Home Office code of practice for the housing and care of pigs intended for use as xenotransplant source animals / [Home Office].

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Home Office Code of Practice for the Housing and Care of Pigs Intended for use as Xenotransplant Source Animals

1. General introduction to this Code of Practice

1.1. In the response to "Animal Tissue in Humans"[1], the report of the Advisory Group on Xenotransplantation, the Government acknowledged the need to minimise, as far as possible, any risk of disease transmission to xenograft recipients from the animals reared for xenotransplantation. The Government also accepted that it is essential that high health status source animals be maintained in biosecure facilities.

1.2. The report of the Advisory Group also recommended that a Code of Practice be issued under the Animals (Scientific Procedures) Act 1986 that:

> has regard for the welfare of source animals used for xenotransplantation; and
>
> includes consideration of, and advice on, the potential conflicts between animal welfare and the requirement for animals of a closely defined microbiological status.

1.3. Under the terms of the Animals (Scientific Procedures) Act 1986 (ASPA), the Secretary of State may issue Codes of Practice for the welfare and care of animals used for experimental or other scientific purposes. This Code, issued under Section 21 of the Act, makes provision for the welfare, care and accommodation of animals used as source animals for clinical xenotransplantation. The Code applies to source production units, holding facilities and tissue harvest areas.

1.4. It is issued following extensive consultations within the scientific community, and with organisations concerned with the welfare of animals. Representatives of the British Laboratory Animal Veterinary Association (BLAVA), Pig Veterinary Society (PVS), Institute of Animal Technology (IAT), the Laboratory Animal Science Association (LASA), Royal Society for the Prevention of Cruelty to Animals (RSPCA), the Universities Federation for Animal Welfare (UFAW), and a number of other experts were invited to consider suitable standards of welfare for pigs used in xenotransplantation programmes.

1.5. The recommendations on housing and care of pigs in European and UK legislation, including Annex II of European Council Directive 86/609 EEC, European Council Directive 91/630/EEC, the Agriculture (Miscellaneous Provisions) Act 1968, and Schedule 3 of the Welfare of Livestock Regulations 1994 (S.I. 1994/2126) have been given due consideration.

1.6. The recommendations of the expert group were based on an agreed consensus of present knowledge and practices and following due consideration of existing guidelines. This Code is very closely based on these recommendations, and has the support of those who participated in its formulation.

1.7. The areas and issues where pig welfare may be compromised by the need for animals of high health status, hereafter referred to as qualified pathogen free (QPF) status, have been clearly identified, and the recommendations made minimise the associated welfare costs.

1.8. Some flexibility in interpretation of the recommendations may be permitted following consultation and with the agreement of an Inspector appointed under the terms of Section 18 of the 1986 Act: for example to allow the introduction of innovative enriched housing systems where improved welfare can be demonstrated without

compromise to the QPF status required for use in a xenotransplantation programme.

1.9. The degree of biosecurity, hereafter referred to as biosecure barrier conditions, recommended in this Code of Practice has been set at a level at which the risk of disease transmission or breakdown can been minimised, but where satisfactory standards of animal welfare can be maintained.

1.10. Issues of welfare concern raised during consultations on this Code have included the use of surgical derivation (hysterotomy/hysterectomy) and medicated/segregated early weaning (MEW/SEW) procedures. These practices may be required to enable an animal of suitable health status to be produced for use in a xenotransplantation programme.

1.11. This Code of Practice does not define the qualified pathogen free (QPF) status of animals required for xenotransplantation programmes. The Code does not provide details of monitoring programmes nor details of pathogens from which the source animals, that is those used for organ harvest, must be demonstrably free. Advice on the specific biosecure barrier conditions for animals in xenotransplantation programmes and guidance on the required QPF status of and surveillance programmes for source animals is the responsibility of, and can be obtained from, the Department of Health.

1.12. This Code of Practice makes provision for the care of all pigs maintained in biosecure barrier facilities for the production of xenotransplant tissues for clinical use whether or not they have been genetically modified.

1.13. In implementing this Code, compliance with all other relevant UK legislative requirements with regard to xenotransplantation and pig welfare is expected, save for those specific circumstances identified in this Code where, due to the requirements of biosecure barriers, pig welfare may be subject to limited compromise.

Application of the Code of Practice

1.14. This Code applies throughout the United Kingdom. In Great Britain, it is administered by the Home Office. In Northern Ireland, it is administered by the Department of Health and Social Services on behalf of the Secretary of State for Northern Ireland. Where the Code speaks of the "Secretary of State" or "the Home Office" it means, in Northern Ireland, the Department of Health and Social Services.

1.15. Establishments where genetically modified pigs are produced, held for use, and used as organ donors must be designated under Section 6 of the 1986 Act as scientific procedure establishments, with the production units also designated under Section 7 as designated breeding establishments.

1.16. As understanding of how best to care for animals evolves, or should the biosecure barrier requirements be changed, the recommendations contained in this Code of Practice may need to be updated. The Secretary of State will keep this Code of Practice under review and will issue revised versions as necessary.

2. General welfare requirements for pigs

2.1. Pigs are intelligent, inquisitive animals that have retained many of the complex behavioural characteristics of their wild ancestors. This includes rooting and exploratory behaviour, and social interactions within small, stable groups. They have limited thermo-regulatory ability, but their hearing and, in particular, their olfactory abilities are highly developed. Housing, husbandry and general management of pigs must take account of these physiological and behavioural needs.

