent evidence suggests the effects are unlikely to be negligible. For example, the cumulative effect of oestrogenic material appears to be responsible, *inter alia*, for a falling sperm count in men in Western countries.

5.3 An ethical evaluation of hormone use for growth promotion

Based on the evidence of recent reports

• Certain adverse effects of their use, such as abnormalities of the reproductive tract and effects on sexual libido, infringe animal telos, while others, such as effects on sexual aggression, infringe behavioural freedom (5.2.1).

• There are small but significant risks to animal welfare through infections developing at the implantation sites (5.2.1).

• Anabolic hormones used as growth promotants in cattle carry a potential risk to humans in view of their envisaged endocrine, developmental, neurobiological, immunotoxic, genotoxic and carcinogenic effects (5.2.3).

• There are also small but significant risks to consumer health and consumer choice from the illegal use of certain banned anabolic hormones (5.2.3).

A precautionary approach, which took account of the ethical impacts on the range of interest groups identified in this analysis, would suggest that the existing moratorium on the use of these hormones in the EU should be extended indefinitely – unless new technological developments were to significantly diminish the adverse ethical impacts described above.

However, if the WTO were to overturn the EU ban there should be no serious obstacles to the imposition of a system of labelling that classifies beef, veal and pigmeat according to whether or not it is from animals that have been given anabolic hormones, since procedures are already established for authenticating the origin of meat from cattle and pigs.

In any case, there is a need for improved methods and procedures for surveillance of residues of anabolic hormones in meat and meat products arising both from the use of banned drugs and from the misuse of permitted drugs.

21 See note 20
22 See note 19
23 Elliott C T et al (1995) Development of a rapid screening test to detect β-agonist residues in bovine eye and hair. Veterinary Record 137, 643-4
24 World Trade Organization (1999) European Communities- Measures Concerning Meat and Meat Products (Hormones): Status Report by the European Communities (14.1.99).

6. ZOOTECHNICAL FEED ADDITIVES

6.1 Background

Zootechnical feed additives (ZFAs) are substances added to animal feeds which are not themselves nutrients but are intended to increase productivity by improving the digestion, absorption and utilisation of nutrients. Most public concern about ZFAs relates to the routine use of 'in-feed' antibiotics, which were formerly classed as PMLs (see Box 1).

It is helpful to understand how this practice came about. The modern, highly intensive, 'factory farming' systems of food production evolved rapidly during the period from 1950-1970. The main economic forces driving this intensification of livestock production were: increased mechanisation of agriculture, permitting the bulk movement of feed and manure; increased profitability of livestock production, based (in some cases) on subsidies, permitting capital investment in buildings and equipment; rising consumer incomes leading both to increased demand for meat and dairy products, and to higher labour costs relative to costs of feed, fuel and equipment; and increased control of animal disease through the development of vaccines and antibiotics - allowing animals to be stocked at high densities, which would formerly have incurred economically unacceptable levels of death and disease.

Prescription of antimicrobial drugs, such as antibiotics and coccidiostats, became routine, especially in intensive pig and poultry units, to control diseases caused by exposure to high concentrations of bacteria and protozoa, respectively. It was undoubtedly effective, within this limited definition of success. Apart from the use of monensin in beef cattle (see Box 3), there has not been a similar routine prophylactic use of antibiotics to control infectious disease in growing ruminants (beef cattle and sheep) for the simple reason that these animals rely on microbial action in the rumen to digest their food. In this case, routine use of most antibiotics kills off rumen microbes and impairs appetite and growth. The rearing of calves on milk for white veal is a special case. These animals are prevented from becoming ruminants, and this has permitted systems for the production of white veal to be as intensive as those for poultry and pigmeat. It has also greatly increased the need for routine use of antibiotics to control bacterial infections.

As the inclusion of antibiotics in feeds became routine, pigs and poultry receiving these medicated feedstuffs often showed improved food conversion efficiency even in conditions where they were not exposed to infection. Confirmation of these observations led to further research to develop the new category of zootechnical feed additive, i.e. a substance which is not itself a nutrient but which is intended to 'enhance' performance by improving the digestion and utilisation of nutrients. (See Box 3)

BOX 3 – The main categories of zootechnical feed additives

Substances which increase digestibility (enzymes): *these improve the digestion and utilisation by the body of (especially) starch and non-starch polysaccharides. There is no reason to suppose that these may cause direct harm to animals (or subsequently to people) provided they are incorporated into a balanced wholesome diet.*

Substances which improve nutrient absorption from the intestine: *the small intestine of any healthy, normal animal contains a large population of commensal bacteria which are harmless, but compete with the host animal for nutrients that could otherwise be diverted to meat production. When used as ZFAs, copper salts and antibiotics such as tylosin or zinc bacitracin greatly reduce the population of commensal microorganisms. This reduces cellular activity (especially in cells of the immune system) and increases the net absorption of nutrients. An in-feed antibiotic also reduces problems of low-grade infection with bacteria sensitive to that antibiotic. However, the use of an antibiotic as a growth promotant does not make the animal healthier. Indeed, it actually increases the risk of infection with bacteria resistant to the antibiotic by impairing the probiotic effects of the natural flora.*

Substances which manipulate fermentation: *ruminant animals, like cattle and sheep, obtain most of their nutrients from the end-products of microbial fermentation. It is therefore possible to alter the nutrient supply to ruminant animals by selectively manipulating the microbial population of the rumen using certain antibiotics or coccidiostats. The most successful drug for this purpose has been monensin sodium, which significantly improves food conversion efficiency in growing cattle. It achieves this effect, in part, by halving methane production, which not only conserves energy for the host animal but also reduces production of this greenhouse gas. By changing the end-products of fermentation it also conserves amino acids, thereby sparing more nitrogen for the growing animal and indirectly reducing nitrogen pollution from ruminants.*

In the 1960s, concern that continued low level use of anitbiotics as growth promoters might result in the development and selection of antibiotic resistant bacteria led to a legal distinction being drawn (in the 1968 Medicines Act) between therapeutic and feed antibiotics. This allowed continued use of feed antibiotics, which it was considered would not pose any risks to the continued efficacy of therapeutic antibiotics. However, the Swann Committee, which reported in 1969 was of the unanimous opinion that: *"administration of antibiotics to farm livestock, particularly at sub-therapeutic levels, poses certain hazards to human and animal health".*[25] The committee made forty two recommmendations on the use, control and supply of 'feed antibiotics'.

However, such cautionary advice, and that of subsequent government committees, has not eliminated the problem. According to a recent report from the Soil Association:[26]

- Approximately 1225 tonnes of antibiotics are used annually in the UK, of which 37% are used on farm animals, 25% on pets and horses and 38% in human medicine.
- Virtually all growing pigs and broiler chickens receive antibiotics in their feed for the major part of their lives.

