

**Technical Expert Working Group
for the revision of Directive 86/609/EEC on the protection of animals
used for experimental and other scientific purposes**

**Final report
Sub-Group Authorisation**

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Review of EU Directive 86/609/EEC
Technical Expert Working Group
Final Report from the Authorisation Sub-Group

2. AUTHORISATION PROCEDURES

Introduction

The subgroup authorisation of the TEWG (Technical Expert Working Group) tasked with addressing the authorisation of procedures, personnel and animals to be used, started at the discussion on 1 July 2003, with the initial meeting in Brussels.

The first draft reports on the various subparagraphs were posted on the Circa website during the week 14-18 July 2003. Second drafts of these reports were posted between 28 September 2003 and 10 October 2003. These second drafts incorporated the comments on the first drafts and the subsequent discussions carried out via the Circa website and by e-mail, involving members of the Authorisation Sub-Group and also other members of TEWG. Also the comments and questions on the first drafts made by the Commission were addressed in the second draft. On 4 November 2003 a third draft, for the first time combining all sub-reports was posted on the Circa website and this was the document used during the meeting of the Sub-Group on 6 November 2003.

This final report takes account of further discussions during the 6 November Sub-Group meeting and during the TEWG meeting on 7 November 2003. If there was no consensus on a topic, this report gives details on the majority point of view and states where the opinions differ. In most cases it will not be mentioned which expert(s) had different opinions.

The discussions took place in the context of advice received from the European Commission that, in relation to the Directive, there was no specific competency for animal welfare at EU level. This competency was a matter for member states. The current Directive was based on a need for good functioning of the internal market and harmonisation of related practices across the EU. On this basis, the scope of the Directive could not extend to the use of animals in basic research or in education and training, although national legislation generally applied to these areas as well as to the areas covered by the Directive. It was understood, however, that legal opinion to the contrary was being submitted to the EC for further consideration.

The revision of the Directive will not lead to a transformation of the Directive into a Regulation. In most member states a system is in place for authorising animal procedures. In our group only a few member states (and one candidate country) were represented, thus making it impossible for us to have a detailed view on all current systems in place. Both these facts should be kept in mind during the whole revision procedure. Especially because some of the questions invite to very detailed subscriptions of how to handle a subject. It is very well possible in several cases to reach the same goal by using other meanings.

As said before it is not a Regulation and thus countries with a different system but reaching the same desired results should not be forced to alter their system completely.

The authorisation subgroup addressed the issues by attempting to answer the questions in the initial Thought Starter and in the comments on a previous draft provided by the Commission one by one, drawing on legislation that is currently in force and working effectively in a number of Member States.

In this report, “(Sub-Group) Members” refers to members of the Sub-Group Authorisation of the TEWG.

In this report paragraph numbers and titles refer to the initial paragraph numbers and titles in the Thought Starter formulated by the Commission. Titles of sub-paragraphs refer to questions in either the Thought Starter or further questions posted by the Commission after the first draft.

2.2.1 Authorisation of procedures/experiments

- **Authorisation of an experiment versus a project (which includes several experiments)**

The term “procedure” should be used rather than “experiment”, to include both procedures with known outcomes (*e.g.* procedures concerned with the production of antibodies) and with unknown outcomes (*e.g.* an procedure conducted to test a hypothesis).

The rapporteurs agreed on using the following definitions throughout all documents:

Technique: A technical act on one or more animals for an experimental or other scientific purpose and which may cause that animal or those animals pain, suffering, distress or lasting harm. Examples of technical acts would be gavage, injection, laparotomy, withholding of food/water. (The definition of “animal” here will depend on the scope of the Directive.)

Procedure: A combination of one or more technical acts carried out on an animal for an experimental or other scientific purpose and which may cause that animal pain, suffering, distress or lasting harm.

Project: A coherent programme of work aimed at meeting a defined scientific objective or objectives and involving a combination of one or more procedures.

The rapporteurs also agreed upon not using the following terms:

Experiment: No longer appropriate as replaced by “procedure”.

Intervention: Synonymous with “technique”.

Protocol: As this term generally implies a written description of some type of procedure, *e.g.* standard operation procedure, its use would be superfluous in Sub-Group reports and should be avoided.



Question: How could each procedure efficiently be covered by a formal authorisation without increase in bureaucracy or processing times?

Background: formal authorisation should be at the level of the project, provided that each procedure within a project is listed so that it can be accounted for and monitored if necessary. A similar system of authorisation to that set out below is already in place in a number of member states (*e.g.* France, Switzerland, UK).

We assume that the term “bureaucracy” means paperwork, in which case the suggested system may well lead to an increase in bureaucracy and processing times in countries that do not currently have an adequate system in place. However, the use of animals in research is a very serious issue for the public and those who undertake such research, so a certain level of paperwork and careful consideration is essential to address these concerns and safeguard the animals involved. Furthermore, good animal welfare leads to good science and therefore to the effective use of resources. This requires proper records, processes and planning.

Answer: Each project should be authorised by the appropriate department of the national competent authority. It is up to the Member States how this authorisation will be conducted practically.

No consensus on whether it should be a condition for authorisation that each procedure within the project is listed so as to give a clear description of its impact on the animals and its potential to cause pain, suffering, distress or lasting harm (see below).

Arguments: some feel each procedure within the project should be listed so as to give a clear description of its impact on the animals and its potential to cause pain, suffering, distress or lasting harm. Others say that this would be equivalent to individual authorisation for procedures, which is not acceptable for bureaucracy reasons and consecutive cost for CA.

DK *e.g.* has a national authorisation board. This board meets once a month and consists of 10-11 scientists and with a national court judge as chairman. They deal with approximately 30 applications every month. The system seems to work in Denmark. **Advantage:** cheap good expertise of people who would perhaps not like to work fulltime in an inspectorate; strong centralised knowledge. **Disadvantage:** time consuming; discussions tend to focus on biology vs. law rather than ethics; inspection of colleagues might be awkward; limited legal knowledge of the scientists in the board; only a feasible system for countries with a limited number of yearly applications.

This system could not be used in other countries with more animal research *e.g.* the NL has close to 90 license holders who may perform animal research, they produce close to 5000 applications every years. 26 approved local ethical committees are active. Each committee meets once or twice per month. **Advantages:** feasible system for large amount of applications; knowledge of the committee tailor-made for the type of research; cross-pollination of different committees through study-meetings, and membership of more than one committee; ethics are discussed. **Disadvantage:** slight differences might occur

between advices from different committees; not every committee has a complete overview.

Both systems are in several other member states installed in slightly different ways.

It showed that it might not be feasible to prescribe exactly how/by whom projects should be assessed, but demand member states to ensure certain prescribed assessments (e.g. ethical review, statistical evaluation, harm-benefit assessment) should be done before an animal can be used in a project.



Question: Should the authorisation system include “bulk authorisation”, e.g. in cases of test houses carrying out repeated regulatory testing?

Background: we assume that “bulk authorisation” means authorisation for establishments which conduct tests to fulfil regulatory requirements, allowing them to carry out certain specified procedures to fulfil those requirements. There was a difference of opinion within the TEWG as to whether this would be acceptable.

Answer: No consensus reached. The members agree that there is a difference between this type of research and fundamental research e.g.. Everybody agreed that a bulk authorisation if given should always be limited. This could be a time limit or a number and time limit. Everybody also agreed that new guidelines, new visions on best practice or alternative methods accepted before the expiry date of the bulk authorisation should always be incorporated. Thus preventing the elongated use of “obsolete” less animal friendly methods due to bulk authorisation.

The difference of opinion focused on the acceptability of bulk authorisation. Some feared bulk authorisation might promote less pensive use of animals. They prefer not to have the possibility of bulk authorisation.

Others felt bulk authorisation reduces bureaucracy, without impairment of animal welfare, taken the right precautions (time/number limit and always keep up with current knowledge/methods). They felt bulk authorisation could especially be possible for e.g. batch testing, regulatory testing esp. low harming repeated testing.

The Members agreed feed back should be given to the regulatory testing bodies concerning new visions on best practice and new/better methods which might influence animal welfare positively.

Arguments: Some members of the subgroup believed that bulk authorisation as defined above would be acceptable for establishments conducting tests to fulfil regulatory requirements as well as for pharmacological procedures (described procedures to be carried out for many different compounds), provided that it was understood that the duty to implement the Three Rs would apply just as strongly as elsewhere. This can be achieved by a discussion on local level.

Another argument brought up in favour of bulk authorisation is, that it allows an adequate oversight of procedures and assessment of harm-benefit.

Providing bulk authorisations include the algorithms and safeguards to ensure any testing undertaken meet the letter of the EU and domestic requirements this may turn out to be a very efficient and effective way to do this.

Others believed that bulk authorisation would not allow for adequate oversight of procedures, or encourage a properly considered harm-benefit assessment¹.



Question: Should experiments/procedures/projects required by legislation be approved in the same manner as those falling outside the regulatory framework?

Background: although the results of some tests are directly or indirectly required by law, there are still many opportunities to reduce animal numbers and to refine both techniques/procedures (including humane endpoints) and husbandry. There are also some opportunities to replace some animal tests with humane alternatives, although such opportunities are sadly limited at present. It is therefore important to ensure that regulatory procedures are authorised in the same way as others so that validated and accepted alternatives will be used wherever possible and animal numbers and suffering can be minimised.

Answer: No consensus. Yes-sayers (most Members): there is no justification for such projects/procedures to be approved differently, with the possible exception of bulk authorisation for repeated testing as above.

No-sayers: There is no consensus on the impact of the assessing. The problem with regulatory testing is that it is required in a prescribed way by other regulations. There is a contradiction in the requirement that something should be done because it is required by law, but, at the same time, this legal obligation could be revoked because of other legislation. This because whenever such a project is neither accepted nor authorised the result will be ceasing of the production of a given drug, foodstuff of other substance or product or withdrawal of the registration. The impact of such a decision is very serious and may result in a substantial loss of investment of time, energy, money and previously used animals. Of course such signals (if a required test is not really ethical acceptable) should be let known to the prescribing body, thus enabling them to reconsider a more acceptable test. Proposed is to register such projects and control whether they are performed according to the requirements.