2.2. Therefore, to achieve high standards of welfare for pigs, the systems of accommodation, husbandry and care should ensure that the animals have: -

2.2.1 company of their own kind, allowing pigs to live in stable groups with other familiar individuals;

2.2.2 adequate amounts of space, in both a lying area (in which all pigs must be able to lie down together) and the general 'loafing'/dunging area, in order to allow all pigs to move around freely;

2.2.3 adequate quantities of clean, fresh water continuously available;

2.2.4 housing which protects against physical discomfort, providing a clean, dry, comfortable lying area, suitable non-abrasive, non-slip flooring, and an enclosure without sharp protrusions or other characteristics likely to cause injury;

2.2.5 a thermally comfortable environment, ensuring that the temperature remains within the pigs' thermoneutral range;

2.2.6 an acceptable atmosphere, maintaining appropriate ventilation and ensuring that aerial contaminants (e.g. ammonia, inhalable dust) are kept within non-aversive limits;

2.2.7 appropriate lighting for a period equivalent to normal daylight hours, and providing a period of darkness;

2.2.8 environmental enrichment, providing straw or other suitable materials for manipulation, to satisfy pigs' behavioural needs in terms of rooting and investigative behaviour;

2.2.9 competent, knowledgeable stock-persons who understand the pigs' needs and behaviours, and are dedicated to ensuring their well-being at all times by preventing or minimising any fear, distress and discomfort;

2.2.10 competent, knowledgeable, specialist veterinary care, by those with experience and understanding of pig health and welfare.

2.3. The requirement to maintain a qualified pathogen free (QPF) status may, to some extent compromise the animals' behavioural needs. Justification is required if this proves essential for the production of a suitable animal for use in a xenotransplantation programme, and efforts must be made to minimise and eliminate where possible any deviation from best welfare practices.

Housing and environment

Animal accommodation

2.4. Animal facilities shall provide a suitable environment for the pigs to be housed, including provision for exercise and social contact, and should incorporate facilities sufficient for the activities carried out within it. The Home Office Inspectorate should be consulted at the planning stage, or when substantial alterations to the designated premises are proposed.

2.5. When planning and siting facilities, these should be designed to be self-contained. If the animal facility forms part of a larger complex, consideration should be given to the activities in the adjacent buildings and any possible

effect these may have on the welfare and health status of the animals.

2.6. To enable an animal of suitable QPF status to be produced for use in a xenotransplantation programme, some form of biosecure barrier system will be required. The term "barrier" identifies a concept rather than a definitive qualitative standard. The concept requires beginning with an animal of defined health status, that is QPF, and maintaining the animal under conditions that minimise microbial contamination. A barrier system consists of several essential elements: - stocking with animals known to be free of pathogens (QPF), appropriate design of housing, effective environmental controls, regular monitoring of health status, and the proper implementation of appropriate operating procedures. As each element of a barrier system can compromise the welfare of animals, the potential problems of each element should be identified, and strategies adopted to minimise any adverse consequences for the animals[2].

Security

2.7. The pig accommodation and its support facilities should be designed to prevent animals escaping. It is also necessary to protect animal facilities against illegal entry by unauthorised persons: advice about security should be sought and taken from Crime Prevention Officers in the local police force, or other experts, during the design of new facilities or modifications of existing premises.

Animal rooms

2.8. For the purpose of this Code, animal rooms are deemed to be the rooms normally used to house stock or breeding animals and animal treatment areas.

2.9. Animal rooms should be constructed of durable impervious materials, with easily cleanable surface materials resistant to attack from the chemicals used to clean or fumigate the rooms. Consideration should be given to the use of materials that are least likely to crack and craze. Floor finishes should be non-slip, and not injuriously abrasive, whether wet or dry. All joints between doorframes and walls should be sealed.

2.10. Services should be installed in such a way that they are either buried within the fabric of the building, boxed in, or clear of wall surfaces for ease of cleaning. When the fabric of the building is penetrated, for example by holes or pipe-work, the holes created should be sealed.

2.11. Building design, and proposed working practices, should take into account the fact that building maintenance may disturb animals, and may compromise the health status of the animals. Whenever possible, services should be installed to be accessible from outside and with fittings that can be removed by the staff for maintenance or repair elsewhere. If possible, provision should be made for the upgrading or replacement of services during the life span of the building, for instance by the insertion of spare ducting in the walls.

2.12. Animal house design should ensure that the animals can be inspected easily. In barrier units, where access may be restricted, suitable arrangements should be made to allow the animals to be clearly viewed from outside the barrier, for example by incorporation of windows or television cameras.

2.13. Precautions should be taken in animal rooms to minimise the exposure of personnel to hazards that may arise from the incorrect handling of animals, for example bites and scratches, allergens and infections.

2.14. There should be special provision to house separately animals that are ill, injured or receiving veterinary treatment. Where possible these animals should remain within sight or sound of other pigs.

2.15. According to the microbiological quality and genetic status of the animals, different levels of separation and physical barriers may be required between breeding and other areas. Appropriate working practices must be adopted to minimise any risk of breakdown of barrier security.

2.16. Adequate arrangements should be made for the receipt of incoming animals. Animals brought into the facility should not put at risk animals that are already there. Space should be provided for acclimatisation and quarantine, where appropriate.

2.17. Source animals for clinical xenotransplantation should be maintained in a biosecure barrier system which

meets similar standards to animal containment level 3 outlined by the Advisory Committee on Dangerous Pathogens[3]. All potential sources of contamination should be identified, and controlled including air input, water, food, bedding material, equipment, personnel and working practices. All materials entering the unit must be sterilised or otherwise effectively decontaminated. The animal rooms must be maintained under positive pressure relative to the surrounding areas, and input air must be filtered using a HEPA (high efficiency particulate absorption) filter (or equivalent).

2.18. Ventilation systems should have sufficient capacity and flexibility to meet the demands of different stocking densities.

Treatment rooms/operating theatres

2.19. General veterinary treatment rooms should be provided. Surgery and euthanasia must not be performed in rooms where animals are normally housed, unless in the case of euthanasia of a badly injured animal where welfare may be further compromised by moving the animal.

2.20. To minimise disruption to the animals, minor procedures, such as blood sampling and simple dosing procedures, may be performed in the animal holding areas.

2.21. All establishments should have access to facilities for diagnostic investigation, post-mortem examinations and the collection of samples for examination elsewhere.

2.22. Where surgery is to be performed, suitable operating facilities must be provided, including separate preparation areas for the animals, equipment and staff. It is not expected that animals used for tissue harvest will subsequently be allowed to recover from general anaesthesia.

2.23. Within a xenotransplant source animal unit three additional specialist areas are likely to be required, a surgical derivation area, an isolator rearing facility and a tissue harvest area.