6.2 Current legal regulation of antibiotics in feeds

The uses of antibiotic (or antimicrobial) productivity promotants as 'zootechnical feed additives' (ZFAs) are subject to EU Directive 70/524/EEC (amended). Market authorisation under this Directive is subject to several criteria, including the requirement that, at the permitted level in animal feed, there should be no adverse effects on human health, animal health or the environment. However, according to the 'safeguard clause' a Member State may suspend or restrict use of a ZFA if it deems that there is evidence that calls the use of the substance into question. In such cases the Commission, in consultation with Member States, decides whether the scientific evidence adduced to support the safeguard clause is justified.[27]

In 1997, appeal to the safeguard clause resulted in an EU ban on the use of avoparcin, because of concerns that its use in animals might lead to development of resistance against the related antibiotic, vancomycin, which is used in human medicine. Subsequently, several other bans were introduced on use of ZFAs linked to antibiotics used in human medicine, while Sweden, on accession to the EU, was allowed to maintain its ban on the use of all ZFAs until the end of 1998. Recently, in response to general concerns about development of antibiotic resistance, the European Commission introduced a ban on four ZFAs (bacitracin zinc, spiramycin, tylosin phosphate and virginiamycin) which will be implemented by all Member States from 1 July 1999, and will be subject to review before 31 December 2000.

In addition to these four, use of two further ZFAs, olaquindox and carbadox, will be prohibited from 31 August 1999, due to concerns over possible adverse effects arising during their manufacture. Hence, from 1 September 1999 only four ZFAs will be permitted in the EU: avilamycin, flavophospholipol, monensin sodium and salinomycin sodium.

6.3 The problem

The distinction between therapeutic, prophylactic and growth promotant uses of antibiotics is not always clear cut. A prime example is the antimicrobial compound tylosin, one of the four ZFAs recently banned in the EU. Before the ban, tylosin was used both as a ZFA to improve feed conversion in (nominally healthy) growing pigs and as a prophylactic to reduce the incidence and severity of enzootic (mycoplasma) pneumonia, a condition that is rarely fatal but does impair growth. Any analysis of the rights and wrongs of banning the use of tylosin in pigs has to consider (at least) the following consequences:

- marginal losses in productive efficiency in healthy animals
- the risk (to pigs) of impaired welfare through increased prevalence of pneumonia
- the risk (to people) of prescribing alternative antibiotics (also used in human medicine) to control pneumonia in pigs
- the reduced welfare of pigs reared in very poor conditions of housing and husbandry where pneumonia can only be controlled by the regular administration of antibiotics.

Another example which illustrates the difficulty of making clear distinctions concerns the use antibiotics prescribed by the veterinary surgeon nominally to control disease. These may be prescribed for:

- All pigs in a group, where only some are observed to be sick. This blurs the distinction between therapy and prophylaxis.
- All pigs in a group, routinely to prevent sickness. This blurs the distinction between prophylaxis and growth promotion, since the drug may be given to preserve normal growth rates in housing conditions likely to predispose to enzootic pneumonia.

These examples illustrate the complexity of the ethical issues and the danger of simplistic solutions, such as a rigid restriction of drugs to therapeutic uses only (the only uses permitted by organic farmers). Without suitable animal management and housing systems, this could do more harm than good.

6.4 ETHICAL ANALYSIS

In the following sections we examine the use of antibiotics and other substances in animal feeds, whether nominally used as prophylactics or as growth promotants, according to the framework provided by the Ethical Matrix.

25 Joint Expert Committee on the use of Antibiotics in Animal Husbandry and Veterinary Medicine (1969). London: HMSO
26 Harvey J and Mason L (998) The Use and Misuse of Antibiotics in UK Agriculture Part 1: Current Usage. Bristol: Soil Association
27 Veterinary Medicines Directorate (1999) Medicines Act Veterinary Information Service (MAVIS) 'EU to ban four antibiotic growth promoters'. Edition 29, 3.

6.4.1 Treated Animals: Pigs, Broiler Chickens and Veal Calves

Several practices adversely affect ***animal welfare***:

• Most compounded feeds for growing pigs, pre-weaning calves and broiler chickens are supplemented with antibiotics. These are most commonly incorporated into feeds for piglets weaned at 3-5 weeks of age. The primary intention here is to control scours (diarrhoea), so this appears, at first sight, to be an action designed to improve health and welfare. However, piglets can be weaned quite successfully without recourse to antibiotics at a more natural age (at least 8 weeks). It is also possible to adopt other more specific approaches to the control of post-weaning scours, e.g. the use of active or passive immunisation (vaccines or antibodies/antitoxins).

• Antibiotics used as growth promotants in broiler chickens may also have a prophylactic role, e.g. in the control of necrotic enteritis. However, this condition is associated with excessive consumption of cereals, which could be avoided. Alternative control mechanisms for this condition include the use of in-feed enzymes, which may be considered a more 'natural' form of ZFA since they address the primary, physiological source of the problem.

• When antibiotics are used simply as growth promotants in broiler chickens, or in pigs after they have overcome the stress of weaning, the effect is greater in the presence of an endemic disease or stressful conditions such as poor hygiene and overcrowding. Hence, ZFAs are able, to some degree, to mask the worst effects of bad housing and hygiene (i.e. overcrowding and squalor). In these circumstances all animals may be denied the freedoms of physical comfort and opportunity to carry out normal maintenance and social behaviour (cf. the principles of ***wellbeing*** and ***behavioural freedom***). Some animals suffer from the symptoms of diseases caused by damage to the digestive tract (whether antibiotics are used or not) and some will die. Despite this, the system as a whole is economically viable.

• Probably the most serious ***welfare*** problems for broiler chickens and (to a lesser extent) growing pigs are the painful abnormalities of the skeletal system caused by animals 'outgrowing their strength' in environments where there is minimal opportunity to assist skeletal development through proper exercise. Broilers in chronic pain with 'leg weakness' are unable or unwilling to support the weight of their body. Lying for long periods on litter exposes them to the corrosive effect of faecal deposits, which may cause breast blisters and hock burns. Such conditions are made possible by routine use of ZFAs. According to a UK Farm Animal Welfare Council report in 1992: "*... the current level of leg problems in broilers is unacceptable.*"[28] The industry has achieved improvements since then, but there is still a long way to go.

• The production of white veal from calves kept in individual crates and reared entirely on liquid feed has been the most extreme example of a production system that fails to respect any of the identified ethical principles (***welfare, behavioural freedom*** and ***telos***). The worst excesses of this system have now been banned in UK, and EU legislation is at last proceeding in the same direction. The abnormalities of normal rumen development in calves, caused by denying them access to solid food, are such that this system can only be sustained by the regular use of in-feed antibiotics.

It is clear that antibiotic ZFA use supports animal production systems which greatly impair animal ***welfare***. The fundamental problem is that many intensively reared animals are kept under conditions which are essentially unsustainable but are nevertheless rendered economic by the routine use of antibiotics. That is to say, real animal welfare problems are masked by an antibiotic 'sticking plaster'. And in that the animals are also treated in a highly instrumental fashion, with little concern for their intrinsic worth, the principle of respect for their ***telos*** is markedly offended.