Another in between solution might be that when testing is done by this prescribed way the authorisation assessment should only focus on if the techniques, husbandry etc. meet the standards. The prescribed test itself should not be assessed. Thus implementing 3 R's as far as possible within the boundaries of the required test. Some tests are less prescriptive than others. Several regulatory testing procedures are not completely standardised. That means there is some room for e.g. refinement of the used method. Also the use of humane endpoints can be promoted if the guideline accepts it.

If researchers choose to deviate from the prescribed method or guideline, they must stress out the reasons for doing so, profoundly.

If feed back to the regulatory bodies might be beneficiary to them it should be given.

¹ A report by the UK Animal Procedures Committee on primate use, with particular reference to regulatory toxicology, considers the granting of "generic" licences to be unsatisfactory for the same reasons. This has been uploaded to the TEWG's library.



- **Level of detail in the authorisation request**

Question: What elements should an authorisation request include?

Background: this is a vital question that is central to the successful implementation of the Directive. The authorisation request is more than just a passive form to be filled in. It should be viewed as a very important, working document that fulfils a number of functions for the benefit of both science and animal welfare. It will need to include adequate information to enable the competent authority (and local or national ethics committee, if applicable) to make its decision, and offer advice, with respect to the justification for the project and whether (and how) more could be done to implement the Three Rs. It will also need to inform inspectors when they visit establishments to advise on the progress of the project and monitor compliance; it will also help staff to monitor their own compliance with the conditions of the authorisation.

The authorisation request should also provide an essential focus for the researchers themselves, to help them to fully consider the lifetime experiences of the animals in their care and ensure that they have taken every possible step to reduce their use and suffering and improve their welfare. If properly set out, it can also be an invaluable tool for improving the quality of the science in each project. The elements suggested in the box below are taken from existing legislation currently in force in France, Germany, the Netherlands, Switzerland and the UK.

Answer: Each authorisation request should include adequate information, clearly and meaningfully set out, with respect to three key areas. These are:

1. background to, and context for, the project, including which procedures will be carried out, where, and the competence of the person(s) authorised to conduct them;
2. the potential harms and benefits;
3. the steps that have been taken to implement the Three Rs.

Additional questions put forward by the Commission:

1. Is the list of these 3 areas exhaustive?
The members of the subgroup felt most topics could be incorporated in one of the three above mentioned groups, so the list could be considered to be exhaustive.
2. Should an explanatory guideline be set to give examples of the type of elements?
It might be helpful, but it should not be mandatory because it might be too rigid and too prescribing, some rough guidelines e.g.
3. Should the applicant demonstrate who in the project has the species specific knowledge/training?
It is up to the authorisation body to decide if that information is necessary. A license holder should always ensure that somebody is available with knowledge of the kept species because a person might fall ill or change jobs. It is the job of the CA to supervise and inspect whether or not the license holder is abiding the law. It is also included in the proposal; Background

bullet point 4 is “the person(s) who will be conducting the procedures and their relevant qualifications and experience”.

The application could include the names and relevant curriculum vitae of the personnel conducting procedures. Names in the project license should not be made publicly available, but should be incorporated in the license to name the persons responsible. That way it is clear who is responsible for what.

Every change should be registered and mentioned to the relevant CA.

The necessary elements for each area in practice are set out below. Note that we are not suggesting that they should fall in this order or even that the form should be divided into three areas in this way – this is just a useful way of setting out the elements for consideration. It is partly up to the Member State as well

BACKGROUND

- an account of the proposed project including the scientific background and objectives, source of funding, outcome of any peer review and relevant references;
- a named person who is responsible for compliance with the conditions under which the licence was issued;
- the establishment or other authorised place(s) where the procedures will be conducted, with reference to the conditions of the accommodation the animals will be submitted to;
- the person(s) who will be conducting the techniques and their relevant qualifications and experience;
- a list of procedures, each of which should include:
 - › description of the techniques/procedures (and its severity, if applicable – this depends on the relevant TEWG);
 - › the species, stage of development, microbiological and genetic status and estimated number of animals to be used each year;
 - › the fate of the animals at the end of the project.

HARMS AND BENEFITS

- description of the potential adverse effects (harms) that may be associated with each element of the project and how they will be prevented or controlled. The experiences of each animal from birth to death should be considered here, *e.g.* source, transport, housing and care, and identification as well as the scientific procedures that will be conducted on each animal;
- potential benefits of the project.

IMPLEMENTATION OF THE THREE RS

- explanation of why it is believed to be necessary to use living animals, including an account of attempts to replace animals with *in vitro* and *ex vivo* techniques and the reasons why this was not possible;
- evidence that proper consultation has taken place with respect to experimental design including statistics (see 2.2.6 below);
- justification for particular uses that raise special ethical or welfare issues, *e.g.* use of wild-caught animals, species of particular concern, techniques of particular concern, re-use *etc.*;
- details of how each of the harms listed in the application will be minimised, including harms caused by housing, transport, identification *etc.* as well as by procedures;

- **confirmation that the authorisation application has undergone ethical review by the local ethics committee.**

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Question: Should the result of an ethical evaluation be part of the request?

Background: this relates to the findings of the TEWG addressing ethical review. The answer below assumes that (1) “ethical evaluation” here refers to an assessment by a local ethics committee with respect to its justification and the implementation of the Three Rs, and (2) that the relevant TEWG will decide that ethical evaluation at a local level, by a local ethics committee, is desirable as an adjunct to the decision-making process set up by the national competent authority. If so, the results of any assessment made by the local ethics committee should form part of the request.

Answer: **If it is decided that a (local) ethics committee should evaluate each proposed project, then it should be confirmed within the authorisation request that this has been successfully carried out. That is to say, without the green light of the ethical review committee no authorisation will be granted. In some countries the green light of the registered ethical review committee is at the same time the authorisation of the project.**

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Question: Should a cost-benefit analysis form part of the request?

Background: suggest that the word “harm” is used instead of “cost”, to avoid confusion with financial costs. The cost-benefit sub-group report has more suggestions on proposed terms to describe this type of assessment or analysis. In this paper the word “harm” will be used. It is essential that the potential harms to the animals and the possible benefits of the project are very clearly stated. Note that harm versus benefit assessments (by the licensing authority) are currently part of the decision-making process in Germany, the Netherlands, Switzerland, Sweden and the UK.

Answer: **The authorisation request should include a harm-benefit analysis set out by the applicant, explaining why s/he believes the project to be justified. This should comprise adequate information set out in a meaningful manner that will enable the competent authority to perform its own harm-benefit analysis and make a judgement as to whether the project should be permitted. The Members thought without a positive result of the harm-benefit analysis a project should not be given its authorisation.**

See for more details on the harm benefit analysis the report produced by the Cost-Benefit TEWG-Sub-Group.

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Question: Should the level of detail be less stringent for *e.g.* regulatory testing?

Background: regulatory bodies set out minimum numbers of animals within test protocols, and some establishments exceed these numbers. The justification for this needs to be assessed in each case. New ways of refining procedures and husbandry are continually being developed and adopted within regulatory testing as in other research areas and there are also developing opportunities to replace animal tests, as mentioned above.

The issue of the utility and benefit of different products was also raised during the TEWG's discussion. In particular, some product types are viewed as more "necessary" than others by the public, yet the harm-benefit assessment (in the UK at least) considers the benefit of evaluating the safety of products rather than the real benefits of the products themselves. Despite this, some testing houses in the UK have made a decision not to test certain classes of product, *e.g.* "household products", on animals. Carrying out ethical evaluations and harm-benefit analyses for regulatory tests as for other types of study would encourage and help establishments to make these kinds of decisions.

Answer: No, the same level of detail as other types of procedures is necessary to ensure that animals are replaced, their numbers and suffering are reduced, and their welfare is improved at every opportunity.

Some are in favour of "YES": If regulatory testing would not need authorisation but registration, the used method, provided it is well described within the regulation, is clear and it won't be necessary to give every detail in that registration.

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- **Changes in the experiment or project**

Question: How should changes in the experiment or project be handled by the authority especially concerning the number or species of animals, level of severity or duration of the experiment/project?

Background: the answer to this question will need the output of the TEWG addressing ethical review. It assumes that a local ethics committee will be mandatory and also makes assumptions about its authority and remit. If there is no local committee, then changes will have to be referred to the licensing authority.

Answer: Some changes don't have any influence on the animals and their welfare: e.g. other personnel. Other changes change the project in essence. E.g. by using other species, performing other or extra research activities on the animals. Some of those changes are minor other major. It is impossible to make an exhaustive list of minor or major changes. Minor changes might be dealt with by a lower body than major changes. It is depending on the system in place which committee should deal with a change. If the new Directive will prescribe in detail how the system should be organised (more or less like a Regulation), then there should be a list with minor and major changes and who should handle them. If the Directive describes the aims and not how to reach them, then Member States should ensure minor and major changes should be addressed in a correct way within their authorisation system.

Arguments: A local ethics committee could approve minor changes on a “fast track” basis and refer major changes to the national competent authority. The Directive could include some guidance on defining major and minor changes, for example changes in species or severity bands will always be major and require central authorisation. Small changes in protocols (which need to be defined) will be minor. It may be acceptable to exceed the estimated number of animals for a particular procedure by up to 10%, but any increase greater than this should be reported to the competent authority prior to its occurrence and should require authorisation.

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Question: How should the authorities control whether the actual experiment or project compares with the authorised one?

Background: making this comparison is an essential safeguard to make sure that national legislation is working effectively to regulate animal procedures and ensure that everyone involved in animal use is competent, has an appropriate attitude to animals and understands why it is important to comply with the law. The answer below depends on the outcome of other deliberations by this TEWG and others.

Answer: There are several components to achieving this. Regular and adequate inspection by the competent authority (2.2.3, 2.2.7) is clearly necessary. At a local level, a system needs to be set up where there are clearly defined duties and roles and adequate training for people holding authority under the Directive (2.2.4) and regular review by the local ethics committee (TEWG on ethical review). The ethical committee should get feed back on projects authorised by them. That might be beneficiary for their knowledge for assessing future projects.

E.g. a person like the AWO, NVS (UK system) or the Lab animal expert in the Dutch system within the institute could play a role by reviewing regularly if all projects within the establishment are performed conform the authorised projects.