Surgical derivation area

2.24. This area will be used to facilitate the initial production of high health status animals and will consist of an animal holding area and an area for surgically harvesting piglets from the sow under general anaesthesia by hysterectomy or hysterotomy. The reception holding area should be of similar construction to animal holding areas, with appropriate environmental controls, and animals provided with similar standards of husbandry and care to those animals held within the main facility.

Isolator rearing facility

2.25. Following surgical derivation, piglets will be maintained and reared in isolators for a period of time, usually a few weeks, until they are sufficiently robust to enter the main unit. This facility should include a clean area with adequate space for servicing the isolators and caring for the animals that they contain, areas for assembly of the isolators, a ventilation system which allows the safe venting of fumigants and other sterilising agents, and adequate storage space for materials and equipment.

Tissue harvest area

2.26.1. The precise technical specifications for the tissue harvest areas will be determined by the Department of Health and set out in other guidance or reference documents, but suitable facilities for holding animals prior to and during the induction of anaesthesia must be provided.

2.26.2. To minimise potential welfare problems in the source animals, and potential compromise to the microbiological status of the harvested tissues, the Tissue Harvest Area should be located adjacent to the Source Production Unit.

2.26.3. However, there may be circumstances in which the viability of the xenotransplantation organ or tissue could be compromised. For example, lengthy journey times post harvest could result in ischaemic damage to the tissues. In such circumstances, where it is considered essential that the source animal requires to be transported to a harvest area close to the transplant centre, this movement should take place a minimum of four weeks prior to harvest, to allow the animal to recover from the effects of transport, and to allow sufficient time for a health screen to be taken to confirm continued suitability for use – that is, to ensure that the health status has not been compromised during the journey.

2.26.4. Live animal travel times should be minimised, and transportation must comply with the relevant transport legislation, with the animals maintained in pairs or groups.

2.26.5. Where Tissue Harvest Areas are separate from the Source Production Unit, suitable holding accommodation must be provided, which meets the same standards as those in the source unit.

2.27. Project and personal licences issued under the Animals (Scientific Procedures) Act 1986 are required to permit tissue harvest from living source animals. Only trained and competent personal licensees may anaesthetise the animals and harvest their tissues.

Service areas and support facilities

2.28. The design and construction of service areas should normally be to the same standard as the animal rooms. The building, working practices and flow patterns, should be planned to prevent cross-contamination between clean and dirty equipment and materials. Corridors should be wide enough for easy movement of personnel and equipment, and should not be used for storage.

2.29. Service areas are subject to rough treatment and wall surfaces should be resistant to impact damage. Surfaces and corners should be easy to clean. Adequate floor drainage should be provided in wash areas, with sufficient ventilation to remove excess heat and humidity.

2.30. Stores must be separate from animal rooms. Adequate storage space should be provided for food, bedding, cleaning materials and other items. Special facilities may be required for handling and storing chemicals.

2.31. Food and bedding stores should be clean and dry. In addition, food stores should be cool and well ventilated. Perishable foods should be stored in cold rooms, refrigerators or freezers.

2.32. A separate collection area should be provided for waste, prior to its disposal. Special arrangements should be made for handling carcasses. Flow patterns within the unit should facilitate the separation of clean and dirty areas to minimise contamination risk. Waste products from genetically modified animals will require to be dealt with in accordance with the Genetically Modified Organisms (Contained Use) Regulations 1992[4].

Facilities for staff

2.33.1. Personnel facilities should include staff and record rooms, changing rooms, decontamination areas, first aid and toilet facilities and space for storing protective and outdoor clothing.

2.33.2. Animal care personnel may be present at times when normal catering facilities may not be available; special arrangements or facilities for meals may therefore be needed. No pig products should be eaten on site. Eating and drinking should be prohibited in all areas other than those staff areas specifically reserved for such activities. Smoking should not be permitted.

2.33.3. Arrangements for visitors, including a specified period when visitors would have no direct or indirect contact with pigs, should be well defined and enforced.

Staffing

2.34. Sufficient trained and competent staff must be available at all times to care for the animals, including during

weekends, holiday periods and when the normal staff are absent e.g. due to sickness. In these circumstances, care must be taken to maintain barrier security.

Training

2.35.1. Appropriate training of staff is essential to ensure that high standards of pig husbandry and care are provided, and that barrier security can be maintained.

2.35.2. The holder of the Certificate of Designation is responsible for ensuring that adequate training, and assessment of competence is provided for all animal care staff. This responsibility is commonly delegated to the named person in day-to-day care (Named Animal Care and Welfare Officer - NACWO). The form and content of training will depend on the activities being carried out, although attendance at formal training courses, offering recognised qualifications, is strongly recommended.

2.35.3. Training should include an introduction to the natural history and behaviour of the pig, which will illustrate their needs in a captive breeding system. Pig husbandry, care and welfare, principles of barrier production and maintenance, barrier hygiene, internal management practices, breeding and health record keeping practices should also be included.

2.35.4. Animal care staff should be trained to recognise normal behaviour, in order that any abnormalities can be identified at an early stage.

2.35.5. Animal care staff are expected, at all times, to have a caring and respectful attitude towards animals in their care, and must be trained to become proficient in their handling, restraint and husbandry.

2.35.6. It is recommended that written husbandry, care and safety instructions be provided to staff, which may include reference to other relevant legislation such as the Health and Safety at Work Act. Written details of routine husbandry, breeding programmes, disposal of waste and carcasses, disease surveillance and control programmes, and emergency action plans should be maintained. Standard Operating Procedures for all routine management and husbandry practices should be produced, maintained and regularly reviewed and revised as appropriate.

2.35.7. Training activities should be documented and competencies recorded.

The Named Veterinary Surgeon (NVS)

2.36.1. Under section 6(5)(b) of the 1986 Act, it is a requirement for certification as a designated establishment that there is a Named Veterinary Surgeon to provide advice on the health and welfare of pigs.

2.36.2. The Royal College of Veterinary Surgeons (RCVS) has published a Code of Practice for Named Veterinary Surgeons[5].

