THE
LABORATORY ANIMAL BREEDERS ASSOCIATION

ACCREDITED HEALTH MONITORING SCHEME MANUAL

LABAHMS

JANUARY 2000

CONTENTS

TERMINOLOGY / ABBREVIATIONS

- **LABA** - Laboratory Animal Breeders Association of Great Britain
- **LABAHMS** - Laboratory Animal Breeders Accredited Health Monitoring Scheme
- **TRUSTEES** - The Accrediting authority of LABAHMS
- **SECRETARY-GENERAL** - The Administrator of LABAHMS
- **HONORARY SECRETARY** - The Honorary Secretary of LABA
- **HONORARY TREASURER** - The Honorary Treasurer of LABA
- **WORKING PARTY** - Consists of the Secretary General, Chairman of LABA and invited experts in the field of laboratory animal science.
- **THE COUNCIL OF LABA (LABA COUNCIL)** - The elected governing body of LABA
- **MEMBER** - A member of LABA
- **LABORATORY ANIMALS** - Species of animals intended for experimental or other scientific procedures including those as defined in Schedule 2 of the Animals (Scientific Procedures) Act 1986.

INTRODUCTION

In 1947 the Medical Research Council (MRC) established the Laboratory Animals Bureau with the intention of raising the standard of supply of laboratory animals available at that time. In 1950 the Bureau introduced its Accreditation Scheme for breeders of laboratory animals and in 1958 changed its title to the Laboratory Animals Centre (LAC). Over the years the LAC Accreditation Scheme developed to cover mice, hamsters, rats, guinea pigs, rabbits, cats and dogs and included a Recognition Scheme for other vertebrate and invertebrate species.

In 1981 the MRC announced its intention to close down the Scheme which had largely achieved its objectives of encouraging the growth of the commercial laboratory animal breeders to a point whereby high quality animals were routinely available. It seemed an appropriate time for an alternative scheme to be established.

In co-operation with the MRC, the Laboratory Animal Breeders Association of Great Britain (LABA) established a Working Party to complete the details of a new scheme which they had previously drafted. The Working Party comprised representatives of the Association of the British Pharmaceutical Industry, the British Laboratory Animal Veterinary Association, the Institute of Animal Technology, the Laboratory Animal Breeders Association, the Laboratory Animal Science Association, the Contract Research Group and an observer from the LAC. The scheme which developed, the Laboratory Animal Breeder's Association Accreditation Scheme (LABAAS) reflected the efforts of that group and benefited from the contribution of each of the organisations involved.

In 1991/92 the Working Party along with a number of invited specialists reviewed the microbiological monitoring programme with the intention of bringing it up to the standards currently adopted by major breeders. This reflected the greatly improved facilities in which many animals are now bred when compared to those of the relatively recent past.

The group also thoroughly reviewed the monitoring process in terms of sample size and frequency of monitoring. It was decided that there was no longer any justification to have different standards of monitoring for different species and/or types of facilities. Schedule A of the LABAAS was amended and the health monitoring programme re-written in the replacement Schedule.

During 1994 the Home Office, after consultation with interested parties, introduced "The Code of Practice for the Housing and Care of Animals in Designated Breeding and Supplying Establishments" (COP) which had the effect of making Schedule A of the LABAAS obsolete. The Home Office COP does not stipulate the health monitoring programmes to breeders designated under the Animals (Scientific Procedures) Act 1986. Members of LABA are committed to satisfying all the requirements of the COP and in addition recognise the importance of maintaining health monitoring regimes which demands high standards of husbandry and management in the production units to enable them to supply animals of a uniform microbiological standard. As a result the Laboratory Animal Breeders Accredited Health Monitoring Scheme (LABAHMS) has been introduced to incorporate the replacement Schedule of the LABAAS manual, “Recommendations for Health Monitoring” and designed to meet the needs of the Home Office Code of Practice for Breeding Establishments with regard to microbiological surveillance programmes as stated in paragraph 3.43 of The Code of Practice.

OBJECTIVES OF LABAHMS

Members of the LABA breed and supply laboratory animals of defined health and microbiological status. Verification of animal health quality is dependent on the results generated by the testing laboratories using the prescribed monitoring techniques. The objective of LABAHMS is to collect, collate and review the animal health testing reports in order to confirm that members comply with The Schedule requirements, in addition:-

1. LABAHMS is an independently administered scheme for members of the Laboratory Animal Breeders Association.

2. LABAHMS monitors the standards for health and disease monitoring of animals bred by accredited laboratory animal breeders.