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2.2.2 Authorisation of breeding, supplying and user establishments

General background:

Article 15 currently states:

Breeding and supplying establishments shall be approved by or registered with, the authority and comply with the requirements of Articles 5 and 14 unless an exemption is granted under Article 19 (4) or Article 21. A supplying establishment shall obtain animals only from a breeding or other supplying establishment unless the animal has been lawfully imported and is not a feral or stray animal. General or special exemption from this last provision may be granted to a supplying establishment under arrangements determined by the authority.

• Authorisation request and period of validity of the authorisation

Question: What elements should an authorisation request include?

Background: We assumed the Commission was thinking of a kind of form that should be filled in by the applicant prior to receiving a license/permit. The National Competent Authority decides whether or not it will grant the applied license. There might be other country related relevant elements. But the subgroup aimed at general points that are probably relevant in every country.

Answer:

- The form used to request authorisation for breeding and supplying establishments should be the same as (or as close as possible to) the form used for authorisation of User establishments.
- The TEWG suggest the use of ‘check boxes’ where possible
- Applicants should state the range of species to be bred.
- Applicants should state that they have appointed the following ‘officers’
 - Authorisation holder; this should be a person of authority – such as a senior director or manager or the director of an institute.
 - Veterinary advisor; A veterinary surgeon or other qualified person to provide advice on the health and welfare of the animals in the facility kept for experimental or other scientific purposes.
 - A named person responsible for the day to day care of the animals in the facility kept for experimental or other scientific purposes.
 - An ethical review body (if procedures will be performed in the establishment e.g. some breeder/supplying establishments might not need one)
- Establishments will provide their national authority with the details of the locations of all premises holding breeding animals or animals intended for use for experimental or other scientific procedures.
- Establishments will state that their premises and practices comply with the Directive and its Annexes. Do we know whether the Annex will be the same as the revised Appendix A to Convention ETS123 (when this is completed)?
- Establishments will state that they operate the principles of the 3R’s

- Certain techniques will not require authorisation **if they are part of the general husbandry or breeding process and are not part of an experiment /procedure /project**, in general these will be techniques performed for normal husbandry purpose and e.g. in farm animals would be part of the normal farming techniques. In general these techniques should at that point of time not be part of a project. They are part of the normal day to day care for kept animals and are performed to cure sick animals, keep healthy animals healthy and are part of normal breeding circumstances (i.e. not e.g. genetic modifications) such techniques are:
 - a. Culling by a method (approved by the CA) performed by or under supervision of a veterinarian (e.g. sick or surplus animals, not as part of a research project).
 - b. Assessment of stage of oestrous
 - c. Hormonal injection e.g. to stimulate ovulation (only if it is done by or under supervision of a veterinarian on indications other than research)
 - d. Veterinary techniques

NB some are in favour of making a and c always part of an authorisation procedure, this might, however, be a problem, especially in case of breeding / emergency culling. A solution might be: the license holder must clarify how non-research culling will be performed, to ensure experienced personnel will cull the animals. Hormonal injection could be seen as part of veterinary techniques.
- The Members of the Scope Sub-Group discussed whether or not animals solely used for tissue harvesting and surplus animals should be within the scope of the Directive. They felt the establishment should provide information to the competent authority how they were dealing with these animals. Because the animals not being in procedures shouldn't exclude them from normal animals welfare policies. The Scope Sub-Group thought it primarily an animal welfare concern that should be addressed in the authorisation procedures of the establishment. The establishment should provide the same minimum husbandry and veterinary care to all animals independent of their status or future in procedures.
- If an authorisation was denied it should always be possible to appeal. An appeal procedure should be available.

Arguments:

Several arguments were introduced in the previous paragraph.



Additional discussion requested by the Commission: Should the application demonstrate who in the establishment has the species-specific knowledge/training?

Answer: As it depends on the system in place whether or not an authorisation will be granted indefinitely or for a (shorter) fixed time period. The Competent Authority should check the qualifications of the personnel. So it is not necessary

to have those names in the license itself, for it is subject to changes, more than e.g. the address of the establishment. But it might be helpful to have the names in the application. Every change should be registered and mentioned to the CA. The CA should be able to verify the facts and when appropriate check if personal facts are correct.

Arguments: An application should only contain information that is useful in the longer term. Of course if the CA would like to see the names on the application form after all (depending on the system in place) they can do so. A license holder should be able to present a list with that information on request of the CA without any difficulties. So the information should be easy available it might not have many advantages in putting this information in the application.

Others are in favour of putting this information in the request. They propose to name the authorisation holder, veterinary advisor, animal welfare officer(s) including details on their relevant qualifications and experience.

Examples: In UK: applicant states: names of the authorisation holder, veterinary advisor, AWO's, the departments of the establishment for which the veterinarian and AWO will be responsible. In NL: An application form asks for all these items as well but they will not be incorporated in the license. So they are known to the inspectorate but not publicly available. All Dutch licences will be gazetted after designation, names are protected and cannot be gazetted.

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Question: What would be the appropriate period of validity for an authorisation of a breeding, supplying or user establishment?

Background: -

Answer: The authorisation should in principle be valid indefinitely – but subject to review after inspection by the competent authority.

Arguments:

The Competent Authority is responsible for reinforcement. If it is considered helpful by the NCA to have a system with limited validity or renewable authorisation, they might decide to implement such a system. The Members felt it creates extra paperwork without creating extra animal welfare. If the CA inspects an establishment regularly and comes to the conclusion that the establishment is not up to scraps the authorisation can be revoked.

So it seems more important to have the possibilities to revoke an authorisation than to work with renewable authorisation or an “expiry date”. But there is nothing against it if an NCA wishes to work with such a system.

Some SG-members were in favour of an expiry date. They feel that co-provides the need for adequate inspection to ensure full compliance with the directive.

Others are in favour of an indefinite authorisation, to prevent extra paperwork.

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- **Record keeping**

Question:

- What is an optimum period for keeping records?
- Does the current requirement of 3 years pose welfare problems?

Background:

The current wording in the directive on record keeping is:

Article 17.

- 1. Breeding and supplying establishments shall record the number and the species of animals sold or supplied, the dates on which they are sold or supplied, the name and address of the recipient and the number and species of animals dying while in the breeding or supplying establishment in question.*
- 2. Each authority shall prescribe the records which are to be kept and made available to it by the person responsible for the establishments mentioned in paragraph 1; such records shall be kept for a minimum of three years from the date of the last entry and shall undergo periodic inspection by officers of the authority.*

Answer: No change to the existing wording of Article 17 is proposed by several members of the subgroup. Others want to specify more details, so it should not be left to the NCA. They have the opinion that the Directive should reflect the need for all establishment to keep meaningful records and the need for types of records other than basic records of animals sold, supplied or dying. They suggest the Directive could specify, that: 1) where appropriate - depending on species - individual health records, (kept for the animal's lifetime); 2) each time when animals are moved, their individual records or copies of them are routinely passed on and maintained. Some of the suggestions for what records should be kept, are mentioned in the argument section.

Arguments: No welfare problems due to three-year record keeping were detected.

The current wording accomplishes records to be kept 3 years after the last entry (i.e. 3 years after completion of the project a/o 3 years after the death of the animal as it seems logical that both events might lead to an entry in the records).

It is up to NCA to decide which records and which details they want to be kept. Although there was not really a difference of opinion which records should be kept, there was a difference of opinion in whether or not it should be specifically stated in the directive or if the current wording was sufficient. The following suggestions were made, though everybody thought this should not be incorporated into such detail in the Directive, but it might be helpful for the NCA:

- Keep meaningful records appropriate to the species. (no veterinary or medical records for rats and mice e.g.)
- Issue the user with the historical details of any medication or treatment of the animals bred or supplied for experiments.
- Retain records of unexpected mortality for review by the NCA. Such records should be appropriate to the species and permit the development of welfare strategies to reduce such mortality.
- Environmental records (room temperature, relative humidity etc) where appropriate, do not require a 3 year keeping period perhaps 1 year might be a reasonable time. Appropriate in the sense of: where the Annexes indicate a

need to keep close control over environmental conditions for some species, the establishments should retain the records of the measurements of these environmental parameters for a period of at least 1 year.

- After revocation of authorisation; The NCA should be encouraged to obtain and retain such records for a period they regard as appropriate

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2.2.3 *Inspections and revoking of authorisation*

- **Inspections**

Question:

- How frequently should breeding, supplying and user establishments be inspected by the authority?
- Should unannounced inspections be carried out?
- If so, how often?

Background: After authorisation of an establishment the CA should ensure the establishment act according to (inter)national legislation, thus keeping it's authorisation rightfully. NCA may have different ways to ensure this, but on site inspection should always be part of it. The subgroup decided the number of yearly extensive and unannounced visits. During such visits the establishment will be checked elaborately. A kind of an overhaul, speaking in terms of car maintenance. If short visits to check on particular details or to address specific subjects, should not be counted (small service).

During an unannounced visit it might be difficult to give complete information. The person responsible might not be available. The subgroup appreciated that problem. The formulated answer describes a visiting regime the subgroup felt a NCA might use to ensure enforcement of the directive. Several suggestions might be stating the obvious.

Answer:

- The subgroup felt that the national authority will visit to verify, at least twice per annum, that Breeding, Supplying and User establishments comply with the recommendations of the general provisions and the species specific provisions of this Directive and its annexes. One of these visits will be unannounced.
- A more intensive pattern of visits will be carried out should there be suspected or actual infractions of this Directive or its Annex.
- At large establishments, more frequent/longer duration visits will be carried out to ensure that the national performance standards are achieved and maintained in all areas holding laboratory animals.
- Also was suggested that NCA could be encouraged to recognise private independent accreditations (e.g. AAALAC). Although standard can vary considerably, it might be helpful.

Arguments:

The number of suggested visits is the absolute bare minimum adequate to ensure that establishments are complying with legislation and have an appropriate culture. (e.g. in the UK each establishment was visited an average of 13 times in 2002). The focus of the NCA should be to ensure license holders abide by the law, on site visits should be part of that.

Member States might be required to set up procedures to demonstrate and monitor that their national performance standards are adopted and maintained in all User and breeding/supplying establishments.