2.36.3 The RCVS expects, and the Home Office requires, veterinary surgeons accepting appointments as NVS to undertake specific training in order to extend their knowledge and thus meet their statutory role under the Animals (Scientific Procedures) Act 1986. The RCVS recommends that such veterinary surgeons should give serious consideration to attending courses specifically aimed at Named Veterinary Surgeons and follow a line of post-graduate training leading to a higher qualification.

The environment

Temperature

2.37.1. Amongst the various environmental variables that can affect the welfare of pigs, temperature is the most important. Pigs should have access at all times to an area, at least equal to the minimum required lying area, which is maintained within the Thermoneutral Zone of the animal. This zone is bounded by the Upper and Lower Critical Temperatures that will be dependent on many factors (including the live-weight of the pig, feed level and type, group size, flooring material and prevailing airspeed) and may consequently differ according to the housing and

management system adopted. These Critical Temperatures can be calculated for any given set of circumstances[6], and representative values are shown in the table below.

2.37.2. Where animals are housed in a single space environment (with no localised heating), the room temperature must be set to remain within this thermoneutral zone. Where there is localised heating and/or kennelling of the lying area to provide a separate microclimate, the room can be significantly cooler without detriment to the pigs. However room temperature should not be allowed to fall to such a value that the desired microclimate cannot be maintained, should not be allowed to exceed the Upper Critical Temperature, and should provide an acceptable working environment for stock-persons.

2.37.3. The following guidelines assume that pigs are housed on insulated solid flooring without draughts, that dry sows and boars are fed at typical commercial levels to maintain adequate body weight, that growing pigs are fed *ad libitum* and that animals are housed in groups.

Guide to Temperature Requirements (°C) for Lying Area and Holding Room

Class of pig		Lying area Minimum °C	Lying area maximum °C	Room minimum °C
Newborn piglet		30	35	20
Suckling piglet	5 day	26	32	18
	14 day	24	30	5
Newly weaned	<10 day	30	35	20
	21 day	28	32	15
Growing pig	(10kg)	22	26	15
	(20kg)	16	24	10
	(50kg)	14	24	10
	(100kg)	12	23	10
Pregnant sow		17	26	10
Lactating sow		Determined by piglet needs	24	Determined by piglet needs
Breeding boar		17	26	10

* for guidance where localised heating supplies microenvironments within the room. The room temperature maximum should not exceed the lying area maximum unless additional cooling provision, such as showers, is provided.

Relative humidity

2.38. There are no reported adverse effects resulting from pigs exposed to wide fluctuations of **ambient** relative humidity. However, lengthy exposure to low humidities should be avoided, with optimal values of 50-80% recommended[7].

Ventilation

2.39.1. Fast movement of air is another potentially negative environmental variable affecting pig welfare. Dusty environments and high concentrations of ammonia and other noxious or gaseous irritants cause harmful effects on the respiratory system.

2.39.2. The ventilation system should:

(i) provide sufficient fresh air of a suitable quality;

(ii) regulate temperature, within prescribed limits;

(iii) reduce the levels and spread of odours, noxious gases, dust and infectious agents.

2.39.3. In the case of xenotransplant source animals, the air input must be filtered using a HEPA (high efficiency particulate absorption) filter (or equivalent). The ventilation system should incorporate a means of preventing reverse air-flows to prevent contamination.

2.39.4. The distribution system should deliver air as evenly as possible to each pen or animal whilst avoiding draughts. Careful attention should be given to air inlet and outlet positions to ensure good air circulation and avoid draughts and noise disturbance.

2.39.5. The ventilation system can be used to create differential air pressures within the building as part of a "barrier" system. "Clean" areas are generally maintained at higher pressure and "hazardous" areas at lower pressure than those adjacent, in order to minimise any leakage of "dirty" air into "cleaner" areas. This is effective only if the supply air is itself clean or is suitably filtered to be free from contaminants.

Lighting

2.40.1. Pigs should never be kept in constant darkness. Cycles of light and dark should be used so that pigs have ample opportunities to carry out their normal behaviour, and to maintain normal reproductive cycles.

2.40.2. A minimum light period of 8 hours should be provided. Lighting should be of a level to permit routine husbandry tasks to be performed properly and safely. Light levels of 40-80 lux are sufficient [7].

2.40.3. In farrowing units, provision of continuous low level lighting may be of benefit, and should be provided.

Noise

2.41. High levels of noise are potential stressors to pigs. Continuous background noise, such as that deriving from the ventilation system, should be kept to a low level. Unexpected loud noise should be avoided.

Emergency alarms and stand-by systems

2.42.1. A technologically dependent animal facility is a vulnerable entity. Such facilities must be appropriately protected to detect hazards such as fires; the breakdown of essential equipment such as ventilation fans, air heaters or coolers; and intrusion by unauthorised persons.

2.42.2. Animal facilities which rely heavily on electrical or mechanical equipment for environmental control and protection will need a stand-by system to maintain essential services and emergency lighting systems as well as to ensure that alarm systems themselves do not fail to operate.

2.42.3. Emergency alarms and systems must be checked at least weekly.

2.42.4. The heating and ventilation system should be equipped with monitoring devices or alarms to ensure that any faults can be quickly identified and promptly rectified.

2.42.5. Clear operating procedures should be in place, and responsibilities assigned, to ensure that prompt action is taken in the event of an alarm.

3. Animal care and health

3.1. Pigs living within a barriered animal unit are totally dependent on humans for their health and well-being. The physical and psychological state of the animals will be influenced by their surroundings, food, water and the nature and quality of the care and attention provided by the animal house staff.

3.2. The aim is to produce animals of a qualified pathogen free status suitable for use in a xenotransplantation programme and to maintain animals in good health and physical condition; with a reasonable expression of their behavioural repertoire; and amenable to handling.

3.3. The general well-being of all pigs must be checked at least twice daily by a competent person. Young animals, in particular those subject to surgical derivation or early weaning techniques, should be checked more frequently.

3.4. Animals must be maintained in groups, or pairs, unless veterinary or defensible husbandry reasons justify single housing. In circumstances where single housing can be justified, and agreed in consultation with the Named Veterinary Surgeon, animals should not be held in complete isolation and should remain in visual and/or auditory range of other pigs.