3. LABAHMS obliges its members to provide their health monitoring results to customers on request.

4. LABAHMS has standardised its microbiological monitoring programme to be sure it meets current standards of animal production.

5. LABAHMS gives users confidence that their animal supplies should be of a high and consistent standard.

SECTION I

GENERAL PROCEDURES

1. LABA members will select testing laboratories. These laboratories may be either in house or independent of the breeder and should have a record of reliable performance within the industry.

   A list of laboratories used by members for the purposes of conducting health monitoring will be held by the Secretary-General.

   Application from LABA members for membership of LABAHMS will be made on an official application form available from the Honorary Secretary. The completed application will be sent to the LABAHMS Secretary-General.

   The Secretary-General and Trustees will, after due consultation with LABA Council, grant or deny membership. A decision will be notified to the applicant in writing.

   Successful applicants will receive a Certificate of Membership which will be reviewed annually and renewed subject to satisfactory compliance.

SECTION II

TRUSTEES

1. ***Trustees***

Trustees will be from a suitable laboratory animal science background and will be approved by the LABA Council.

Trustees will be required to declare in writing that they have no affiliation with any commercial microbiological laboratory or commercial breeder or supplier of laboratory animals.

Trustees will notify LABA Council of any change in their professional circumstances.

2. ***Number of Trustees***

There will be a minimum of two Trustees.

3. ***Meetings***

Meetings of the Trustees will be held as required. In addition to the Trustees, the meetings should be attended by the Secretary-General and a member of the LABA Council, or their nominated deputies.

4. ***Confidentiality***

Trustees will treat in strict confidence all the information gained as the result of their responsibilities.

5. ***Responsibility***

The trustees will be required to meet whenever there is sufficient business to justify a meeting in the opinion of the Secretary-General.

The Secretary-General and the Trustees will grant or withhold membership. The decision reached by the Secretary-General on the status of membership shall be final. An appeal may be made by the member to LABA Council.

The Secretary-General and Trustees will make recommendations to improve the Scheme in the light of their experience and current knowledge. Any alteration to the Scheme must be approved by the LABA Council.

6. ***Term of Office***

Trustees will be appointed for a maximum term of five years. Upon completion of a term, or upon resignation of a Trustee, the Secretary-General will be requested to nominate a replacement for approval by the LABA Council. Retiring Trustees may be nominated for a further term of office.

SECTION III

SECRETARY-GENERAL

1. The Secretary-General will be required to declare in writing that he or she has no affiliation with any commercial breeder or supplier of laboratory animals or microbiological testing laboratory.

   The Secretary-General will be appointed by the Council of LABA and shall be the administrator of the Scheme.

2. The duties of the Secretary-General will to:-

   a) receive applications;
   b) serve as liaison officer between the Trustees, the LABA Council, LABA members and the research community;
   c) channel official communications;
   d) call meetings of the Trustees;
   e) review Health Monitoring reports and the testing schedule from LABA members,
   f) determine that animals selected for screening are representative of the colonies held,
   g) maintain details of members breeding units;
   h) record the minutes of the meetings;
   i) maintain the Register;
   j) keep all relevant records;
   k) perform such other duties as may be requested by the Council of LABA;
   l) sign certificates of membership.

SECTION IV

RULES OF THE SCHEME

The Health Monitoring Scheme is governed by rules designed to maintain high standards in all aspects of health monitoring of commercial laboratory animal colonies. Failure to comply may result in the loss of membership.

Breeders and Suppliers

1. Applicants will pay an annual fee pursuant to a schedule established by the Council of LABA. The fee schedule thus established may be amended from time to time. Annual fees must be paid within 60 days of the invoice date.

2. Breeders and Suppliers must comply with the health monitoring requirements as laid down in the Schedule and elsewhere in this Manual.

3. Breeders and suppliers should have a policy, specific to their own organisation, for notifying customers of any changes to the health status of their animals since the last report. Quarterly results must be sent to the Secretary-General for checking, collating and archiving.

4. Breeders and Suppliers who exceed the monitoring requirements of the Schedule should supply customers with the complete results upon request.