The commission wonders if a national inspectorate should be required to carry out inspections, because the subgroup refers to “national inspectorate” and “inspectors” at several points. The thought starter contains detailed questions. All subgroup members originate from countries with some kind of inspectorate responsible for reinforcing lab animal welfare legislation. This might lead to some bias in the answers.

It is up to the NCA of the member states to choose the system they want to put in place in order to ensure those involved in animal experiments don’t ride roughshod over the law. The kind of (inspection) apparatus that will be used to enforce this directive, may differ between countries but the aim should be the same. The NCA is responsible for the enforcement. But the way it’s done should be imbedded in the National enforcement systems.

As a guidance the subgroup suggests some duties of an inspectorate of the NCA:

1. To advise the national authority on applications for authorisations under this Directive or for their revocation, variation or renewal.
2. To visit places where the regulated procedures under this Directive are carried out, for the purpose of determining whether those procedures are being carried out in accordance with the authorisations.
3. To visit authorised places to ensure that the conditions detailed in the Annexes of this Directive are being met.
4. To assist the investigator to understand their project authorisation conditions
5. Some members of the subgroup feel strongly for an advisory role of the inspectorate. Others have very mixed feelings on an official advisory role. Not due to a lack of knowledge of the inspectors but advice from a supervising body cannot really be considered as advice but will end up as an order. E.g. if a license holder decides not to act on the advice of an inspector and the advice is not based on legislation but noncommittal, one might end up with no authorisation if the inspector is not amused because the license holder did not follow his “noncommittal” advice. These Members advocate there are plenty very capable advisers from several NGO’s available for giving advice. However, member from NGOs do not believe that there are sufficient NGO advisors to fulfil this role or that there is an effective structure in place to ensure that their advice can always be given where it is needed.

In the end the Members agreed “advisory role” might be wrong wording. But the knowledge of inspectors due to their visits to a large number of premises was largely admitted as being very useful. NGO-advisors don’t come in all places. Perhaps especially not in the places that could benefit the most from knowledge of other establishments. Inspectors could prevent every establishment having to re-invent the wheel. The Members thought that inspectors should share information, promote best practice, encourage beneficiary changes, and share practical experiences. See also section 2.2.7 on this subject.

6. The role of the inspectorate in the ethics committee was also discussed. It was suggested by some the inspectorate could liase with the ethics committee (local or central depending on the system in place). Others were not in favour of this role. This because they strongly believe a committee must be autonomous. If a local inspector has the power to influence the committee, (the committee will always comply with the inspectors wishes for fear of antagonising him/her) this might lead to reprisals in other ways.



- **Revoking of the authorisation for an establishment**

Question:

- What circumstances could result in revoking the authorisation?
- Who should decide on revoking an authorisation?
- Should there be a time limit in which the dispute has to be resolved?

Background: It might be helpful to have some guidelines on when and how to revoke an authorisation. It is up to the NCA how it should be organised in detail, perhaps the thoughts of the subgroup members on this subject might be helpful for the MS.

Answers:

1. The national authority will issue time limited warnings if the conditions of this Directive are not met. Upon receipt of such a warning, the holder of the authorisation will be given a reasonable time to implement a plan of remediation (approved by the national authority) which is designed to bring the practices of the holder of the authorisation into compliance with the Directive and its annexes.
2. Revocations may be at the level of:
 - a. The person authorised to carry out experimental or scientific procedures.
 - b. The authorisation of the entire project or series of linked experimental or scientific procedures. As this paragraph refers to the authorisation of the establishment. An establishment authorisation would not necessarily be revoked because of infringements in a. and b. it should depend on the responsibility of the establishments in the occurrence of these infringements.
 - c. The authorisation of the 'User' or breeding/supplying establishment.
3. Revocation may be at the request of the holder of the authorisation
4. Authorisations will be reviewed by the national authority at least every three/five years. At such reviews, the national authority will consider whether any variation of the authorisation is necessary. Some people felt 3 years might be the appropriate time others thought 5 years might be better. It is a gut feeling reaction and it also depends on the frequency of visits that inspectors perform on the premises. The NCA should be able to decide which frequency fits best for the establishments and the inspection-system in use in their country.
5. If it appears to the national authority to be urgently necessary for the protection of the welfare of the animals used in the authorised experimental or other scientific procedures, then an authorisation may be suspended e.g. for a period of up to three months. During this period, an investigation will be carried out by the national authority to determine whether there is any need for the authorisation to be revoked or varied.
6. An establishment should have the possibility to appeal.
7. Always should be prevented animals will be suffering (additionally) due to the suspension or revocation of an authorisation. E.g. suspending a project may lead to the necessity to repeat the project or use additional animals. That

should be prevented if possible. Also revocation of an authorisation of an establishment may lead to euthanasia of the animals. That should also be prevented, if the reason to do it is not to prevent (further) impairment of welfare of these particular animals. Clear decision should be made on the future of the animals in the establishment. Should they be killed? By whom? Should they be kept alive? Who pays for their food and care? Who will look after them?

8. It should be decided whether the authorisation of the whole establishment should be revoked or that only part of the establishment will be affected by the revocation. Thus also limiting the animal welfare problems.
9. The type of action to be taken should be down to the NCA and depend on the type of infringement.

Arguments: Several arguments were mentioned in the “answer”-paragraph.

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2.2.4 Authorisation of personnel and requirements for education and training of personnel.

- **Authorisation of personnel**

Questions:

- Should all personnel who deal with animals be authorised?
- For how long should the authorisation be valid?

Background: There are a lot of people involved with lab animals at various levels. The decision whether or not authorisation is required co-depends on their function, tasks, remit and kind of procedures they are involved in. In the answer to this question this was made explicit. Of course there might be different systems in different countries working satisfactorily. The aim should be that there is a system in place that ensures people performing only procedures they are able to perform to minimise the level of distress and breaches of animal welfare. The answers of the TEWG subgroup to both of the above mentioned questions will be answered per level in the following paragraph.

During the discussions in the TEWG it became very clear that there are a lot of differences between the countries that were represented. Probably that means that the current practice differs among all member states and pre-accessing countries. This does not mean that one system in place is per definition better than another, but some consideration must be given to level of detail to be used in the descriptions in the new regulation.

It is very important not to focus on the exact names we are using in this description, but to concentrate on the different roles/duties that should be fulfilled in establishments. In order to simplify the discussions it was easier to use names, rather than use complete descriptions every time. Currently there are several systems in place in different EU countries. Throughout the EU some names are used in different countries for different roles. This causes some additional confusion, unfortunately. The reader is advised to consider throughout this document the names of the various levels of personnel within the definitions and descriptions that are given in this document. The Commission is advised to describe various roles in the new Directive but refrain from giving names to these functions.

Combining levels could e.g. the case in some countries (see several comments throughout this part of the report).

On sundry occasions FELASA recommendations and systems are mentioned. The Members are not sure how and if this could be incorporated within the new Directive.

Answer: The various levels of personnel having contact with an animal on experiment/procedure require definition and might include:

- 1. Animal Care Staff/Husbandry technician whose role is to satisfy the animal's husbandry and basic care needs.**

This individual is described in the FELASA recommendations on the education of training persons working with laboratory animals (uploaded to TEWG library) as Category A – persons taking care of animals. They will not be expected to perform invasive procedures/experiments on animals but to report any clinical signs/abnormalities to the appropriate person. However, their duties may include euthanasia, which has the potential to cause suffering if it is not carried out competently and sympathetically. Certain simple procedures could also be delegated, under indirect supervision, to the Category A person e.g. the provision of diets containing test compounds.

It is expected that this category of personnel will be required to attain a level of competence/knowledge to allow them to work with laboratory animals but that there should be no formal system of authorisation. The only exception to this should be personnel who will be euthanasing animals, for which authorisation should be required. The TEWG will need to discuss whether this ought to be at a local or a national level.

2. Personnel responsible for performing procedures/experiments (FELASA category B).

This individual will be performing procedures/techniques of varied complexity, both surgical and non-surgical. There appears to be differing levels of authority within the Member States but the whole group agreed that there should be a requirement for the individual to be authorised/licensed before he/she is allowed to perform procedures/techniques on living animals. This would enable the authority to decide minimum standards of competency/training and would provide consistency amongst the Member States.

This category of personnel does need to be authorised and the authority should be granted for life but be reviewed on a regular basis – every 5 years – and include some form of refresher training?

3. Personnel responsible for directing the project (FELASA category C).

Following appropriate training the person should be authorised, see comments made under 2.2.1 and authority should be valid for the duration of the project, (Note: in the UK this is for a maximum of 5 years at which time should the work need to continue a new licence must be negotiated with the authority) .

Several members of the group feel the cat C authorisation may as well be granted for life with perhaps a review or compulsory continuous training program. This is the current practice in several countries.

4. Veterinary surgeon.

Each establishment should have an authorised veterinary surgeon who may be a permanent member of staff or contracted in for advice, routine visits and emergencies. Some argue to consider demanding an ECLAM as a veterinary surgeon. (note: This might be a problem because only veterinary surgeons can be diplomated, some countries have also several medical doctors and biologists with a special curriculum

who had a post academic training in lab animals working as lab animal experts in establishments)

5. Animal welfare officer

Each establishment should have at least one authorised in-house animal welfare officer responsible for the day to day care of the animals. (see 2.2.5)

To illustrate the difference between the AWO and the NVS in the UK, the SG-members felt it might be helpful to set out their roles, as defined by the Royal College for Veterinary Surgeons and the Institute for Animal Technology respectively (paraphrased):

NVS	NACWO
Maintain overall responsibility for the veterinary care of the protected animals at the designated establishment	Be aware of required standards of care, accommodation, husbandry and welfare and ensure that they are met
Provide advice on animal health and welfare to all including scientists and technicians	Be knowledgeable about permitted methods of euthanasia; either be competent in them or able to contact others who are
Notify experimenters of animals whose condition gives cause for concern and arrange for humane killing if necessary	Ensure that every animal is seen and checked at least once daily by a competent person
Determine whether animals remain alive at the end of procedures	Know how to contact, at any time, persons such as the veterinarian, experimenters, persons competent to euthanase animals etc.
Certify fitness of animals to leave the establishment if permitted	Assist in ensuring that suitable records are maintained
Participate in the ethical review process	Take an active part in the ethical review process
Ensure that appropriate records are maintained	Know which areas of the establishment are listed in the establishment authorisation certificate and the purposes for which their use is approved

Although it was generally agreed defining the roles is more important than stipulating who performs them, most were also in favour of dividing the roles between two people. Two people bring two different perspectives- a NACWO will have years of hands-on experience in caring for animals and managing the animal house that an NVS will not. People with two different working roles, training and working history could complement one another and are less likely to miss issues that could have a direct bearing on animal welfare. Also, you can have one NVS (who may not even be there full time), but as many NACWOs as you need.