3.5. Pigs should have regular exposure to human contact, as this will minimise stress during handling and procedures. However, to reduce the risk of cross-contamination, the frequency of contact may be reduced from that encountered in conventional pig units. It is therefore recommended that, when contact is necessary for any reason, staff be encouraged to provide additional socialisation time with the animals.

Responsibility for animals

3.6. Responsibility for the care and welfare of the pigs falls to:

(i) the person undertaking daily care of the animals;

(ii) the person named as responsible for the day-to-day care of the animals (NACWO);

(iii) the named veterinary surgeon who monitors and advises on the health and welfare of the animals (NVS);

(iv) the holders of personal and project licences; and

(v) the holder of the certificate of designation.

Acquisition of animals

3.7.1 Under section 10(3) of the 1986 Act, unless an exemption has been issued by the Secretary of State, the types of animal listed in Schedule 2 to the Act must be obtained from designated breeding or supplying establishments. Schedule 2 includes pigs that have been genetically modified.

3.7.2 The introduction of animals listed in Schedule 2 from non-designated sources (either from within UK or from overseas) for a scientific purpose, requires justification and is conditional upon the prior permission of the Secretary of State.

3.7.3 The importation of animals from overseas is also controlled by the Animal Health Act 1981. European Council Directive 92/65/EEC (the BALAI Directive) states the requirements for the movement of some species of commercially traded laboratory animals within the Member States of the European Community. Details of licences, health certificates, rabies and other quarantine requirements should be obtained from the Animal Health Division, MAFF, or the Scottish Office Agriculture, Environment and Fisheries Department (SOAEFD). In Northern Ireland, importation is controlled by the Department of Agriculture.

3.7.4 When the importation of animals is proposed, the use of embryos and semen should be given due consideration, as there are welfare benefits and a reduced risk of biosecure barrier breakdowns using this approach.

Reception

3.8. New breeding or stock animals should be removed from their transport containers and examined by a responsible person without delay. The animals should then be transferred to clean pens and be supplied with food and water as appropriate. Animals that are sick, injured or otherwise out of condition must be kept under close observation, housed separately and examined by a competent person as soon as possible and appropriate action taken. A record should be made of animals received, their provenance and date of arrival as required by section 10(6)(b) of the 1986 Act.

Despatch

3.9. Both consignor and recipient should agree the conditions of transport, including the estimated departure and arrival times, so that full preparation can be made for the animals' arrival, in order that they can be placed in previously prepared pens, fed, watered and rested. Responsibility for the care and welfare of animals for all stages of the journey should be clearly assigned.

Transport

3.10.1. Transporting animals within and between facilities may, in addition to the general welfare considerations, compromise the microbiological status of the animals.

3.10.2. All transport must comply with the requirements of the Welfare of Animals (Transport) Order 1997 [8], and, in the case of genetically modified pigs, with the GMO regulations [4].

3.10.3. Stress during transport should be minimised by making animals as comfortable as possible in their pens or containers and, if confinement is to be prolonged, food and water must be provided. Time in transit should be kept to a minimum. Animals that are incompatible should not be transported together.

3.10.4. The number of animals within any single pen or container must be such that animals travel in comfort with due regard to conditions likely to prevail throughout the journey.

3.10.5. The sender should ensure that the animals to be transported are in good health. Prior to loading each animal should be examined by an experienced, trained and responsible person. When animals are acquired from outside the UK, recipients should make it a condition of order that the above requirements are met.

3.10.6. Consideration should be given to food withdrawal prior to transport as there is evidence that pigs may become travel sick [9]. Withdrawal of food for 4 hours prior to transportation is recommended, although free access to water (and milk in the case of pre-weaned piglets) should be provided at all times.

3.10.7. Pregnant animals should not be transported during the first six weeks of pregnancy, nor within 48 hours of expected birth.

3.10.8. Special consideration must be given to the welfare of young piglets during transport, in particular with regard to the maintenance of suitable environmental controls and arrangements for feeding and watering.

3.10.9. Loading ramps should be of appropriate design, and have suitable flooring and slope to minimise the risk of injury during loading and unloading of animals.

3.10.10. The pen or container in which the animals travel should:

i. confine the animals in comfortable hygienic conditions with minimal stress for the duration of the journey;

ii. contain sufficient bedding so that animals remain comfortable and in conditions close to their thermo-neutral zone;

iii. be of such a design and finish that an animal will not damage itself during loading, transport, and unloading;

iv. be designed to give each animal sufficient space to lie down in a normal resting position;

v. be escape-proof, leak-proof and capable of being handled without the animals posing a risk to handlers;

vi. be designed to minimise the risk of microbiological contamination;

vii. be designed so that they can be thoroughly disinfected between shipments, if intended to be reusable;

viii. allow sufficient ventilation, which can be controlled as necessary; and

ix. be clearly labelled.

3.10.11 Containers holding animals should be moved carefully without rough handling, excessive noise or vibration.

3.10.12 Animals should be loaded into containers as near as possible to the time of departure. Personnel responsible for the care and welfare of animals in transit must be aware of the needs of the animals under their care, and of biosecurity requirements. This applies to cargo handlers, carrying agents and drivers of vehicles. Their training and competence should be reviewed regularly.

3.10.13. Emergency plans should be in place to deal with problems during transport, such as vehicle breakdown.

3.10.14. Transport of animals by air should comply with current IATA Guidelines [10].

3.10.15. A Home Office Inspector must be consulted about authority to transfer genetically modified animals to other designated premises. Where animals are to be exported or imported advice and permission should be sought from the Home Office and the local Divisional Veterinary Office of MAFF.

Care of animals

Animal accommodation

3.11. The housing system is one of the most important elements in the physical and social environment of animals. It should be designed carefully to ensure animal well-being, particularly when breeding animals may be maintained for considerable periods of time. The environment must take into account the welfare needs of the animal, and be designed to protect them from physical and thermal discomfort, fear and distress, and allow them to perform their natural behaviour.

3.12. The housing system should: -

a. provide adequate space that permits freedom of movement and normal postural adjustment, and has a dry resting place;

b. provide a comfortable environment;

c. provide an escape-proof enclosure that confines animals safely;

d. provide easy access to food and water;

e. provide adequate ventilation;

f. meet the biological needs of the animals - e.g. maintenance of body temperature, urination, defecation, and, if appropriate, breeding;

g. avoid unnecessary physical restraint;

h. take into account the behavioural needs of the animal.