5. Breeders and Suppliers must observe all statutes and regulations governing the breeding and supply of laboratory animals, but need not be limited to any such minimum standards.

6. Breeders and Suppliers must complete and return the bi-annual and other reports and documents requested by the Secretary-General.

7. In consultation with the Secretary-General and Trustees, the Council of LABA may amend or modify the Scheme. Notification of such change will be in writing to the Breeders, Suppliers and Accredited Laboratories.

8. Infections and/or clinical outbreaks of disease which the Named Veterinary Surgeon considers of sufficient impact should be reported to the customers of Breeders and Suppliers and the Secretary-General whether they are associated with the screening requirement or not.

9. A list of commercial Breeders and Suppliers who are members of the Health Monitoring Scheme will be published and made available on an annual basis.

SECTION V

FISCAL

The fiscal year for the Scheme will be the same as the fiscal year of LABA, April 1- March 31.

1. All financial transactions concerned with the Scheme will be the responsibility of LABA.

2. All income and expenditure concerned with the Health Monitoring Scheme will be through a specified LABA bank account.

3. The Secretary-General will have no responsibility for financial transactions.

4. Audit of the Scheme income and expenditure will be incorporated with the annual audit of LABA accounts.

5. An annual honorarium to be determined by LABA Council will be paid to the Secretary-General.

6. The Trustees will serve without remuneration.

7. Expenses claimed by the Secretary-General and Trustees will be reimbursed in accordance with the rates laid down by LABA Council.

8. Application fees and annual membership fees will be established in accordance with the rules.

9. Application fees will be non-returnable and must be paid at the time of application.

SECTION VI

DISSOLUTION

The Scheme is operated on a voluntary basis and is intended to be self financing through income from application fees and annual membership fees. Operation of the Scheme will incur expenses for administration and meetings of the Secretary-General and Trustees. If at any time, in the opinion of the Council of LABA, the Scheme cannot be properly administered or financed, the Council will suspend activities and inform members in writing.

SECTION VII

MISCELLANEOUS

1. Consultants

The advice and recommendations of expert consultants may be employed at the discretion of the Secretary-General, Trustees and LABA Council.

2. Records

All files and records of the Scheme will be held in strict confidence and no such confidential data will be released without the written agreement of the Breeder/Supplier.

3. Publicity

A Register of Commercial Breeders/Suppliers who are Scheme members shall be published. Other material shall be published to advertise the Scheme and impart general information from time to time.

4. Certificates

Certificates shall be issued to each Breeder/Supplier member but such certificates shall remain the property of LABA. Certificates will display the effective dates.

SECTION VIII

LATEST REVISIONS

1. Immunodeficient mice housed in isolators.

Previous LABAHMS schedules have been restricted to the breeding of animals in barrier rooms. However there is a commercial demand for breeding immunodeficient mice of a high health status, particularly mice homozygous for the *nu* mutation ("nude" mice) and for the *Prkdc*^{scid} mutation ("SCID" mice).

Current barrier rooms are highly effective at excluding infectious agents which are considered primary pathogens of a particular species. However it is clear that certain bacteria such as coagulase positive *S. aureus* constitute part of the normal human skin flora but can be pathogenic in immunodeficient mice. For this reason immunodeficient mice are usually bred in isolators as human-animal contact is eliminated and environmental organisms are more effectively excluded.

The schedule for the mouse now distinguishes between animals bred in an isolator and a barrier room and allows for environmental monitoring of the microbial status. The frequency of monitoring of animals is reduced to reflect the increased reliability of bioexclusion measures but contamination by an infectious agent is also more likely to present as clinical disease in immunodeficient stock.

2. Individually Ventilated Cage Racks.

Recently there has been a surge of interest in using individually ventilated cage racks (IVCs) for housing rodents, particularly mice, due to effective air containment or exclusion at the cage level. In some respects these systems fall between barrier rooms and isolators in the way that routine husbandry is managed. The effective sampling of a population of animals housed in an IVC for health monitoring is a challenge as each cage may be regarded as a different microbiological entity especially if a dedicated cage-changing station is used.

Although IVCs are not being widely used to commercially breed rodents for general supply, there is benefit in outlining a strategy for health monitoring using sentinels exposed to soiled bedding. How effective a given strategy is likely to be will depend on how rigorously the system for air handling and cage cleaning is managed.