The problems of 'factory farming' cannot be blamed solely on use of ZFAs. Nevertheless, the routine use of in-feed antibiotics has been an essential contributor to the economic success of many of the most intensive systems of animal production, i.e. the systems of pig, poultry and veal production which were condemned by the Brambell Committee as long ago as 1965.

On the other hand, provided that they are applied correctly, there appear to be no adverse effects on ***animal welfare*** from the use of enzymes and monensin sodium, which act by improving digestion and selectively manipulating the microbial population of the rumen, respectively. However, it should be noted that that there are some hazards associated with these substances, e.g. monensin sodium is toxic to horses.

28 Farm Animal Welfare Council (1992) Report on the Welfare of Broiler Chickens. Tolworth: MAFF.

6.4.2 Producers

Clearly, farmers neither like to see their animals suffer nor to spend money unnecessarily. Thus they do not use antibiotics unless they feel they need to. A global, properly enforced, ban on the use of certain antibiotics as growth promotants would almost certainly be acceptable to farmers because it would not put them at a comparative economic disadvantage. Indeed, even in the absence of any such general ban, many farmers are exploiting the commercial potential of marketing their meat as free from antibiotics, most effectively through organic farming schemes.

BOX 4 – The Scandinavian Experience

Sweden *enacted a ban on ZFAs in 1986. This led to initial health problems in pigs and poultry because veterinary surgeons were largely unprepared. In fact, total use of antibiotics remained fairly stable at about 35 tonnes of active substances p.a. However, it is claimed that antibiotic use in Sweden has now reduced by 55%.*

This has been achieved by a combination of different strategies:

- *Reduced stocking density*
- *Improved hygiene and housing systems designed to reduce stress*
- *Changed feed composition*
- *New feeding strategies*

In ***Denmark****, at the beginning of 1998 the animal food industries adopted a voluntary ban on the use of antibiotic ZFAs, and began a number of scientific studies to determine the effects on morbidity and on therapeutic antibiotic use in pigs and broilers. With reference to commercial broiler flocks, by May 1999 there had been no increase in general morbidity and no significant increase in the use of antibiotics for therapy. However, there was an increase in the number of flocks suffering from the Clostridium perfringens-related diseases necrotic enteritis and chronic hepatitis.* Since March, 1998 there has been no use of antibiotic ZFAs for finisher pigs (subject to random testing and fines for violations). Some herds have made the transition with no observable effects, although there is a tendency to looser excreta, which is often rectified as the intestinal microflora stabilise. In other cases, diarrhoea responds to changes in feed and housing conditions.***

* Dr Flemming-Bager (11.5.99) - Personal communication.
** Kjeldsen N (1999) Proceedings of the British Society for Animal Science: Scarborough (22-24.3.99).

However, conversion to organic farming is a risky, long-term process – so that the UK Government's recent doubling of the payment rates to farmers wishing to convert to organic farming[29] is a welcome, if not totally adequate, initiative. However, other, less intensive, systems which accord greater to respect animals and reduce risks to humans, will also require substantial investment, which many farmers will be unable to afford. In such terms, producer ***autonomy*** is only partially respected.

6.4.3 Consumers

The main consumer concern relating to the widespread use of antibiotics in farm animals relates to the risk of antibiotic resistance in bacteria responsible for human diseases (cf. ***food safety***).

The issue has been the subject of numerous reports during the past eighteen months and it would be superfluous to make more than brief reference here to the major features. The House of Lords Select Committee on Science and Technology report, together with its extensive evidence, provides a comprehensive analysis of the problem, which left the authors *"convinced that resistance to antibiotics and other anti-infective agents constitutes a major threat to public health."*[30] While acknowledging that unnecessary prescription of antibiotics in human medicine contributed to the development of antibiotic resistance, they warned that *"there is a continuing threat to human health from imprudent use of antibiotics in agriculture."* The authors went on to recommend that *"antibiotic growth promoters such as virginiamycin, which belong to classes of antimicrobial agent used (or proposed to be used) in humans and are therefore most likely to contribute to resistance in human medicine, should be phased out, preferably by voluntary agreement between the professions and the industries concerned, but by legislation if necessary."*

Most recently, the EU DG 24 Scientific Steering Committee on Antimicrobial Resistance has made similarly strong recommendations, pointing to the *"use/misuse (of antibiotics) as feed additives"* and the need for prompt action *"to reduce the overall use of antimicrobials in a balanced way in all areas"*, including veterinary medicine and animal production.[31]

The Soil Association's recent report 'The Use and Misuse of Antibiotics in UK Agriculture'[32] went further in calling for (*inter alia*):

- a ban on all non-medical uses of antibiotics in agriculture
- prophylactic use to be limited to cases of genuine need, as part of a planned disease reduction programme involving changes in housing, feeding and management
- a ban on the advertising of antibiotics directly to farmers

29 MAFF News Release (12.4.99) Boost for Organic Farming: new organic scheme launched
30 House of Lords (1998) Select Committee on Science and Technology report: 'Resistance to Antibiotics and other antimicrobial agents'. London: The Stationery Office
31 European Union DG XXIV (1999) Scientific Steering Committee on Antimicrobial Resistance (28.5.99): Brussels
32 See note 26

However, without a simultaneous radical change in animal management and housing systems, the ban on a wide range of antibiotics used as ZFAs might itself create a serious concern. Although ZFAs such as avoparcin and virginiamycin may carry a risk of increasing antibiotic resistance in human pathogens, they were originally selected for use as ZFAs because this risk was considered small relative to that involved with the widespread use of antibiotics of first choice in therapy (e.g. the penicillin and tetracycline series).

Tylosin is classed both as a ZFA and a medicated feedingstuff (POM), so that one can envisage two scenarios. If tylosin were to be banned altogether, a veterinary surgeon, presented e.g. with a pen of pigs with enzootic pneumonia, might feel obliged to treat the whole pen (and probably the whole house) with a therapeutic antibiotic such as a tetracycline (with associated risks in terms of human health). If, on the other hand, tylosin were only to be banned for use as a ZFA (as is currently the case), farmers and their veterinary surgeons, operating under extreme economic pressure, might elect to dispense it to most or all the growing animals, nominally to control infectious disease but, in practice, to improve profit margins.

Under such circumstances there would seem to be a need for changes in the law. A recent British Veterinary Association working party report recommended that *"following a scientific review, these substances should be re-authorised as medicines and used only under veterinary prescription"*.[33]

However, withdrawal of routine use of antibiotics (whether nominally prophylactic or productivity promotant) would need to be coupled with the radical changes in animal management and housing which have been adopted in Sweden and other Scandinavian countries (see Box 4).

6.4.4 The Biota

It is claimed that ZFA use is environmentally beneficial because both feed intake and manure production are decreased per unit of meat produced. However, such benefits may well be offset by the fact that, since antibiotics are not absorbed into the animal's body, they are excreted, probably in active form, in faeces. Disposal of excreta, for example as broiler house litter, may thus disperse antibiotics into the environment, with likely adverse effects on the biota. This must constitute a hazard, although its scale seems not to have been investigated.