3.13. Size, shape and fittings of pens should be designed, as far as is practicable, to meet the physiological and behavioural needs of the animals. The shape of the pen, its complexity and contents can be as important to the animal as overall size.

3.14. Social relationships are as important as stocking densities, and space must be provided to allow for stable groups to be maintained during growth of the animals.

3.15. Minimum pen dimensions and space allowances for individual and groups of animals are specified below. These are based on the recommendations contained in the Home Office Code of Practice for the Housing and Care of Animals used in Scientific Procedures, and comply with the recommendations of the appropriate European Convention [11] and of the European Directive 86/609 EEC [12].

Space Allowances for Weaners, Growing & Adult Pigs

Species - Pigs	Minimum Floor Area - Groups	Minimum Floor Area - Single Pigs	Minimum Resting Area	Minimum Feed Rack
Up to 10kg	0.25m²	1.0m²	0.15m²	0.15m
10 – 20 kg	0.5m²	1.5m²	0.20m²	0.20m
20 – 30 kg	1.0m²	2.0m²	0.25m²	0.20m
30 – 50 kg	1.3m²	2.0m²	0.35m²	0.25m
50 – 100 kg	2.0m²	3.0m²	0.45m²	0.30m
100 – 150 kg	2.7m²	4.0m²	0.5m²	0.35m
Over 150 kg	3.75m²	5.0m²	1.0m²	0.40m
Adult Boars	-	7.5m²	1.0m²	0.50m

Service pens should have a minimum floor area of 10.5m², to allow a sufficient area for mating.

3.16. It is important in the design of pig accommodation to strike a balance between insufficient and too much space. Although increased space allowances may offer an increased opportunity to forage, the usage of areas within the pen may be significantly disrupted, and the decreased stocking densities may adversely effect environmental controls. The minimum space allowances should permit sufficient space to express a reasonable behavioural repertoire, but this is possible only if the space provided offers some degree of environmental complexity.

3.17. A comfortable, solid floored resting area must be provided, which must be of sufficient size to allow all pigs in the group to lie together in lateral recumbency.

3.18. The enclosures should be made of materials not detrimental to the health of the animals and which are durable and will withstand normal cleaning techniques. They should be designed to minimise risk of injury with comfortable floors that permit easy removal of excreta. Floors, walls and doors should have surfaces that are resistant to wear and tear caused by the animals or by cleaning procedures. All internal fittings and fixtures to which the animals have access must be designed, constructed, maintained and regularly inspected to ensure that there are no sharp edges or protrusions likely to cause injury or distress to the animals.

3.19. Housing systems should facilitate separation of functional areas (feeding, resting and dunging area), or prevent direct contact with faeces in the dunging area.

3.20.1. Floors must provide adequate grip to prevent slippage, whilst not causing physical injury or excessive abrasion to the feet or legs.

3.20.2. Where a slatted system is used, care should be taken to ensure that the slats are of suitable design and construction for the size of the claws of the pigs kept on the floor (such that the likelihood of trapping, discomfort whilst standing or walking is minimised), and that the slats are suitably maintained and replaced as necessary [13].

3.21. The use of sow stalls and tethers became illegal in agricultural pig units on 1st January 1999 [14], and such practices will not be permitted in the systems used for production of source pigs in a xenotransplantation programme.

Food

3.22.1 Diet should be formulated to satisfy the nutritional requirements of the animals and ensure good welfare.

3.22.2. In the selection, production and preparation of food, precautions should be taken to avoid chemical, physical and microbiological contamination. Packing, transport and storage should be such as to avoid contamination, deterioration or destruction of food. Suitable sterilisation/decontamination procedures for all food entering the unit are necessary to ensure that health status of the unit is not compromised.

3.22.3. Where animals are held in groups, care should be taken to ensure that subordinate animals have adequate access to food and water. Lack of feeding space is a potential source of aggression. Provision of food *ad libitum* reduces agonistic competition at feeding times. Where *ad libitum* practices are not used, sufficient trough space must be provided to allow all animals access to the trough at the same time.

3.22.4. Pregnant sows should be fed individually according to their dietary needs. This will reduce bullying and will optimise dietary intake for the individual animal all the way through pregnancy.

Water

3.23.1. Adequate quantities of clean drinking water must be available to all animals at all times. The water should be regularly monitored for contaminants, and treated if necessary.

3.23.2. A lack of a sufficient number of drinking outlets, and inadequate flow rates, can result in aggressive behaviour and stereotypies. For group housed animals a minimum of two drinkers per pen must be provided, with additional outlets provided for more than 20 animals per pen (one drinker per 10 animals). Where channel drinkers are used a single drinker may suffice, but a minimum of 30cm per ten pigs of trough space must be provided. A minimum flow rate of 750ml per minute should be provided for all classes of animal, with lactating sows being provided with a minimum flow rate of 1000ml per minute.

3.23.3. The operation of automatic systems should be checked daily. Such systems must be properly serviced and cleaned regularly to avoid malfunction and the risk of spread of disease.

3.23.4. Emergency water supplies should be available in case pipes freeze or supply fails.

Resting area

3.24. A comfortable resting area will be provided.

Farrowing area

3.25.1. Farrowing crates significantly limit the behavioural repertoire of the sow. However, with present knowledge, there is no validated alternative that adequately addresses the sow's needs, without compromise to piglet welfare and operator safety. As more welfare friendly systems become available, it is expected that these will be promptly adopted as an alternative to the farrowing crate.

3.25.2. The design of the crate should be appropriate for the size of the sow, to allow the animal to lie down comfortably, to stand upright and to expose all teats to the piglets.

3.25.3. Non abrasive non-slip flooring should be provided. Although a partially slatted floor is acceptable, the sow must be provided with a solid floored lying area, at least equal to 75% of the overall area.

3.25.4. Although the ability of the sow to exhibit nesting behaviour is limited, some form of nesting material should be provided, especially as farrowing approaches.