The Members agreed that during working hours and where animals are present, all of the time an officer should be available to be responsible for animal welfare and care, like e.g. the person fulfilling the NACWO-role. In some exceptional cases even that

might not be necessary. E.g. telemetric research with wild caught and immediately released animals to monitor and observe their behaviour.

It is not always necessary to have a veterinary as the overall supervisor (the NVS). It might in some cases be better to have someone with other expertise. A marine biologist in a fish research establishment could fulfil the NVS role probably better. (In that case veterinary techniques should of course not be performed by the biologist). Generally was agreed NVS should have at least additional training in the species they were working with. Also should they have had additional training in performing biomedical research in general.



Question: What circumstances should result in revoking the authorisation?

Background: In some cases it may be necessary to revoke an authorisation. The subgroup decided it is not possible to be exhaustive in examples. Thus it was decided to formulate a kind of general guideline.

Answer: In the absence of a Central EU Inspectorate (see 2.2.7) revocation of authority to perform a procedure or to direct a project involving the performance of procedures on protected animals must be the responsibility of the national inspectorate. This would normally result from the infliction of unauthorised levels of pain, suffering, distress or lasting harm to animals or failure or continued failure to observe any terms or conditions laid down in the project or individual's authorisation. It would be expected other sanctions, falling short of revocation, could be exacted on an individual responsible for a more trivial infringement. These could include a warning letter from the authorising body as to the individual's future conduct, mandatory re-training, calls for direct supervision etc.

Argument: It is important to balance the penalty (revocation, warning, formal warning etc) and the infringement. In all cases the welfare of the animals should not be (further) compromised.



- **Categories**

Question: What type of personnel should be used?

Background: A lot of information on this question can be found in the answer to the first questions in 2.2.4.

Answer: There should be minimal standard levels of training for all staff involved in the care, welfare and use of laboratory animals and training courses established to train the various categories of personnel. FELASA have produced recommendations on education requirements and these should be adopted as a guide to the skills and knowledge required. Each Member State should produce a list of qualifications that

are deemed to meet or exempt an individual from the formal training courses. Adequate, but not excessive time should be allowed to reach these levels and during this time individuals should be closely, but not necessarily directly, supervised by a named individual who has a responsibility for their conduct and training.

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Questions:

- Should there be a formal categorisation of staff?
- If so, what would be the optimum categorisation of personnel?

Answer: The FELASA recommendations are based on functions rather than the nomenclature, which can, and may, vary between Member States but will be in line with those mentioned earlier.

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• **Education & Training Categories**

Question: What would be the minimum educational background (per category)?

Background: There was some obscurity on what is meant by some of the terminology and the following is what the subgroup has taken to be intended:

Educational background; formal education – academic achievements, school, college.

Training – successful attendance on a work-related course e.g. FELASA education and training; or, instruction in a particular technique

Work experience – competence gained whilst completing a task over time and under supervision.

Answer:

Animal Care Staff. There was some uncertainty within the group as to what was meant in Article 14 to the Directive where it referred to “Persons who carry out experiments or take part in them” It was assumed this meant assistants performing subaltern duties such as restraint of the animal, maintenance of equipment, but could include the provision of husbandry. A basic level of literacy and a general science education is required but more emphasis should be placed on an individual’s attitude to his/her development and the concept of lifelong learning rather than on formal qualifications. Training towards the appropriate level of Category A (FELASA) should be mandatory. As mentioned previously close and structured supervision is necessary during a probationary period to ensure the individual’s development.

Those responsible for performing procedures on animals. To some extent the level of academic education required for this role may be similar to that of animal care staff. There are many experimental techniques performed on animals that can be performed competently by people with basic academic qualifications. The level of qualification required will depend on the complexity or type of procedure for which authority is sought and this should be at the discretion of the national inspectorate. All personnel must have successfully completed a nationally recognised training course prior to being granted authority to perform experimental techniques on animals.

Personnel directing the project.² Projects may vary considerably in both their size and the complexity of the under-pinning science. Whilst research projects would require the minimum of a degree in the appropriate discipline it is conceivable that projects in the former category could be managed successfully by someone not meeting this academic standard. It is, therefore, difficult to specify the minimal level of academic attainment required to manage successfully the programme of work and this should be left to the discretion of the national inspectorate and operated on a project by project basis. All personnel must have successfully completed a nationally recognised training course prior to being granted authority to manage a project involving the use of experimental procedures on animals.

Veterinary surgeon

In addition to a formal veterinary qualification the veterinary surgeon at an establishment should be in possession of a nationally recognised qualification in the health and welfare of laboratory animals. In some cases it might be more appropriate to have e.g. a marine biologist as a NVS in a complete marine research establishment. These exceptions should be looked at, at an individual basis by the NCA. For some specialist establishments the common courses in lab animals welfare might not be appropriate. People working with only exotics need different knowledge than people working with rodents only.



- **Expiry date of authorisation**

Additional question:

- What is the argumentation for an indefinite authorisation for cat B but a cat C only authorised per project (e.g. current practice in some MSs)?

² FELASA guidelines outline a comprehensive curriculum for the various categories of persons working with laboratory animals. At some levels, and in particular “Persons responsible for directing animal experiments” it can be argued that the time recommended to complete the syllabus (80Hrs) is rather excessive and that some of the topics to be covered are unnecessary this was felt by some Members. In DK this course consists of a 150 Hrs course, in NL it is a 120 Hrs course. Both were not considered as excessive within the respective countries. It should be noted, however, the latter are recommended topics and there ought to be guidance, at a National level, as to what should be included.

Answer: Some spoke out in favour of a granted for life authorisation for cat C as well. E.g. with compulsory continuous learning programs of a 5-yearly review.

Cat C licenses persons responsible for directing animal experiments, i.e. directing a particular project, which will have a defined time span. Cat B licenses persons carrying out experiments, who may be operating under more than one authorised project. Whatever the period of authorisation for Cat B, there should still be adequate requirements for appropriately regular checks on competency and continuous learning.



Expiry date of authorisation

Additional question:

- As a general rule, could an authorisation be always limited in time but renewable?
- Requirement for a refresher training could it be linked with continuous learning?
- Please provide further argumentation

Answer: One aim is to prevent personnel developing wrong routines in the course of years. Another aim is to give personnel access to new information and methods developed after their graduation. Also personnel re-entering a job with experimental animals after working in another field for a long time should refresh their knowledge. Compulsory renewing of an authorisation too frequently, produces a lot of red tape but does not ensure the above.

Continuous Learning (CL) is important in any field of endeavour and its importance with respect to both the science and animal welfare needs to be recognised and more widely accepted. Professionals working in science also the ones working with (lab) animals should keep up to date with their scientific field. Keeping up to date with ethical and welfare issues should not be different, particularly since good science depends on good welfare, and the continued funding of science depends in part on public support.

The Members agreed a personal license could have indefinite validity. The license could be revoked or a person could get an official warning if s/he doesn't follow a CL programme or breaches the law.



Criteria for curriculum

Additional question: What should be the minimum criteria for the curriculum?

Background: the commission requests to give some consideration to formulate minimum criteria, including such elements as:

- practical implementation of 3Rs
- humane endpoints
- species specific training (e.g. non-human primates)

Answer: There are many differences between the school systems in different countries. This directive cannot change this. So it might be helpful to follow FELASA but leave it to the NCA to decide if the actual education is sufficient and is in accordance with the FELASA guidelines.

E.g. in the Netherlands a school has to have its curriculum evaluated by a commission of experts in education, lab animals, 3Rs, and the inspectorate. If the evaluation is positive the graduates have a degree that allows them to work as a licensed animal technician with lab animals. In order to obtain a license as a researcher one has to have a biomedical academic degree combined with additional education + diploma (120 hours).

A few general criteria might be formulated but it should not be very rigid or detailed to allow changes when necessary. FELASA might play a role to harmonise.

The Members proposed also to include different methods of euthanasia, their advantages, their disadvantages and how to conduct them as humanely as possible.

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Formalising continuous learning

Additional question:

- could this be linked to the authorisation of an establishment to demonstrate a CL program covering care, performing and directing staff?
- And/or could this be linked to the review of the authorisation of personnel to demonstrate training undergone prior to previous review?

Answer:

Both are responsible for a good CL programme: the establishment and the person with a personal license. The license holder of the establishment is responsible for giving personnel the opportunity to attend and/or facilitate the desired CL programme. And the person in question is responsible to attend the course. If a person did not attend a course and it is not his/her own fault but s/he is not given the opportunity by his/her employer s/he should not lose his/her personal license. In that case the license holder of the establishment should be warned. If a person categorically refuses or avoids attending the required CL programme s/he should lose (in the end) his/her personal license.

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Probation period

Additional question:

- Probationary period for personnel please propose a probationary period for cat A?
- Should it be required also for the personnel performing procedures? If yes, for how long?

- What are the benefits/disadvantages

Answer:

The Members agreed on not advising a fixed period. It might depend on the person, the activities in the establishment etc. The Members also felt this might be too detailed information for the Directive. FELASA is doing a lot of work on this area should we not kind of follow them?

A probationary period might be helpful but it should not be formalised in a fixed time. Every new procedure/technique for a person should be conducted with the assistance/under the supervision of a person experienced in and licensed to perform that technique.

If a fixed probationary period would be used, and very few procedures would be performed during that period than someone might end up doing difficult techniques for the first time on his own. That would not be advisable. The supervisor should have a voice if not a vote in assessing whether or not someone is ready to perform on his/her own.

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2.2.5 *Animal welfare officer in user establishments*

- **Tasks, remit and independence**

Question: Should each user establishment have an animal welfare officer?