Such environmental impacts of antibiotics (on ***conservation, biodiversity*** and ***sustainability***) would then seem to be inextricably bound up with the human health impacts discussed above.

6.5 An ethical evaluation of the use of zootechnical feed additives

On the basis of evidence in a number of recent reports (e.g. from the EU and the House of Lords)

• Antibiotic ZFA use supports systems of animal production for chickens, pigs and calves which show little respect for their wellbeing, behavioural freedom or telos as sentient beings (6.4.1).

• However, certain agents, such as monensin sodium and enzymes, may be seen as distinct from other ZFAs in that they do not appear to significantly infringe the same ethical principles, while respecting producer wellbeing, consumer affordability and environmental sustainability (6.4.1)

• Antibiotic ZFA use threatens human welfare through aiding the development of antibiotic resistance bacteria (6.4.3)

• Adverse environmental impacts of antibiotic ZFAs might be anticipated from their dispersal, in active form, in the excreta of treated animals (6.4.4)

There is now a strong case, in terms of protecting public health and with respect to the Precautionary Principle, for phasing out the use of all unnecessary antibiotics, such as those used merely to increase productivity, as soon as is practicable.

An additional reason for this is to ameliorate the very poor welfare of animals raised in systems which only remain economically viable because of the use of antibiotic ZFAs.

The analysis suggests that a legal distinction should be made between antibiotics used for medical purposes (including treatment and justifiable prophylaxis) and non-medical (growth promotion) purposes and that all antibiotics should be re-classified as medicated feedingstuffs, i.e. POMs.

Maintaining animal production systems without recourse to routine administration of antibiotic ZFAs requires a totally new approach to animal management and housing, which cannot be introduced overnight without jeopardising animal welfare.

33 British Veterinary Association (1998): Report of the Antimicrobials Working Group. (17.9.98)

7. THE WAY AHEAD

7.1 A basis for Trust

Food for people which is of animal origin is potentially riskier than food from plants for the simple reason that animals are so like us in their biochemistry. What is chemically correct for us is also chemically correct for the microorganisms that graze on us and on them. Hormones too, work in much the same way in people as they work in animals. Thus, most food scares concern food of animal origin.

Public perceptions of risk associated with food-borne disease may not always be fully informed, but then why should every citizen be required to understand the principles of microbiology and epidemiology? What the consumer needs is to be able to have ***trust*** in the quality and safety of food of animal origin. This trust has, in recent years, been eroded by a series of outbreaks of disease, some little more than scares grossly overdramatised by the media; others, such as E.Coli 0157 and new strain CJD, very serious indeed.

Public concern about the use of hormones and antibiotics does, however, go much deeper than simply a feeling for personal safety: it also relates to the ethical acceptability of the ways in which veterinary drugs are used in producing food. All departures from natural food production - factory farming, antibiotics, hormones, genetic engineering, irradiation - tend to be treated with suspicion. And while the suspicions may not always be well founded, these concerns are often consistent, as we have tried to show in this report, with the principles encompassed by 'common sense ethics'.

7.2 The role of Science in political decision-making

It is rational to insist that any decisions as to the application and impact of biotechnology on food and agriculture must be informed by a thorough review of the technical evidence according to the rigorous discipline of scientific method. It is not however, rational to assume that such decisions can be based on scientific evidence alone. When the U.K Agriculture Minister, Mr Nick Brown, stated: *"the EU ban* (on steroid hormone use in beef cattle) *is not justified by the science"*[34] he was simply broadcasting advice given to him by scientists, operating rationally but within their own limited terms of reference. (The assumption that science alone can inform such decisions exemplifies the so-called 'naturalistic fallacy', which refers to the claim that "You can't get an 'ought' from an 'is'".) What he did not convey was any sense that consideration had been given to the impact of ethical principles which respect autonomy and justice.

On 23 February, 1999, several broadsheet newspapers published a letter from nineteen Fellows of the Royal Society which began: *"We believe that the time is right to bring good science into the centre of decision making and focus its impact on our increasingly technologically-driven world"*.[35] We suggest that science (and scientists) are already making a sufficient impact on the decision-making process. What is needed is the wisdom to choose ***good technology***, both for reasons based on good science *and* on reasons that transcend science. Technology assessment should have at least as much to do with the 'ought' as with the 'is'.

Hence, it is central to the case presented here that political decisions concerning the impact of biotechnology on food production cannot be based simply *'on the science'*. In some extreme cases, such as the BSE epidemic, this is because the 'best available' evidence is very weak. In the context of this report, the scientific evidence concerning the routine use of hormones and antibiotics in food animals is much more extensive, but it is by no means unequivocal. It is, moreover, important to distinguish between objective evidence obtained through the use of scientific method and the 'spin' put on such evidence by individuals to support their own ideological position or their careers. It follows from this that scientists cannot assume the 'right to the last word'.

But even were there to be universal scientific agreement on the (biological) risks associated with a particular technology, this would not provide definitive grounds for a decision because the *acceptability* of risks is not a matter on which science can pronounce. Some people risk their lives climbing mountains, others dare not risk going out without a hat: there is no 'right' answer. However, in this simple example, individuals are at least accorded respect for their autonomy, allowing them to define the acceptability of risks in their own terms. It is reasonable to expect that individuals should be permitted a similar degree of autonomy as to the acceptability of the food they eat, and that both producers and consumers should be treated fairly.

7.3 The Precautionary Approach

It is a characteristic of entrepreneurial activity that it involves taking risks: and according to free market philosophy, those who take risks successfully should be rewarded for their business acumen. However, in the new world order, where globalisation ensures that technological innovations might not only have global benefits but also produce global risks, it is prudent (and ethical) to

34 See note 15
35 Heap B et al (1999) 'The misappliance of science'. Letter to the Guardian (23.2.99)

proceed with more circumspection than market forces are inclined to allow. There is a need, that is to say, to pay serious attention to the Precautionary Principle (PP).

The PP was developed at a time when doubts first began to arise that the 'environment' was so robust that it was capable of absorbing the impact of all human activities. Recognition of the growing significance of several serious environmental problems (global warming, holes in the ozone layer, accumulation of environmental toxins) changed these perceptions and led to the formulation of the PP, which *"In its various legal forms... insists that where a substance or a technology is potentially damaging to the environment, regulation should be considered irrespective of 'final scientific proof'"*[36]

The PP is now incorporated into international law and some domestic laws concerned with the environment. In applying the PP to the use of veterinary drugs it is clear that its remit is being extended substantially beyond the original environmental locus (although there is an environmental dimension to veterinary drug use). Appeal to the PP has already been made with respect to the ban on the use of certain antibiotic feed additives in the EU (see 6.2). However, the animal feed industry has responded with the claim that the PP is being used in this case as a mere 'political expedient' and should be abandoned in favour of 'sound scientific evidence'.