3.25.5. Consideration should be given in the selection of breeding replacements to select for good temperament to minimise stress during confinement, and good maternal qualities to minimise piglet losses.

3.25.6. The period of confinement should be minimised, with animals crated no more than 5 days pre-farrowing, and returned to an extensive group housing system at weaning, generally by 4 weeks post-partum. Animals must not be confined in a farrowing crate for longer than 5 weeks around each farrowing.

3.25.7. Consideration should be given to the use of farrowing crates which can be adapted to give the sow greater freedom in later lactation when piglet viability is well established.

3.25.8. The use of segregated/medicated early weaning systems will significantly reduce the time during which the sow remains in the farrowing crate.

Pig behaviour and enrichment

3.26. Except in the case of the farrowing/lactating sow, and unless there is an overriding veterinary requirement, all animals must be allowed adequate space to express a wide behavioural repertoire. Animals should be socially housed wherever possible with compatible individuals, and only single housed if there is good justification on veterinary, husbandry or welfare grounds.

3.27. Although basic pen designs provide space and surfaces, adequate complexity within this space is necessary to allow the animal to carry out a range of normal behaviours. Restricted environments can lead to behavioural and physiological abnormalities. The use of appropriate enrichment techniques extends the range of activities available to the animal.

3.28. Environmental enrichment should be allowed for at the design stage and incorporated at every opportunity thereafter.

3.29. In extensive systems pigs spend many hours exploring their environment, using their highly sensitive snout to root. Housed pigs in contrast spend a relatively short time eating as their food ration is concentrated and therefore ingested quickly, and often have little opportunity for exploratory behaviour. Denial of opportunities to satisfy these motivations can lead to abnormal behaviours, such as bar chewing, and increased aggression. Pen design should account for the needs of pigs to investigate and manipulate materials and minimise competition.

3.30. Pig stereotypies tend to develop in the absence of suitable foraging substrate and when there is insufficient diet to maintain satiety. Bedding material, such as straw, can provide many of these behavioural requirements; where such material is not provided alternative enrichment strategies should be included e.g. food balls; chains; scratching posts; showers.

3.31. Where pigs develop stereotypies or abnormal behaviours that injure other animals (e.g. tail, ear or vulva biting) additional enrichment to encourage foraging/rooting must be provided as a matter of urgency. In these circumstances the programme of enrichment should be discussed and revised as appropriate in consultation with the Named Animal Care and Welfare Officer (NACWO) and the Named Veterinary Surgeon.

Welfare of adult boars

3.32.1. Due to aggressive behaviour, adult boars are commonly housed singly. However, animals raised together from birth have been maintained successfully in pairs as adults.

3.32.2. Boar pens must be sited in the same building as other pigs. Auditory and olfactory stimuli should be available at all times, with the opportunity for visual contact and safe tactile contact.

3.32.3. As these animals tend to be physically segregated for long periods of time, particular care should be taken to provide an enriched environment that addresses their behavioural needs.

Social structure and mixing

3.33. The domestic pig develops a social hierarchy within groups from an early age. Disruptions to established social groups can be very stressful [15]. The mixing of pigs, unfamiliar with one another, should be avoided whenever possible. If pigs have to be mixed, this should be done at as young an age as possible, preferably before weaning. When pigs are mixed, they should have adequate opportunities to escape and hide from other pigs. Pens used for newly mixed sows should be designed to minimise the results of aggression allowing sows to establish the hierarchy with minimum damage.

Surgical interventions

Castration

3.34. Castration of xenotransplantation source animals should not be necessary, in view of the likely weight/age range at which tissues will be harvested. Only in exceptional circumstances, when it is planned and necessary to maintain source animals for harvest at an age beyond sexual maturity, and where there are insufficient numbers to maintain single sex groups, should castration be considered. In these circumstances, and with the prior agreement of the Home Office, the procedure may be performed under the direction of the Named Veterinary Surgeon using appropriate anaesthesia and analgesia, in accordance with the appropriate welfare legislation: Protection of Animals (Anaesthetics) Act 1954 (Amendment) Order 1982 and the Veterinary Surgeons Act 1966 (Schedule 3 Amendment) Order 1982.

Tooth clipping

3.35.1. Tooth clipping is often used in young piglets to minimise damage to the dam's teats, and to other piglets. This practice can cause gum damage and splintering of teeth, which can lead to bacterial infection, and is considered to cause pain.

3.35.2. Schedule 3 of the Welfare of Livestock Regulations 1994 (S.I. 1994/2126)[14] requires that tooth clipping shall not be carried out routinely, but only when there is evidence that injuries to sows' teats or other piglets have occurred or are likely to occur as a result of not carrying out this procedure.

3.35.3. This procedure should only be used on the advice of the Named Veterinary Surgeon, its continued use regularly reviewed, and may only be performed by trained and competent staff using the correct equipment [16]. There is some evidence [17] that teeth grinding/polishing causes less damage to the teeth/gums than clipping, and should be considered as an alternative method. Tooth clipping may only be performed in animals during the first week of life.

Tail docking

3.36.1. Tail docking is employed to avoid tail biting problems. This procedure causes both acute and chronic pain. Tail biting is an indication of an inadequate environment and indicates that welfare is poor in the animal carrying out the biting [7].

3.36.2. If tail biting occurs, the animals' social and environmental conditions must be reviewed as a matter of urgency. The problems of injury following tail biting should be resolved by improved management practices rather than by tail docking.

3.36.3. Tail docking must never be performed routinely, and must only be used in situations in which the Named Veterinary Surgeon considers that the individual animal may benefit, for example by removal of a damaged tail [16].

4. Procedures required to improve health status of herd

4.1. **Surgical derivation** and **segregated/medicated early weaning** are two procedures used in veterinary practice to assist in the production of high health quality pig herds.

4.2. The requirement for Qualified Pathogen Free (QPF) xenotransplantation source animals will almost inevitably need at least one, if not both, of these procedures to provide an animal of suitable health quality for use in humans.

4.3. **As the practices of surgical derivation and early weaning have adverse welfare consequences for the animals, these may only be used when considered essential to the production of an animal of suitable health quality for use in a xenotransplantation programme, and where there is a demonstrable need to eliminate specific micro-organisms.**

Surgical derivation

4.4.1. This procedure involves the removal of near term piglets from the sow's uterus in a sterile manner, and transfer into a barrier facility.