Recommendations for health monitoring of animals in IVCs are set as follows:

- The range of agents should include viruses, bacteria/mycoplasma, and parasites as indicated in the attached schedules for a particular species using 4 animals per rack.
- Identify a sentinel cage in the rack and add weanling animals; expose to soiled bedding from cages in different levels in the rack for 4 weeks before anticipated health screen.
- If retired breeders are available then these should be used for serology and taken from different levels in the rack.

3. Range of agents monitored.

Research conducted into infectious diseases of laboratory animals has identified some pathogens which previously went unnoticed in rats and mice and the lists have been revised accordingly. Examples are: the parvoviruses of rats and mice, MPV and RPV which are serologically distinct from the more familiar parvoviruses namely MVM, Toolan's H-1 and KRV; *Helicobacter hepaticus* and *H. bilis* which are pathogenic for immunodeficient rats and mice (although the former can cause lesions in immunocompetent mice); and also *Corynebacterium bovis* which causes hyperkeratosis in nude mice. Although ginuea pig adenovirus is yet to be isolated in cell culture, there is concern that this agent may cause clinical disease in guinea pigs. There is currently no serological test for this agent which uses guinea pig adenovirus antigen and the best substitute is mouse adenovirus which has cross-reacting epitopes.

The lists of bacteria have been drawn up in an attempt to focus on primary pathogens and zoonosis. The immunocompetence of the host is therefore an important consideration. Many bacteria are classed as opportunists and are unlikely to cause disease in the immunocompetent rodents which are routinely held in barrier rooms. Such agents include *Pasteurella multocida, P. pneumotropica*, *Bordetella bronchiseptica*, β-haemolytic streptococci spp (with the exception of *S. zooepidemicus* in guinea pig), *Corynebacterium bovis*, *Y. pseudotuberculosis*, *P. aeruginosa* and *Clostridium spp*.

The list of microorganisms to be monitored and the sample size and frequency represent a minimum standard. Breeders may exceed this standard.

The screening profile for each species is based on the importance of infection for that species in terms of clinical disease in animals, risk of infection in humans and effects on experiments.

Given the appropriate conditions, for example immunosuppression, many bacteria may be pathogenic. However in barrier-reared immunocompetent animals their presence may not cause any clinical or subclinical effects. Examples of such organisms are *Pasteurella* spp., *Pseudomonas aeruginosa*, *Staphylococcus aureus*,.

Some organisms may be transient in a population, possibly introduced by personnel, for example *Bordetella bronchiseptica* and β-haemolytic streptococci and may have no effect on animals. Such agents may only be detected as transient because the agent fails to transmit to other animals in the population because the species is not the natural host for the organism.

For these reasons, such organisms as described above have been omitted from the primary list of bacteria to be monitored in immunocompetent, barrier-reared rats, mice, hamsters, gerbils, rabbits and guinea pigs.

THE SCHEDULE

RECOMMENDATIONS FOR HEALTH MONITORING

OF

MOUSE, RAT, HAMSTER, GERBIL,

GUINEA PIG, RABBIT, DOG, FERRET

BREEDING COLONIES

AND SUPPLIERS OF NON-HUMAN PRIMATES

This schedule denotes the requirements for health monitoring by species. Breeders may operate a more comprehensive programme, as dicated by their own policy.

For the purpose of microbiological screening, a Unit is considered to be "The area contained within defined limits which can be considered as a microbiological entity and is sampled, screened and declared as a single unit." Agents known to be present need not be monitored at subsequent screens provided that they are declared in the health report.

Commercial breeders may use any of the following four classifications to denote the type of facilities that their animals are bred in:-

Non-barrier unit
Part-barrier unit
Full-barrier unit
Isolator
Individually ventilated cage rack
Supplier

These classifications are based upon the standards of facilities and systems of operation. Adequate resources, methods of operation and microbiological screening results ensure that the user can have confidence that the standard of animals supplied is unlikely to alter substantially with time.