Thus, it seems important to explore the usefulness of the PP with respect to the ethical acceptability of veterinary drugs. The essence of the PP is that it is unwise to take serious risks which may jeopardise human, animal or environmental life or health. Where there is uncertainty, the grounds for proceeding with a new technology are problematical: but uncertainty is the product of current and theoretical limits, i.e. the unknown and the unknowable. The former category can be addressed by appropriate research and/or expertise. The latter, 'unknowable,' category describes, especially, situations where the risks are low and/or multifactorial and/or long term. In these situations (e.g. diet and coronary heart disease, BSE and CJD) the damage may be done before we can 'scientifically' identify the problem.

Veterinary drugs, by design, have significant physiological effects on the treated animals. When they are used for therapeutic purposes it is assumed that the beneficial effects outweigh any potentially harmful side-effects. It is recognised in principle and in law that their use might be hazardous to the animals, to those who consume their products and to other life forms within the environment. Indeed, legislation to regulate (e.g.) withdrawal periods for antibiotics used therapeutically on animals in the food chain, or the use and disposal of sheep dips, is based not on 'sound science' but on scientific uncertainty. This is the PP in practice. However, the principle does not always seem to apply when dealing with non-therapeutic agents.

7.4 Impact of the World Trade Organisation (WTO)

Ultimately, many of the concerns expressed in this report have implications for trade and hence are affected by WTO rules, which are designed to ensure that there are no barriers to international trade. However, individual trading nations frequently have different ethical positions and these are often reflected in national legislation. If the benefits of trade liberalisation are given absolute priority then attempts by individual nations (e.g. to protect the vital interests of people and their cultural diversity, animal welfare and the environment) will be undermined. And this may lead to a loss of public support for the international trading system in general.

We believe that such national differences should be respected when they are genuine expressions of ethical concern, which are not adopted merely to gain trading advantages. If 'free trade' is to be ensured at all costs, then policies which seek to promote concerns such as social justice, animal welfare and environmental sustainability seem doomed to failure, because adoption of most of such measures involves additional financial costs. Regrettably, like many other things, ethics does not come free.

Hence, a complementary relationship needs to be established whereby policies which promote ethical advancement are facilitated rather than obstructed by those adopted to ensure free trade.[37] In the mean time, it may be necessary in some circumstances, according to WTO rules, to pay compensation.

7.5 Changing for the better: the levers

Effective programmes for change require well-considered strategies. Even if attempts to effect change at the level of the WTO seem daunting, other levers may be more accessible and effective in a national context.

- EU legislation determines national policies of Member States through EC Directives. This has resulted in actions supportive of several of the recommendations made in this report, e.g. in relation to the bans on the use of BST and steroid hormones and on the importation of beef from the USA which involves treating cattle with hormone pellets.

- UK legislation has often been in advance of EU legislation in relation to several concerns in this report, e.g. in the banning of veal crates and sow stalls. Thus, working for ethical advances through UK law is certainly a feasible aim, but pressure can also be exerted for changes in EU law through the UK's influence in the European Parliament and in the Council of Ministers.

36 Parker J (1998) Precautionary Principle. In 'Encyclopedia of Applied Ethics' ed Chadwick R. vol. 3, pp. 633-641. San Diego: Academic Press
37 Royal Society for the Prevention of Cruelty to Animals (1998) Conflict or concord? Animal welfare and the World Trade Organization. Horsham: RSPCA

• Supermarkets, which now account for most of the retail trade in food in the UK, have considerable influence on food safety standards and integrity. The recent decisions of major supermarket chains not to sell 'own-label' genetically modified foods is a graphic illustration of that fact. 'Ethical trading' in the broadest sense is becoming an increasingly important sector of the market, as demonstrated by the rapidly increasing sales of organic food and the RSPCA's Freedom Foods.

• An alternative explanation of the trend to 'ethical trading' is that it is a response to consumer demand. There can be little doubt that there is a widespread concern in the UK over the use of drugs in food production, and that this consumer power – coupled with the amplifying effects on supermarket policy – represents a genuine avenue for change for the better in the food system. While WTO rules tightly constrain governments, the relatively low percentage of income spent on food in developed countries, together with an increasing awareness of food technologies, has given consumers a much greater influence over the way food is produced and marketed. However, widespread ignorance of the practices involved in modern food production is probably the major impediment to more rapid change.

• Farmers clearly have some influence over whether or not they employ drugs in animal production systems (although in the EU the choice is currently limited to a few antibiotic growth promotants). Advertising of antibiotics in the agricultural trade press is common, a practice which MAFF's Veterinary Medicines Directorate claim is allowed under the Medicines Act but which is deprecated by the British Veterinary Association. In reality, in many cases, farmers' choice is likely to be severely constrained by economic considerations: the playing field is not of their making.

• Veterinary surgeons clearly also have a major responsibility for prescribing, and advising farmers on the use of, veterinary drugs. In some cases alternative methods of disease control might be available (e.g. vaccination) but it is a fact that vets derive a substantial income from such drugs, and this may militate against radical and necessary change. However, it is in the mutual interest of farmers and their vets to promote preventive medicine schemes that reward the veterinary surgeon for ensuring herd and flock health rather than dispensing drugs. The UK veterinary professional bodies (the Royal College of Veterinary Surgeons and the British Veterinary Association) could play a significant role in promoting the appropriate practices recommended in this report.

We believe that conscientious attempts to introduce appropriate changes at these various levels will engender a 'culture of care', the essence of an ethical approach, which will provide a necessary counterbalance to the currently dominant 'culture of profit'.

7.6 Procedural concerns

There are three general types of concern over the assessment procedures for veterinary drugs (and indeed, more generally, relating to all biotechnological procedures applied to food) which have profound implications for trust.

A)
First, there is the question of the criteria on which regulatory decisions are made (whether these should be based solely, as at present, on 'safety, quality and efficacy' or on a system which incorporates these three criteria into a broader ethical framework)

B)
Second, there is the question of the provision of the scientific evidence on which decisions are made (its source, objectivity, reliability and adequacy).

C)
Third, there is the question of the composition of the committees charged with decision-making (their expertise and impartiality).

We have argued in this report that 'sound science' is not enough: respect for a number of ethical principles as they affect a range of interest groups should also influence the outcome of decision-making procedures. Moreover, scientific evidence needs to be, and be seen to be, impartial, comprehensive and trustworthy. Data collection by those with a vested interest in the product (even 'disinterested scientists' whose career prospects might, however, depend on continued commercial funding), or assessments performed by regulators who have close links with the manufacturing industry, would undermine public trust in the decisions made. Non-disclosure of safety data under the legal protection of commercial confidentiality is likely to have the same effect. Moreover, to ensure public trust, the decision-makers should be totally independent individuals – in Rawlsian terms *"competent moral judges"*[38] - who are able to combine dispassionate objectivity in considering the facts with an imaginative sensitivity in assessing their impacts on society as a whole. There has, indeed, been much recent concern that the screening of appointees to regulatory committees in the USA may not always be sufficiently rigorous, allowing those with vested interests to play significant roles in drug licensing[39] In the UK, the articulation of the Nolan Principles on Standards in Public Life[40] is an important development, which needs to be incorporated into the appointment procedures of all regulatory committees at the earliest opportunity.