Background: Animal welfare officers are in several countries already common practice. It seems logic to make use of the experiences with AWO in those countries. Some countries are not familiar with animal welfare officer as such. In this document the presumption was made AWOs are animal technicians by training with special additional training on animal welfare and special tasks and remits compared to “common” animal technician. An AWO is a kind of super animal technician. For countries currently not working with AWOs their introduction might need some adaptation time.

There was some concern within the Sub-Group the system currently in practice in the UK might be used as a foundation. This might have great bearings on the systems currently in practice in other countries. Especially in countries where AWO is a vet supervising the animal welfare in the whole establishment. Again this is a discussion on describing roles and responsibilities rather than names of functions.

Answer: The experience of those countries having a person(s) in this position would suggest this a vital and important role. Having an animal welfare officer should thus be compulsory. Some countries have a different system and don't have AWOs as in the UK.

Arguments: As was already stated in the answer. There is practical experience with AWO and it is positive.

There are also members in the group who have the opinion that the current directive, especially the arrangements as stated in article 5, 14, 16, 19, are not to be changed. These articles ensure animal welfare and state clearly which responsibilities should be addressed. Of course Member States should implement the directive accordingly thus ensuring minimum standards. These articles already point out there are several responsibilities. These responsibilities can be divided over several persons. It is up to member states who they appoint as the responsible person(s) for the items of the articles 5, 14, 16, 19.



Question: Should each user establishment have an animal welfare officer be compulsory or voluntary?

Background: see previous question.

Answer: Some kind of animal welfare officer should be compulsory. See also the next question. It seems that throughout member states there are differences between the function and role of AWO.

Arguments: As was already stated in the previous question, there is practical experience with AWO and it is positive. An AWO is very beneficiary and should be compulsory.

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Question: What should be his/her remit and tasks?

Background: The level at which this role is pitched appears to vary between countries. In the UK the majority of AWOs (or Named Animal Care & Welfare Officers – NACWO - as they are known under UK legislation) are senior animal technicians whereas in Holland/Portugal this role appears to be performed by a veterinary surgeon. Experience within the UK would suggest there is a need for both vet and AWO and these should be different individuals fulfilling different roles – the vet primarily responsible for health and welfare of the animals and the AWO for their husbandry and care on a daily basis. There will, of course, be overlap between the two roles. A “Spy within the establishment” is how the role has been described but this is a description we have tried to avoid in the UK in favour of “the animal’s advocate”. When there is an AWO as well as a vet, they should combine forces to enhance animal welfare.

Answer: The NACWO’s primary responsibility is to make certain all the animal’s husbandry and welfare needs are met, wherever possible to improve its life by promoting and influencing refinement opportunities and to ensure compliance with the legislation and codes of practice. Should the NACWO meet with resistance or non-compliance they can, and have reported this to the authorising body. See also in the answers in 2.2.4 on the definitions of different types of personnel.

Arguments: As was already stated in the previous question, there is practical experience with AWO/NACWO’s and it is positive. To have both levels seems to be beneficiary, especially because a AWO/NACWO

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Question: How to guarantee his/her independence?

Background: An animal welfare officer should be independent. An animal welfare officer should also be a person with a close connection to the daily practice in the establishment. Those two might give some friction theoretically. Important is to prevent a certain blindness due to getting into a rut.

Answer: As long as the holder of the role is a member of the establishment there can be no cast iron guarantee! The risk of the AWO hiding, or ignoring, contentious issues can be reduced by laying down careful selection procedures, visible and easily available support and guidance (NACWO Guidance notes uploaded) from the authorising body, and mandatory training.

Arguments: see answer.



additional question: Should an AWO always be in-house?

Background: -

Answer: A person fulfilling an AWO-role should be available for questions from technicians and researchers, in establishments with animals. Also infringements (intended and unintended) will be detected and addressed earlier if an AWO is always available. If an AWO is a special technician like the NACWO in the UK, there should always be an AWO in-house. In smaller establishments it might not be necessary to have a NVS always in-house. IF the attending vet is part-time, then s/he should not also be the only AWO – a full-time, in-house AWO should be taken on as well.

It was also brought up that AWOs are people who should have a good understanding of the systems of work within the establishment and the staff, including those in an ancillary role. This intimate knowledge of the workings of the establishment can only be quickly and thoroughly gained by those in full-time employment. The AWO should therefore be an in-house appointment and the holder of the post should be able to provide his/her expertise on a daily basis and at relatively short notice.

Arguments: see answer.



Question: Should the tasks include checking of compliance with project authorisation and highlighting of any deviations?

Answer: Compliance with the project authorisation should be checked; if that should be done by the AWO is the question. Should it not be left to the member states to decide who should check? The license holder is responsible for the compliance and everybody involved in an experiment should be aware of the project authorisation and know their part by heart. Thus enabling them to act in compliance with the authorisation and noticing infringements. Everybody involved is responsible to act in compliance. An AWO could be appointed as a confidential agent for other personnel detecting smaller or larger breaches.

In the UK, these tasks (checking compliance with project authorisation and highlighting deviations) do not come within the remit of either the veterinarian or NACWO (although it would of course be their duty to report infringements tot the national inspectorate). See also 2.2.4 with the roles of the NACWO. If AWOs under the revised Directive are made responsible for checking compliance with project authorisation, it is essential to make sure that this does not detract from their other duties.

Also was mentioned that many in the UK strongly believe the role of the AWO should be just that – ensuring the welfare of the animals within the establishment speedily and thoroughly and this should not include the added responsibility of ensuring compliance. The best people to fulfil the function of AWO are representatives from the animal husbandry staff and these are not necessarily the right people to be responsible for compliance. The CA within the MS should make the decision as to level at which this authority should be held.

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Question: Should a regular activity report from AWO be required to promote independence and transparency?

Answer: an activity report might be helpful. This could be part of the proposed support and guidance of the AWO. But a report written for whom; if it is for the NVS it has an indication function for the NVS if problems might be developing. Or is this a report for the CA? That would make the AWO a part of the national inspectorate. That might not only lead to formal problems but might also influence communication between AWOs and other employees within an establishment. What should it be a report on, and what would it include? An activity report may or may not be useful; there should be a clear thought about its nature and purpose. Also, it is very important to set out a Directive that will encourage good, free communication between researchers, ethics committees, AWOs and inspectors of the CA in the first place.

An AWO should of course keep records of events relating to animal welfare and these should be available to the CA, on request.

Members suggested an AWO should keep records of his/her advice given to personnel. This could be done in a kind of diary. Open communication is of the utmost importance and everything should be done to promote that. Compulsory reports of an AWO to supervisors or the inspectorate/CA could hamper open communication between the AWO and shop-floor workers.

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2.2.6 *Statistician in user establishments*

- **Named statistician and the statistical evaluation**

Question: Should each establishment have a named statistician?

Background: the aim here should be to ensure that each project will produce statistically significant results and use the minimum number of animals possible to do so. The TEWG does not believe that a named statistician would be necessary at every establishment to achieve this. However, proper consultation on statistics is essential for good quality, humane science (see “Implementation of the Three Rs”, page 4).

Answer: There should be a requirement for appropriate statistical consultation within the authorisation request. However, a named statistician is not necessary at every establishment to achieve this.

Additional question: if no named statistician is required, how can we ensure the quality of the statistical consultation?

Answer: The review or authorisation committee should decide how they want to review the statistical evaluation presented by the applicant. If they don't trust the quality of the consultation they can e.g. require an additional statistical evaluation. Also could be insisted on one member of the committee having expertise in statistics.

A named statistician would not, on its own, ensure quality. Better training of scientists in experimental design including statistics is necessary at a tertiary education at post-graduate level. A statistical evaluation is a critical part of experimental design from a scientific point of view as well as with respect to animal welfare. No sound science without sound statistics!



Question: Should an ex-ante statistical evaluation be provided for all types of experiments, e.g. regulatory testing including for where the number of animals is set by the test protocol?

Background: as explained above, some establishments exceed the minimum number of animals required in protocols set out by regulatory bodies. Applicants who wish to exceed minimum numbers in this way should have to justify this and provide evidence that they have obtained expert advice from a statistician.

Answer: Proper statistical evaluation should be mandatory for all types of project. There could be one exception to this, where regulatory tests are proposed that would use the minimum number of animals required by the relevant regulatory body.



Question: Should an ex-ante statistical evaluation form a part of the authorisation request or should it be available already prior to the ethical evaluation?

Background: We need to define “ethical evaluation”. The answer below assumes that this means review by a local ethics committee before the formal authorisation request, in which case it is contingent on the outcome of the TEWG on ethical review.

If the local ethics committee is to be responsible for ensuring the effective implementation of the Three Rs, including reduction, then it should be presented with evidence that the potential to reduce animal numbers has been fully explored. A statistical evaluation is vital for good science and the effective use of resources, so this should be done early in the project planning process. Therefore, the statistical evaluation ought to have been carried out by the time the project is reviewed by the ethics committee, which means that presenting it to the committee should not lead to a significant increase in bureaucracy or paperwork but could in fact speed up the process.

Answer: A proper statistical evaluation should be carried out early in the project planning stage and so it should be available for either or both the local ethics committee and the competent authority when the authorisation request is submitted.

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2.2.7 Central EU inspectorate

- **Feasibility of a central EU inspectorate**

Question: Is there a need for a central inspectorate? If yes, would it be efficient?

Background: We assumed the Commission was thinking of a body like the Food and Veterinary Office, with inspection teams visiting all member states. Checking implementation of the Regulation, and daily practice in the field: visiting CA (national inspectorate) national level and local level, and visiting together with the national CA a variety of establishments.

Answer: There was consensus against the establishment of a centralised inspectorate. But there was also consensus on the need to harmonise national inspectorates.