AGENTS MONITORED IN MOUSE BREEDING COLONIES

	Viral agents	Immunocompetent (barrier room)	Immunodeficient (isolator)
1	Minute virus of mice (MVM)	•	•
2	Mouse hepatitis virus (MHV)	•	•
3	Mouse rotavirus (EDIM)	•	•
4	Mouse parvovirus (MPV)	•	•
5	Pneumonia virus of mice (PVM)	•	•
6	Reovirus type 3 (Reo-3)	•	•
7	Sendai virus	•	•
8	Murine encephalomyelitis (TMEV)	•	•
9	Hantavirus	•	•
10	Lymphocytic choriomeningitis virus	•	•
11	Ectromelia virus	•	•
12	Lactate dehydrogenase virus (LDV)	•	•
13	Mouse adenovirus (Mad)	•	•
14	Mouse cytomegalovirus (MCMV)	•	•
15	Mouse pneumonitis virus (K)	•	•
16	Mouse polyoma virus	•	•
17	Mouse thymic virus	•	•

	Bacterial and mycoplasmal organisms		
	Bordetella bronchiseptica		•
	Citrobacter rodentium	•	•
	Clostridium piliforme	•	•
	Corynebacterium kutscheri	•	•
	Corynebacterum bovis		•
	Helicobacter hepaticus	•	•
	Helicobacter bilis		•
	Mycoplasma pulmonis	•	•
	Pasteurella multocida		•
	Pasteurella pneumotropica		•
	Pseudomonas aeruginosa		•
	Salmonella spp	•	•
	Staphylococcus aureus		•
	Streptobacillus moniliformis	•	•
	β-haemolytic streptococci (ex group D)		•
	Streptococcus pneumoniae	•	•

	Parasitic infections		
	Intestinal protozoa	•	•
	Intestinal helminths	•	•
	Arthropods	•	•

SCREENING SCHEDULE IN MOUSE BREEDING COLONIES

Sampling frequency

	Immunocompetent (barrier room)	Immunodeficient (isolator)
Viral agents		
nos. 1-8	Quarterly	Annually
9-12	Annually	Annually
13-17	After restocking	After restocking
Pseudomonas aeruginosa *Staphylococcus aureus*	-	Quarterly
Remaining bacteria, mycoplasma and parasites	Quarterly	Annually

Sample size

		Number	
	Age	Barrier room	Isolator
Serology for viral agents*	> 10 w.o.	8	2
Bacteria, mycoplasma and parasites	4-5 w.o.	4	2

* half of the animals submitted are also screened for bacteria, mycoplasma and parasites.

AGENTS MONITORED IN RAT BREEDING COLONIES

Viral agents

1	Hantaan virus
2	Kilham rat virus (KRV)
3	Pneumonia virus of mice (PVM)
4	Reovirus type 3 (Reo-3)
5	Sendai virus
6	Sialodacryoadenitis virus/ Rat corona virus (SDA/RCV)
7	Theiler's murine encephalomyelitis virus (TMEV)
8	Toolan's (H-1)
9	Rat parvovirus (RPV)
10	Lymphocytic choriomeningitis virus (LCMV)

Bacterial and mycoplasmal organisms

Clostridium piliforme
Corynebacterium kutscheri
Helicobacter hepaticus
Leptospira (icterohaemorrhagiae, ballum)
Mycoplasma pulmonis
Salmonella spp
Streptobacillus moniliformis
Streptococcus pneumoniae

Parasitic infections

Intestinal protozoa
Intestinal helminths
Arthropods

Sampling frequency

Viral agents nos. 1-8	Quarterly
9	Annually
Bacteria, mycoplasma, parasites	Quarterly
Leptospira spp	Annually

Sample size

	Age	Number
Serology for viral agents*	> 10 w.o.	8
Bacteria, mycoplasma and parasites	4-5 w.o.	4

* half of the animals submitted are also screened for bacteria, mycoplasma and parasites.

AGENTS MONITORED IN HAMSTER AND GERBIL BREEDING COLONIES

Viral agents

1	Lymphocytic choriomeningitis virus (LCMV)
2	Sendai virus

Bacterial and mycoplasmal organisms

Clostridium piliforme
Salmonella spp
Streptobacillus moniliformis
Streptococcus pneumoniae

Parasitic infections

Intestinal protozoa
Intestinal helminths
Arthropods

Sampling frequency

Viral agents nos. 1-2	Quarterly
Bacteria and parasites	Quarterly

Sample size

	Age	Number
Serology for viral agents*	> 10 w.o.	8
Bacteria and parasites	4-5 w.o.	4

* half of the animals submitted are also screened for bacteria, mycoplasma and parasites.