4.4.2. Sows should be transported to the holding area no more than ten days and no less than two days from expected farrowing date. Animals should be moved in pairs or groups. Pens of suitable size should be provided with appropriate nesting material to satisfy the animals' behavioural need.

4.4.3. This procedure will be performed either following killing of the sow by a Schedule 1 method, or while the sow is maintained under general anaesthesia. The sow will not be permitted to recover from anaesthesia.

4.4.4. The surgery will be carried out under aseptic conditions in a designated operating room.

4.4.5. In existing stocked units, this procedure may be used to introduce new lines of animals without compromising the microbiological status of the unit. In such circumstances, the programme should be planned to ensure that cross-fostering of the surgically derived piglets can be achieved.

4.4.6. For new units seeking to control microbiological status where there are no sows in the unit to allow cross-fostering, it is necessary to orphan rear piglets. Piglets are reared artificially from birth, generally, for the initial rearing period of 2-3 weeks, in an isolator system, which allows the precise required environmental conditions to be maintained.

4.4.7. Special diets are required, and very carefully controlled environmental conditions are necessary, as neonatal piglets are particularly susceptible to temperature fluctuations. The early introduction of a specified microflora is recommended, as survival rates are significantly enhanced.

4.4.8. Temperature must be maintained in the resting area between 35-38 degrees Centigrade.

4.4.9. Piglets should be housed in pairs or groups (minimum space allowances per piglet of $0.25m^2$ of which $0.15m^2$ must be resting area). A comfortable lying area must be provided.

4.4.10. As robust nuzzling, leading to umbilical herniation, is an acknowledged problem with this procedure, it may be necessary to single house piglets for up to the first three days of life. In such circumstances the animals should have tactile, olfactory and visual contact with other piglets. By two weeks of age, the animals are generally becoming more robust, and are better able to cope with a more conventional pen design - i.e. a resting, dunging and feeding area should be provided.

4.4.11 The essential components of a successful derivation programme are experienced staff combined with appropriate working practices, a carefully controlled environment, and suitable diets. Unless experienced trained staff are available and high quality accommodation is provided, losses may be in excess of those achieved by conventional rearing.

4.4.12 No obvious long-term behavioural problems have been recorded with this procedure, but data are sparse and similar problems to those associated with segregated/medicated early weaning might occur where piglets are reared away from the sow.

Segregated/medicated early weaning

4.5.1. Segregated/medicated early weaning is an alternative strategy to surgical derivation, which has been used commercially to improve the qualified pathogen (QPF) status of the herd [18].

4.5.2. The procedure involves weaning of the piglets from the sow at 5-7 days of age (segregated early weaning - SEW). In some circumstances, to eliminate particular pathogens, antibiotic medication is administered at this stage (medicated early weaning - MEW). In the case of medicated early weaning, the use of antibiotics must be approved by the Named Veterinary Surgeon.

4.5.3. Although the piglets are removed from the sow at 5-7 days of age, the animals should remain on a primarily milk based diet until around 4 weeks of age.

4.5.4. Weaning before 21 days of age is in breach of Schedule 3 of the Welfare of Livestock Regulations 1994 [14]. However, segregation at 21 days does not provide the same opportunities for disease control, as infection with many pathogens will occur before this age [18].

4.5.5. Under ideal conditions, with experienced staff and good housing, this procedure can be performed with losses similar to, or less than, those recorded with conventional rearing.

4.5.6 Early weaned piglets will be housed in pairs or groups.

4.5.7. Physiological disorders [19] and some abnormal behaviours in the piglets have been reported following early weaning, such as belly nosing and increased vocalisation, some persisting for several weeks [20, 21].

4.5.8. Care must be taken to monitor the sow for evidence of mastitis, but no increased incidence has been reported. Some reduction in fertility as a consequence of this technique is reported [19].

Summary of use of surgical derivation and early weaning procedures

4.6.1. These procedures may only be used when considered essential to the production of an animal of suitable health quality for use in a xenotransplantation programme, and where there is a demonstrable need to eliminate specific micro-organisms.

4.6.2. Only with high standards of accommodation, husbandry and care, can satisfactory standards of welfare be maintained using the procedures of surgical derivation or segregated/medicated early weaning.

4.6.3. In circumstances where success rates are poor, or there is evidence of significant welfare problems associated with the use of these procedures, the Home Office will review the relevant project licence authorities.

Use of gnotobiotic (germ free) animals as xenotransplantation source animals

4.7.1. Gnotobiotic animals are obtained by surgical derivation, and are wholly maintained in isolators (in contrast to QPF pigs, which may be reared for a short period of time in an isolator following surgical derivation).

4.7.2. Due to the high welfare costs to the animals, in terms of being raised in a barren environment with little or no social contact, **source animals must not be reared beyond four weeks of age in an isolator**. Isolator rearing of piglets should only be necessary following surgical derivation into a "new" or refurbished biosecure barrier unit.

4.7.3. In addition to the concerns over welfare, there are practical difficulties in maintaining large animals in isolators over long periods, and concerns over the physiological suitability of tissues harvested from animals maintained under such conditions.

5. Record keeping systems

5.1. Section 10(6)(b) of the Act requires that records be maintained of the source, use, and final disposal of all animals bred, kept for breeding, or for subsequent supply for use in scientific procedures.. These are important for husbandry and planning purposes and as an indicator of the animals' well-being and welfare.

5.2. Breeding performance is a sensitive barometer of good husbandry, and can provide an indicator of the welfare of the animals. However, high performance figures do not necessarily equate to high welfare standards.

5.3. Data should be maintained on herd size, individual performance per breeding female and breeding boar, total output of the colony, litter size, number of litters in a given period, pre-weaning and post weaning mortality. The data should be averaged over appropriate periods so that any change in performance can be rapidly identified.

5.4 Detailed records should be maintained of all surgical derivation and segregated/medicated early weaning procedures. Records should be maintained of any unusual or unexpected traits, such as abnormal phenotypes or behaviours.

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