Arguments:

Applicability throughout EU

- Legally, Animal Welfare is not a specific Community competency, therefore would not be applicable throughout EU

Justification

- this would not by essence improve the animal welfare (only the implementation at MS level of the requirements of the Directive's will improve animal welfare)
- the Commission has already taken appropriate actions when it was felt that the Directive was not appropriately implemented in national legislations
- there is no evidence of a lack of inspection by national competent authorities

Feasibility & practicality

- Since the Directive only provides minimum requirements, and since each country has its own specific requirements and standards (high disparity across the various countries in terms of both animal welfare and acceptability of procedures), there is no agreement across the whole EU about welfare and procedures. Until then, National inspectorates will have to be pursued, and a centralised inspectorate will be impossible and unfeasible.
- A central (EU) inspectorate would have to tackle issues related to human resources, administration, languages, enlargement, mobility, etc.; This would (in comparison to regional/national inspectorates):
 - decrease efficiency/effectiveness
 - increase cost which would not be compensated by cost reduction in inspections at national level and that will still be needed for matters not covered by the Directive and national specific requirements
 - increase administrative work
 - extend current procedures
 - etc.

Overall, this would place the European industry in an uncompetitive situation within the global environment, without a beneficiary impact on animal welfare.



Question: Would a central inspectorate provide added value to the national inspection procedures?

Background: see previous question.

Answer: There was consensus against the establishment of a centralised inspectorate. This implies an added value was not obvious according to the group members. But the principle of harmonisation between national inspectorates should be considered as very important. There is within the Sub-group discussion on whether or not the inspectorate should officially fulfil an advocacy/advisory role and how it should participate/collaborate with the ethics committee (should this be mandatory).

Arguments:

See previous question.



- **Practicalities of establishing a central inspectorate**

Question: What could be the remit and the tasks of a central inspectorate?

Background: As mentioned at the background of the first question on a central inspectorate. We assumed the Commission was thinking of a body like the Food and Veterinary Office, with inspection teams visiting all member states. Checking implementation of the Regulation, and daily practice in the field: visiting CA (national inspectorate) national level and local level, and visiting together with the national CA a variety of establishments.

Answer: There was consensus against introducing a central inspectorate. For additional information see first question on 2.2.7.

Arguments: See previous question(s).



Question: How should a central and national inspectorate interact?

Background: As mentioned at the background of the first question on a central inspectorate. We assumed the Commission was thinking of a body like the Food and Veterinary Office, with inspection teams visiting all member states. Checking implementation of the Regulation, and daily practice in the field: visiting CA (national inspectorate) national level and local level, and visiting together with the national CA a variety of establishments.

Answer: There was consensus against introducing a central inspectorate. For additional information see also the background, answers, and arguments on the

other questions of 2.2.7. A central inspectorate should operate like the FVO: make a list of things they want to see, do and know and send it prior to the mission to the CA. The CA will organise the mission in accordance with the request. The central inspectorate will have an initial meeting to start of the mission with the relevant civil servants. A civil servant will accompany them during their stay to facilitate the mission, and at every location they visit the relevant people will be available (inspector, NVS, AWO, the license holder or someone representing him/her etc). At the end of the mission a concluding meeting with preferably the same civil servants as at the initial meeting will be held. During this meeting the central inspectorate should give their main conclusion. Thus enabling the CA to give a reaction to the findings of the Central inspectorate.

Arguments: See previous question(s).

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Question: How to avoid duplication of work?

Background: As mentioned at the background of the first question on a central inspectorate. We assumed the Commission was thinking of a body like the Food and Veterinary Office, with inspection teams visiting all member states. Checking implementation of the Regulation, and daily practice in the field: visiting CA (national inspectorate) national level and local level, and visiting together with the national CA a variety of establishments.

Answer: There was consensus against introducing a central inspectorate. For additional information see other questions on 2.2.7.

The role of a Central inspectorate (of which we are not in favour) should be like described above. This is an other role than the national Cas.

The database as described in our additional question should prevent double work of national CA. E.g. if a supplying establishment in a third country has been visited by one MS other MS can use that information when they have to decide whether or not they would allow that establishment to be used as a supplier.

Arguments: See previous question(s).

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Additional question formulated by the group members:

It is more important to find a way to harmonise the national inspectorates in order to ensure no large differences between member states. How can this be ensured?

Background: Some differences exist between member states on the inspectorates. Because we had only a small selection of countries represented in our group we don't claim to have a profound overview on the practical situation in all MS and CC. But among the countries that were present differences exist. Although it should not be the

aim to force all inspectorates to work in the same manner, they should all have the same goals.

Answer:

A list of duties of the national inspectorate is included in the answers to 2.2.3.

An inspector has a definite role in checking whether or not projects are performed according to the license.

Also inspectors should be encouraged to share information on e.g. refinement, best practice, practical tips and legal issues. Inspectors see a lot of different places and have entry to all establishments, thus amassing a lot of wisdom they can share with others.

Supplementary the Members would like to emphasise, they feel a central database and a communication forum or bulletin board might be far more helpful than a central inspectorate. Only the inspectorates or the national CAs should have admission to this central database and forum and it should include:

- **a list of establishments in all MS, with the type of authorisation they have (breeding, supplying etc, species) and their core business (very roughly described). This enables an inspector of a MS to see if in other MS comparable research is done or species are kept. The inspector will be enabled to exchange or share information with a colleague working with the same type of animal/establishment that way. Members felt this would be very beneficiary. Apart from a Continuous Learning Programme this would also help inspectors to keep up with new developments.**
- **A bulletin board and discussion room, where inspectors of all MS can share their knowledge and the problems they encounter. This helps the inspectors also in keeping up with new developments and lowers barriers between countries.**
- **a list of establishments in third Countries that CAs have information on (positive information as well as negative! E.g. giving marks?!). Mainly it should tell an inspector in another country if a 3rd country supplier is a good one or not. It should include contact details of CA/person who was additional information, to enable the interested colleague to contact the person who has the details.**
- **The Members suggested the European Commission should coordinate the inspections of third Country suppliers. Inspectors of the National Inspectorates could carry out the actual inspections. Every MS could supply a list to the Commission with inspectors and there specialities. The information from these inspections will be put into the database.**

Of course the database should not be made public and should only be available to the CA in order to protect the privacy of the inspectors concerned and the establishments.

This database should prevent double work, but can only do so if it is kept up to date very precisely! IF that would not be the case, it won't be any use. So it would take a lot of discipline from CA and database keeper.

Arguments: Some are in favour of an official advisory role for the CA as well. Others are against an official advisory role because it advice from the CA cannot be looked upon as advice. Who would like to argue with the CA on their “advice”... There are many NGO’s who can provide the necessary advice. In practice a license holder or NVS or AWO can always turn to the inspectorate to ask their opinion if they would feel like it.

In the end all Members were happy with wordings were using the term “advice” explicitly could be avoided. Encouraging, share information, provide practical solutions as they were applied in other establishments to the same problems, were felt as good descriptions of what was felt as an important role of the inspectors. (see also 2.2.3 on this subject)

The role of the inspectorate in the ethics committee was also discussed. It was suggested by some the inspectorate could liase with the ethics committee (local or central depending on the system in place). Others were not in favour of this role. This because they strongly believe a committee must be autonomous. If a local inspector has the power to influence the committee, (the committee will always comply with the inspectors wishes for fear of antagonising him/her) this might lead to reprisals in other ways.

A database with the suggested items helps to harmonise decisions.

Members of the Sub-Group agreed CL is also very important for inspectors. The NCA/Inspectorate should pay attention to CL of their inspectors. Part of such a programme might be visiting inspectorates in other MS to exchange knowledge, as a sort of work placement or apprenticeship.





The discussion on the (future) usage of F2 primates will be reported in the scope document. This subject is of course closely related to the discussions on breeding and supplying establishments in 3rd countries. As most imported primates originate from 3rd countries. Members of the Authorisation Sub-Group joined in the discussions via the Scope Newsgroup and e-mails.

2.2.8 Breeding and supplying establishments in 3rd countries

General Background

Every year, large numbers of mice and rats³, and smaller numbers of guinea pigs, hamsters, rabbits, non-human primates (hereafter referred to as primates), dogs, cats, ferrets and quail, are imported from 3rd countries for use in the European Union (EU). Imports of each species represent different proportions of the total number of animals used⁴. For example, the EU uses approximately 7,500 primates per year, around half of which undergo international transport, mainly from 3rd countries⁵; imports of mice and rats from 3rd countries represent a much smaller proportion of the numbers used (each less than 5%).

The welfare of animals, including their health, can be substantially affected in the course of, and as a result of, transport. This can have a direct effect on the quality of science. In recognition of the suffering involved with transport, the European Commission's Scientific Committee on Animal Health and Welfare (SCAHAW) recommends that animal transport should be avoided wherever possible and journeys should be as short as possible (SCAHAW 2002a).

In the case of primates used in research and testing, the acquisition of some species⁶ may involve capture from the wild, inadequate husbandry, and/or lengthy, multi-staged travel from the country of origin to the user establishment. Thus primates may endure considerable 'harms' even before they reach the laboratory⁷. In view of their advanced cognitive capacities and highly social nature compared to other laboratory animals, these harms may cause primates a great deal of psychological distress.

³ For example, 166,952 mice (including transgenic mice) and 38,629 rats were imported to the EU from 3rd countries in 1999 (European Commission 2003).

⁴ For the number of animals used in the EU in relation to their place of origin see European Commission 2003.

⁵ 3,512 of the 7,284 primates used in 1999 were obtained from outside the reporting country; 2,924 from outside the European Community (European Commission 2003). These figures equate to around 48% and 40% of the total numbers used for that year. For some EU countries, the percentage of primates used undergoing international transport is even greater. For example, the UK, which is the major user of primates in the EU, imports around 57% of the primates it uses (Prescott 2001).

⁶ Mainly long-tailed macaques (*Macaca fascicularis*), but also rhesus macaques (*Macaca mulatta*) and squirrel monkeys (*Saimiri* spp.).

⁷ In recognition of these harms to primates, the UK Animals (Scientific Procedures) Act (UK Government 1986) sets additional controls for the acquisition and use of these animals. For example, special justification must be given for the use of primates rather than other animals, use of wild-caught primates is prohibited except where exceptional and specific justification can be established, and account is taken during the authorisation of primate use of the potential adverse effects which primates may encounter before their arrival at the designated user establishment.

Adequate husbandry at breeding centres is particularly important for primates given that breeding animals may be held for 20 years or more.