AGENTS MONITORED IN GUINEA PIG BREEDING COLONIES

Viral agents

1	Lymphocytic choriomeningitis virus (LCMV)
2	Sendai virus
3	Mouse adenovirus

Bacterial and mycoplasmal organisms

Clostridium piliforme
Salmonella spp
Streptobacillus moniliformis
Streptococcus pneumoniae

Parasitic infections

Intestinal protozoa
Intestinal helminths
Arthropods

Sampling frequency

Viral agents nos. 1-3	Quarterly
Bacteria and parasites	Quarterly

Sample size and class of stock

	Age	Number
Serology for viral agents*	> 10 w.o.	8
Bacteria and parasites	4-5 w.o.	4

* half of the animals submitted are also screened for bacteria, mycoplasma and parasites.

AGENTS MONITORED IN RABBIT BREEDING COLONIES

Viral agent

Rabbit poxvirus (myxomavirus)

Bacterial organisms

Clostridium piliforme
Bordetella bronchiseptica
Pasteurella multocida
Pasteurella pneumotropica
Salmonella spp
Yersinia pseudotuberculosis

Parasitic infections

Encephalitozoon cuniculi
Intestinal protozoa
Intestinal helminths
Arthropods

Sampling frequency

Viral agent	Quarterly
Bacteria and parasites	Quarterly

Sample size

	Age	Number
Serology for viral agents	> 7 w.o.	4
Bacteria and parasites	>26 w.o.	4

AGENTS MONITORED IN DOG BREEDING COLONIES

Viral agents

* Canine distemper virus
* Canine hepatitis virus
* Canine parvovirus

Bacterial and fungal organisms

Bordetella bronchiseptica
Campylobacter jejuni
Salmonella spp
** Leptospira canicola*
* Leptospira icterohaemorrhagiae

* Screening for these organisms may be omitted when there is a declared vaccination policy under veterinary supervision in accordance with the manufacturers' recommendations. The vaccination policy must be made known to customers on request.

Parasitic infections

Helminths
Arthropods

Sampling frequency

Viral agents, bacteria, fungi and parasites	Quarterly

Sample size

	Age	Number
Eight animals from each breeding unit	Adults	4
	Weaners	4

Samples to be taken

Plucked hair, ear swab, serum (if there is no vaccination policy – see above), faeces, pharyngeal swab

AGENTS MONITORED IN FERRET BREEDING COLONIES

Viral agent

* Canine distemper virus

* Screening for this organism may be omitted when there is a declared vaccination policy under veterinary supervision in accordance with the manufacturers' recommendations. The vaccination policy must be made known to customers on request.

Bacterial and fungal organisms

Salmonella spp

Parasitic infections

Helminths
Arthropods

Sampling frequency

Viral agents, bacteria and parasites	Quarterly

Sample size

	Age	Number
Eight animals from each breeding unit	Adults	4
	Weaners	4

Samples to be taken

Plucked hair, pharyngeal swab, serum (if there is no vaccination policy – see above), faeces

AGENTS MONITORED IN NON HUMAN PRIMATES (MACAQUES)

LABA Council strongly encourage primate suppliers to work towards regular and reliable microbiological screening in the country of origin including replacement breeders. Also the establishment of fully closed colonies is desirable.

It is important that consideration be given to choosing sources of animals that are free of major pathogens e.g. Herpes B virus

Tuberculosis

Filoviruses

Simian Retrovirus D (SRV-D)

Simian Immunodeficiency Virus (SIV)

Simian T-Lymphotropic virus (STLV-1)

Ongoing reliable monitoring of the source is necessary to confirm this.

When the source is known to be Herpes B virus positive it is essential that animals are monitored on an ongoing individual basis. Having imported only negative status animals this should be checked on arrival and at least every 3 months to sexual maturity, decreasing gradually to every 6-12 months for long term holding.

Tuberculosis – should be continually monitored in all imported macaques, using a standard protocol involving the most appropriate test currently available. Accepting that current tuberculin skin tests cannot be taken as a definitive test for all mycobacterial species.

Salmonella/Shigella screening – is recommended on a minimum of 10% of the animals imported each year through a supplier, to assess the status of the source for these bacterial pathogens.

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Additional screening will depend on the needs of the customer concerned, relative to the proposed use of the primate.

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