Only in this way will public accountability be assured.

38 Rawls J (1951) Outline of a decision procedure for ethics. The Philosophical Review 60. 177-197
39 Report of the General Accounting Office (B-257122) Conflict of Interests Review (19.10.94)
40 See for example: The British Council (1999) Governance and law: Ethics in public life and corporate governance. London: The British Council

8. RECOMMENDATIONS

Below we offer below some recommendations for future action based on the implications of the three 'procedural' concerns (A, B and C, listed in 7.6) and on the ethical analyses performed in this report. The recommendations are proposed as interim steps in an ethical trajectory because it is recognised that, however desirable any proposed course of action might be, in our complex modern world, implementation of ethical initiatives often has to await political and economic opportunities. This is, of course, often the excuse of the 'realist' for not seeking to bring about change. However, we believe that there are a number of positive steps which could be made by decision-makers in government and commerce (and, indeed, by people at large exercising their choice as 'ethical consumers') to pave the way for the more fundamental changes required at the international level.

We conclude with some specific recommendations (D) for practical action which, we are persuaded, follow from the analyses performed in this report.

A: Recommendations relating to the criteria on which regulatory decisions are made

1. A legal distinction should be drawn between the use of veterinary drugs to control disease and those used merely to increase productivity, effectively ensuring that the latter are subjected to more stringent approval criteria.

There is a very clear difference of motive in using drugs to treat or prevent disease and in using them to force animals to grow faster or yield more milk. In common parlance, the latter process 'isn't fair' to the animals, in a way which is somewhat analogous to that exploited by an athlete taking drugs to gain (a foolhardy) advantage on the sports field. When we examine that initial reaction in the light of a broader ethical analysis it may be seen to have a much more substantial basis.

Animals receiving drugs to relieve sickness are treated for a limited period, with benevolent intent, and precautions exist (e.g. compulsory disposal of milk) to protect consumers from adverse effects of the treatment. By contrast, animals receiving growth promotants or yield stimulants may be treated throughout their lifetimes, in systems which often impair their health and welfare and offend their intrinsic worth as sentient beings, and which pose risks to human health, the environment and public acceptability. The differences are apparent in Table 2. We believe that these differences must be reflected in law. The assessment criteria should take account of a wide range of ethical issues which, in effect, would result in the licensing of non-therapeutic drugs being subject to a more rigorous examination than that for therapeutic drugs which are aimed at reducing suffering.

Table 2	*THERAPEUTIC AGENT*	*PRODUCTIVITY PROMOTANT*
Length of treatment	*Approx. 5 days*	*Indefinite*
% Animals treated	*Possibly 5%*	*Possibly 90%*
Food consumers	*None*	*Possibly 90%*
Animals monitored for adverse effects	*Possibly 100%*	*Few*
Humans monitored for adverse effects	*Not applicable*	*None*
Improved quality of life for animals	*Yes*	*No, often reduced*

2. Regulatory authorities should make decisions on veterinary drug use with reference to a recognised ethical framework and not simply on the basis of scientific evidence

We believe that the assessment of veterinary drugs should take account of a much broader range of issues than the standard criteria of 'safety, quality and efficacy'. The Ethical Matrix is recommended as framework for use by advisory committees in ethical decision-making relating to agricultural and food technologies. The assessment of drugs according to a broad ethical analysis of this type would lead to a more rigorous, and publicly acceptable, form of assessment.

3. Because current WTO rules prevent any distinction between food products based on methods of production (cf. Article III), except that according to Article XX, restrictions on international trade might be permissible:
• to protect 'public morals'
• 'to protect human, animal or plant life or health'
• 'relating to the natural conservation of exhaustible natural resources',
it is recommended that the full significance of these exemptions be explored by the EU in the interests of advancing animal welfare, consumer choice and environmental protection.

For example, according to EU Trade Commissioner, Sir Leon Brittan, trade-related animal welfare measures could theoretically be afforded protection under Article XX but the EU has been unwilling to put this to the test. However, *"there is nothing within the drafting history of Article XX to suggest that such measures to protect animals should not fall within (its) scope"*.[41]

41 See note 37

4. The Precautionary Principle, incorporating the nine elements defined below, should be established as a cornerstone of biotechnological decision making in relation to agricultural and food systems, including those employing veterinary drugs.

From the ethical perspective adopted in this report, we recommend that the PP should incorporate the following nine elements with respect to the use of drugs in food animals. They apply to all uses but have particular relevance to the use of drugs designed for productivity promotion, i.e. when they confer no net benefit to the animals receiving the treatment.

- Risks refer not only to threats to physical conditions, such as food safety or animal welfare, but also to infringements of principles such as 'consumer autonomy', 'biodiversity' and 'animal telos' (with reference to the Ethical Matrix). None of the latter might necessarily cause direct harm, in the usual sense, but they matter from a comprehensive ethical viewpoint.

- Since all drugs alter the natural physiological state of the animal, there should be a presumption against their use unless good reasons can be advanced to overrule this presumption: such a principle ('No, unless') forms part of the legal regulation of genetic engineering applied to animals in the Netherlands.[42]

- In assessing whether use of a particular veterinary drug should be licensed, due attention should be paid to whether the perceived problem addressed, or advantage envisaged, might be delivered by some alternative process which involves lower risks.

- In assessing whether a particular veterinary drug should be licensed, serious consideration should be given to the real-life circumstances in which it is likely to be employed. The conditions in which drugs tend to be tested (viz. those prevailing on research institute farms, where veterinary care and appropriate technological support are usually readily available) may only rarely obtain on the majority of commercial farms.

- Risks are best identified when a wide range of expertise is involved in consultation and decision making. In principle, it would be advantageous to seek the opinion of all those with relevant expertise, *especially those who dissent* from the majority opinion.

- The need to take risks associated with uncertainty is justified by the need to take action. The need for actions to avoid the threat of global disaster ranks higher than threats of fatal diseases affecting a few, which rank higher than risks of minor illnesses affecting many. Marginal reductions in the price of food can hardly merit any risks at all.

- Many risks that are associated with lack of current knowledge can be addressed by further research. Such risks ought not to be taken when the required research is feasible and affordable.

- If such risk-taking is deemed necessary, contingency plans should be made for dealing with adverse effects, including 'worst case scenarios', before authorisation is granted.

- If risk-taking is deemed necessary, there should be a requirement for effective monitoring of potential adverse effects, together with mechanisms to suspend authorisation expeditiously if this is deemed appropriate.

We believe that these elements of the PP are based on sound principles of both science and ethics. It would be profoundly unscientific, imprudent and unethical to proceed with a technology for essentially trivial reasons if its risks were undefined.

However, we wish to emphasise that the PP should not be used as a (political) device simply to obstruct the vital contribution of technological innovation to modern civilised society. Luddite opposition to all technological development is as bigoted as the belief that all human problems are soluble by the application of 'technological fixes'. Rather, what is required is an approach in which technological inventiveness is tempered by a sensitivity to ethical concerns expressed within society, that displays a prudent recognition of human weakness (appreciating that even the strictest forms of regulation may be circumvented), and which has the humility to realise that 'we don't know what we don't know'. The Greeks had a word for it - *phronesis*- or practical wisdom.

B: Recommendations relating to the provision of scientific evidence on which regulatory decisions are made

5. Scientific data on which assessments of the safety, quality and efficacy of veterinary drugs are based should be provided by independent scientists, operating through a Government administered procedure, and on the principle of 'blind trials'. We recommend that responsibility for setting national standards and ensuring their effective control be vested with the new Food Standards Agency.

It is anomalous that such a procedure (which is accepted practice in the assessment of drugs for use in humans, i.e. 'double-blind trials') is not mandatory for veterinary drugs which may enter the human food chain. This recommendation would entail the setting up of a scheme, under Government control and

42 Advisory Committee on Ethics and Biotechnology (The Netherlands) (1990) Report on Ethics and Biotechnology in Animals. Wageningen: NRLO

possibly within the remit of the prospective Food Standards Agency in the UK, whereby testing of veterinary drugs would be carried out in independent laboratories, which would be funded by the companies wishing to market new drugs. This would not necessarily involve extra expense for the companies, since current testing is either done 'in-house' or contracted to outside laboratories.

6. The legal provision by which manufacturers may keep confidential information on the safety of veterinary products, under Section 118 of the UK Medicines Act (1968), should be repealed.

This confidentiality clause, which prevents open discussion of food safety risks, appears anomalous in that, as pointed out by the House of Commons Select Committee on Agriculture, it applies to the Veterinary Medicines Directorate but not to the deliberations of the Pesticides Safety Directorate. To quote their report:

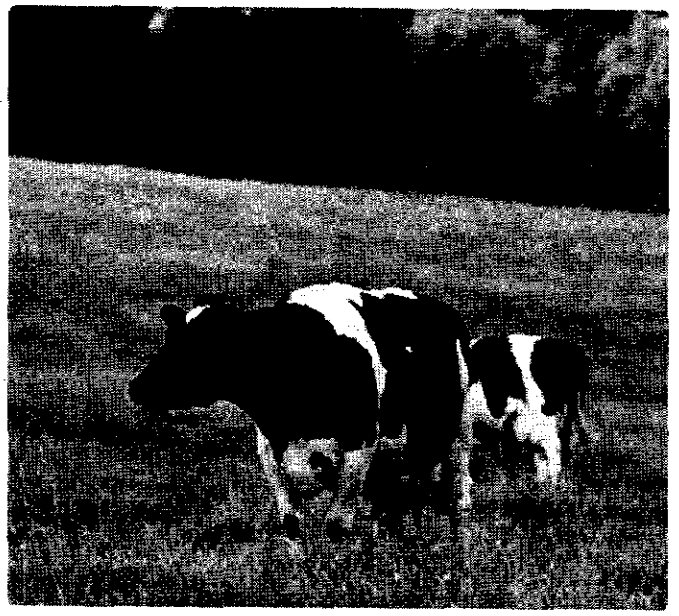
"We find it illogical that pharmaceutical manufacturers should require a higher degree of confidentiality than agrochemical manufacturers, and we would like to see swifter progress towards openness in the VMD's licensing activities than that implied by the Minister's evidence to us".[43]

C: Recommendations relating to the composition of regulatory and advisory committees

7. UK Government Advisory Committees considering the application of biotechnology (including veterinary medicines) to food production and processing should be reconstituted to include a broader range of perspectives, with less emphasis accorded to scientific expertise and rigorous application of the Nolan Principles.

There should be strict observance of the principles contained in the Nolan Report on standards required of those acting in public service.[44] Any vested interests in the use of drugs in food animals would be incompatible with most of these principles. It is encouraging that the UK Environment Minister, Michael Meacher, has recently recognised the importance of a more balanced membership of the Government's Advisory Committee for Releases to the Environment,[45] with respect to the safety of GM crops.

8. In making appointments to the Joint Expert Committee on Feed Additives, the Codex Alimentarius Commission, the World Trade Organisation and similar international regulatory committees, mechanisms should be introduced to ensure that advice given is not influenced by vested interests.



The UK Government and the EC should exert political pressure to reform these institutions in the interests of protecting animal health and welfare, consumer choice, respecting cultural diversity and with due regard to longer-term effects on environmental sustainability. The Precautionary Principle should be accorded priority in all discussions.

D: Specific recommendations on drug licensing, labelling and research

9. In view of the ethical analyses presented in this report (supported by the recent reports of the EU DG24 Scientific Committee on Animal Health and Animal Welfare and of Health Canada), we recommend that commercial licensing of BST in the EU to increase milk yield in dairy cattle should be prohibited indefinitely.

Moreover, a recent survey suggests that the overwhelming majority of both consumers and dairy farmers in the UK consider BST to be 'ethically unacceptable'[46] so that if BST-products were marketed in the EU there should be a requirement for positive product labelling (as recommended by the EU Group of Advisers on the Ethical Implications of Biotechnology report on BST[47]) to facilitate consumer choice.

10. In view of the ethical analyses presented in this report (supported by the recent report of the EU DG24 Scientific Committee on Veterinary Measures relating to Public Health), we recommend that the EC should maintain its position on banning the importation into the EU of beef from animals treated with anabolic hormones.

43 House of Commons Agriculture Committee (1995) 5th Report: Pesticide Safety Directorate and Veterinary Medicines Directorate. Paragraph 101.
44 See note 40
45 Parker G (1999) 'Shake-up for modified foods body: ten advisers to go after claims that committee was too close to biotech industry'. Financial Times (12.4.99) p. 1
46 See notes 8 and 11
47 See note 12

The position of the UK Government needs to be challenged, revealing as it does an undue emphasis on the role of scientific evidence in political decision-making (7.2) while ignoring the wider ethical concerns discussed in this report.

In effect, recommendations 9 and 10 would entail all hormonal preparations (BST, PST, anabolic steroids etc) only being available on veterinary prescription, and veterinary surgeons only being permitted to administer them (presumably very rarely, if at all) for therapeutic purposes.

11. In view of the ethical analyses presented here (supported by evidence from several recent prestigious reports), we recommend that the use of antibiotic feed additives (ZFAs) as growth promotants should be phased out as soon as is practicable. All antibiotics administered to animals, for whatever purpose, should be classified as prescription only medicines/medicated feedingstuffs.

Because antibiotic ZFAs constitute a more difficult case where they are also used therapeutically and/or prophylactically, legislation will need to be introduced to require that these substances be re-classified as medicines and only used under veterinary prescription, as proposed by the recent report of the Antimicrobials Working Group of the British Veterinary Association.[48] The EU should seek to build on the experience of the Scandinavian countries who have already successfully overcome the short term problems associated with the phasing out of these drugs.

The potential risks of such drug use to human health have already led to *ad hoc* prohibitions of certain ZFAs in the EU in recent months. However, much less attention has been paid to the use of ZFAs in masking the adverse effects of intensive production systems (e.g. on the welfare of pigs and poultry). This implies that antibiotic ZFAs should be phased out regardless of whether they are considered to be a public health risk.

12. Any food product derived from animals treated with drugs designed solely to increase productivity (cf. Recommendation 1) should be labelled accordingly.

It has to be recognised that in the current global market there are strong pressures for international trade in food to be governed by safety standards based on the notion of 'substantial equivalence', a criterion which recognises only the physico-chemical attributes of a food product. If a food produced with the aid of veterinary drugs is considered substantially equivalent to one produced without those drugs, there are currently no legal grounds for import restrictions. We have argued in this report that issues of human food safety (important as they are) are an inadequate basis for the ethical acceptability of food. Individual consumers have differing views on the acceptability of drug use, and their right to avoid food produced in this way deserves respect. Although consumers can purchase meat certified by UKROFS as not produced from such animals, some cannot afford to do so.

13. The UK Government should invest more resources in research on organic and similar systems of sustainable food production, which are based on good husbandry rather than dependent on the use of drugs.

The UK Government's funding for research in agriculture and food, under the auspices of the Biotechnology and Biological Sciences Research Council (BBSRC) and the Ministry of Agriculture Fisheries and Food (MAFF) is currently focused on 'hi tech' approaches, often pursued in partnership with Industry. In contrast, the allocation of research funding to organic farming/sustainable systems is a very small percentage of the total research budget. Yet not only is the demand for organic produce increasing greatly but, as a holistic, sustainable and welfare-sensitive form of agriculture, organic farming represents a philosophy which demands increasing attention, even if its large-scale adoption is not entirely unproblematical (see Appendix 3).

FOOD ETHICS
COUNCIL
THE INDEPENDENT COUNCIL FOR ETHICAL STANDARDS IN FOOD AND AGRICULTURE

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48 See note 33

APPENDIX I

ETHICS OF DRUG USE IN FOOD ANIMALS

Questionnaire sent to selected individuals

HORMONAL PRODUCTION ENHANCERS

1. Do you consider that the use of bovine somatotrophin (BST) within the EU will, on balance, be beneficial / harmful / neutral to EU producers, cows, consumers and the overall economy?

2. Do you consider that the use of BST in less developed countries will, on balance, be beneficial / harmful / neutral to producers, cows, consumers and the overall economy of those countries?

3. What, in your opinion, are the most significant issues concerning BST use?

4. If BST is licensed for use in the EU, should milk from BST-treated cows be labelled as such?

5. Currently, the EU operates a ban on the importation of meat from cattle treated with steroid hormones, but this may be shown to contravene international law under the provisions of the WTO. Do you consider that the use of steroid hormones for such purposes within the EU will, on balance, be beneficial / harmful / neutral to EU producers, cows, consumers and the overall economy?

6. If your answer to question 5 is 'Yes', do you believe that the EU should comply with the law or face payment of a fine in the interests of maintaining its autonomy?

7. Do you consider that any future use of other production enhancers, such as porcine somatotrophin and β agonists, within the EU will, on balance, be beneficial / harmful / neutral to EU producers, cows, consumers and the overall economy?

ANTIBIOTICS IN ANIMAL FEEDS

8. In the opinion of the European Scientific Committee on Animal Nutrition (SCAN), the risks of development of antibiotic resistance in human pathogens as a result of use of antibiotics in animal feeds (zootechnical feed additives – ZFAs) are 'unproven'. In your opinion, does this imply that:
- no changes are required in the regulation of ZFA use?
- the current ban on avoparcin should be reversed?
- further restrictions on ZFA use should be imposed in accordance with the Precautionary Principle?

9. Sweden banned ZFAs in 1986 and now maintains its livestock industry with reduced use of antibiotics. Is this a practice that could be introduced elsewhere, and if not, why not?

10. In your opinion, what are the first priorities for action (in medical and veterinary fields) to reduce the risk of antibiotic resistance in man and animals?

11. If ZFAs were to be banned immediately in the EU as a whole, what measures would need to be taken to cope with likely problems such as increased animal morbidity and mortality and decreased productivity?

12. If ZFAs were to be phased out progressively in the EU as a whole, what actions would need to be taken, and over what time scale, to protect public health and the livestock industry?

GENERAL QUESTIONS

13. What importance do you attach to the 'Precautionary Principle' in the context of non-therapeutic agents in animal production systems?

14. What lessons have been learned from the BSE and E Coli 0157 crises?

15. Should there be different criteria for authorization of the use of drugs for veterinary medicinal purposes and those (such as ZFAs) to be used for non-therapeutic purposes?

16. If your answer to Question 15 is 'Yes', what criteria should apply in the case of non-therapeutic agents?

17. Do you believe that the concept of risk relating to drug use in food animals can be defined simply in terms of the criteria of safety, quality and efficacy?

18. If your answer to Question 17 is 'No':
a) what other criteria need to be taken into account?
b) what other representation is needed on regulatory committees to ensure that these are taken into account?

19. If the answer to Question 18b is 'Yes', how should such members be appointed?

20. Whether or not you are a vegetarian (but please indicate), do you consider that meat and other animal products are too cheap in Western countries and that improvements in animal welfare, food safety, environmental protection, consumer choice etc ought to be reflected in higher prices?

APPENDIX 2

Those consulted in the preparation of the Report

Ms Gillian Asbury	Consumers in Europe Group
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Ms Joyce D'Silva	Compassion in World Farming
Mr Roger Ellis	Royal College of Veterinary Surgeons
Mr Patrick Holden	Soil Association
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Ms Jeanette Longfield	Independent Commentator
Mr Keith Meldrum	Former Chief Veterinary Officer
Prof Hugh Pennington	University of Aberdeen
Ms Pauline Rolfe	University of Nottingham
Prof Sir Colin Spedding	Former Chair, Farm Animal Welfare Council
Mr J. S. Ware	Royal College of Veterinary Surgeons
Dr Julia Wrathall	Royal Society for the Prevention of Cruelty to Animals (RSPCA)

APPENDIX 3 – Organic Livestock Farming

In the UK the standards for organic food production are set by the UK Register of Organic Food Standards (UKROFS), which is licensed to certify organic food production and processing under EC Regulation 209/91.

The standards define the principles and practice of agricultural systems which promote:

- Production of nutritious food
- Working as much as possible within a closed system, drawing on local resources
- Use of management practices which sustain soil health and fertility
- High standards of animal welfare and contentment
- Lowest practical levels of environmental pollution
- Minimal dependence on non-renewable forms of energy and burning of fossil fuels
- Decentralised systems for processing, distributing and marketing products
- Enhancement of the landscape, wildlife and wildlife habitat

With reference to the use of antibiotics in animal agriculture, Soil Association standards state: "*The use of antibiotics and some other conventional products may reduce natural immunity and, although providing rapid initial recovery, can leave the animal prone to re-infection. They should only be used under the advice of the nominated veterinary surgeon where effective alternative treatments are not available and where they are considered the best method of reducing suffering, saving life or restoring the animal to health.*"