In December 1997, sixteen Member States and twelve professional organisations became signatories to a ‘Declaration of Intent Concerning Animals Used for Scientific Purposes’ (Council of Europe 1997). Recognising the need for humane and proper treatment of such animals, and the need to reduce and replace the use of animals, the signatories agreed to improve the breeding, keeping and use of animals in accordance with the provisions of Convention ETS 123 (which are similar to the provisions of Directive 86/609/EEC). In particular, they agreed:

- *“to contribute to the improvement of the breeding, keeping, transport and use of animals in accordance with the principles set out in the Convention;*
- *to encourage the acquisition of animals only from establishments which provide housing, care and welfare compatible with the requirements of the Convention;*
- *to encourage and to contribute to the exchange of information on the different breeding and supplying establishments in order to allow a careful choice of these establishments;*
- *to make a careful choice of the means and route to ensure that transport is carried out efficiently to avoid delays and so as to limit the stress and the suffering of the animals;*
- *to provide the public with accurate information on the use of animals, in particular primates;”*

and furthermore in relation to primates:

- *“to require precise information on the origin and provenance of the animals with the objective of limiting the use of animals to those which are purpose bred;*
- *to encourage initiatives and measures to end the use of wild-caught primates.”*

Again in relation to primates, prior to the review of Directive 86/609/EEC the European Commission asked the SCAHAW to prepare a report on the welfare of primates used for experiments (SCAHAW 2002b). The SCAHAW’s mandate was to identify the most important issues for the EU and propose how the welfare of these animals can be improved, taking into account the most recent scientific information. Some recommendations from the report are repeated here.

The review of Directive 86/609/EEC offers an important opportunity for achieving the intended aims by signatories to the Declaration of Intent, and in particular for significant improvements in standards at breeding and supplying establishments and major reductions in the negative impacts of breeding and supply on animals and their welfare. The review also provides an opportunity to address the issues and concerns regarding the acquisition and use of primates highlighted by the SCAHAW. Regarding 3rd countries specifically, the review should aim to provide a basis for the development of a rigorous system, with clearly defined criteria, for assessing and authorising supply from breeding and supplying establishments in 3rd countries so as to reduce suffering and improve animal welfare and quality of science.

Method of Working

We have addressed this issue by attempting to answer the questions in the Thought Starter, considering the questions on Authorisation and Inspections separately. Some of the answers depend on the output of other TEWGs. Although the main focus of this document is on primates, because of the additional concerns surrounding the acquisition and use of these animals, the general principles within the document are applicable to other types of animal imported for use in the EU.

Rodents from third countries mainly originate from laboratories in the USA. Wild caught rats and mice originating from third countries used in EU research are non-existing. So the main concern for these animals is transport.

Cats and dogs originating from third countries also need attention. The general principles on primates are very much applicable to these species as well.

All Members felt the base should always be minimising harm, distress and stress for the animals, but also taking into account animals should be from a suitable source, have the right quality, microbiological status, otherwise the animals could have a negative effect on the quality of the research. That was considered to be undesirable.

Transport is distressing to animals. So it should be minimised in duration as well as in stages. E.g. a longer continuous journey might in most cases be preferable to several short journeys with several loading and unloading moments. Some means of transport might be preferable above others, depending on the species. Three questions were felt to be crucial:

1. Are these animals best suited for the project?
2. Where are these animals available?
3. How can the animals be transported with the least amount of distress etc.



• Authorisation

Questions (1 & 2):

- How should national authorities ensure the quality of the breeding and supplying establishments in 3rd countries?
- Should the importer be made responsible to demonstrate the quality of his supplier and the origin of the animals?

Background

If the national authority were to require that the user establishment demonstrate the quality of its supplier (in terms of standards at the source and of the quality of animals) this would not only facilitate better assessment of 3rd country sources, but would also illustrate to such sources the significance awarded to animal welfare by the national authorities and scientists in user countries. The information could be used to form a national, and perhaps international, database to allow for informed choices about how and from where animals are to be acquired (see Section 4) - this is important both for good animal welfare and for good science.

We recognise that national authorities have no formal remit (legal jurisdiction) to 'approve' breeding and supplying establishments in 3rd countries. However, we presume they can refuse to allow use of animals from a source if standards do not meet pre-established criteria. This could bring pressure to bear to improve standards and hence lead to better animal welfare and science. Because national authorities have no formal remit it might also be a problem to receive information on establishments in 3rd countries, e.g. national authorities from the EU don't have the right to visit such an establishment. This emphasises the importance of sharing information between national authorities of member states.

Answer

Applicants seeking permission to obtain any type of animal from breeding and supplying establishments in 3rd countries should be required to demonstrate to the appropriate national authority that no suitable animal of that species can be obtained from an authorised source within the user country or other EU Member State. Suitability is determined by particular factors such as strain, genotype, phenotype, age, weight and health status. It might be a problem with WTO and trade legislation. This should be considered by the Commission. There might be a need to council DG Enterprise on this subject?

A member of another Sub-Group suggested that authorisation for projects should not be given unless the supply establishment outside the EU met the housing, husbandry and transport requirements of the Directive. Otherwise, animal welfare would be adversely affected; EU suppliers would be at a competition disadvantage; there would be an incentive for EU suppliers to move their operations outside the EU (with obvious welfare indications); and scientific quality could be affected. There were in his view no insuperable trade law obstacles to his proposal.

This suggestion was not discussed within the Sub-Group so the opinion of the Members is not clear. Obviously it would lead to different views. Implementation might e.g. lead to moving the research projects abroad instead of moving suppliers abroad.

Having established that it is necessary to acquire animals from a 3rd country, the prospective user is responsible for demonstrating to the national authority the quality of its supplier and the origin of the animals via a dossier of evidence, submitted with the request for authorisation of procedures/experiments. It is recognised that conditions in breeding and supplying establishments in 3rd countries may be different from those in European establishments - nonetheless, compliance with the minimum standards of the revised Appendix I of the Council of Europe Convention ETS 123 is expected.

Any problems with animals from particular sources should be reported to the national authority immediately.

Although the above situation might be how it would be ideally, some members of the subgroup mentioned it might be far from what is practically possible. Currently there is no obligation to seek permission to obtain any type of animal. So this causes a big change in the current practice. As said there might be a problem with international trading laws. Another way of addressing the problem might be by requiring a

certificate delivered by the exporting country's authority based on their inspection findings declaring the compliance with animal welfare standards of the establishment. Also should there be a reasonable implementation time especially when major changes to the current practice are considered. These concerns are also valid for the special paragraph on primates below.

Additional information

In addition to these measures, the Commission could recommend that each breeding and supplying establishment supplying the EU develop its own standard operating procedures (SOPs) which detail all aspects of animal care, handling and other relevant procedures. The SOPs should be prepared as a formal document which forms the basis of the establishment's animal care programme and is open to inspection and/or comment by customers, regulators (national authorities) and independent accreditation scheme administrators (see Section 5). These groups can then use this document to assure themselves of the quality of the supply and that all aspects of animal care and use at the establishment are being continuously reviewed and refined.

Primates

In recognition of the level of concern about the acquisition and use of primates, a more detailed authorisation process is proposed for these animals.

Each consignment of primates from a source outside of the user country (i.e. from other EU Member States as well as 3rd countries) should be separately authorised, and the transport arrangements (in particular, the journey plan) approved, by the national authority. In addition, the national authority should be supplied with details of the health status of the animals on, and after, arrival at the user establishment.

These requirements should be an integral part of the authorisation process. (They could be embodied in special conditions attached to the relevant authorisation of user establishments and procedures/experiments). There should be a person at the user establishment with designated responsibility for ensuring that animals are obtained and used only in accordance with these requirements.

Approval for acquisition of primates from sources outside the user country should only be given if the conditions at the breeding or supplying establishment are acceptable to the national authority. Approval should also be conditional upon life-time health records being supplied with the animals and being made available to the national authority on request.

The national authority should develop criteria for assessing such sources and these should be made available to those responsible for funding, carrying out and reporting use of primates under national legislation on animal use so that everyone is aware of the standards expected. In the interests of transparency, the criteria could also be made publicly available. The aim should be to develop an inventory of conditions/benchmarks that must be satisfied before a centre can be authorised (together with accompanying explanatory text where necessary). For example, it might be expected that each breeding and supplying centre implement a suitable environmental enrichment programme, developed in conjunction with an appropriately qualified ethologist (a person formally educated in ethology and trained

and experienced in the behaviour of the particular primate species). This was recommended by the SCAHAW for all establishments with primates.

Existing detailed guidelines may be useful when establishing the criteria for assessing sources. For example, the minimum standards set out in the revised Appendix I of Convention ETS 123 and the International Primatological Society (1993) International Guidelines for the Acquisition, Care and Breeding of Nonhuman Primates⁸.

Sources should be assessed by the national authority on the basis of the following issues:

- incidence and methods of capture from the wild;
- standards of housing and husbandry;
- level, nature and effectiveness of enrichment;
- variation in diet composition and presentation;
- conditioning practices;
- breeding systems;
- identification;
- handling;
- socialisation, habituation and training;
- animal health;
- animal-care staff ratios;
- staff training;
- transport.

The prospective user should have primary responsibility for compiling a dossier of evidence to satisfy the national authority that the source operates to a high standard. There is a need for comprehensive and meaningful information from the prospective user on all the issues listed above – this may require carefully worded questions from, and/or face-to-face discussion with, the national authority. Applicants should be required to sign a declaration stating that the source meets the minimum standards set out in the revised Appendix I of Convention ETS 123.

Additional relevant information may also be taken into account in the assessment. For example, photographic and/or video evidence of the standards of housing, husbandry and care at the source, SOPs, or details of membership of any accreditation scheme (e.g. AAALAC) (see Section 5). This information may be supplemented by information acquired from visits to the source by the national authority and/or staff from the user establishment (see Section 4).

Having developed and agreed its criteria the national authority should apply these in a consistent manner⁹. The information supplied in support of the application should be

⁸ The UK currently requires compliance with the IPS Guidelines. As far back as 1993, the European Primate Resources Network (EUPREN) advised that housing conditions for primates should be standardised and that the IPS Guidelines must be accepted and implemented by all EUPREN participants (Council of Europe 1995).

⁹ It is unlikely that all centres will immediately be able to satisfy all requirements. The national authority will then need a mechanism for deciding how to deal with this in the short-term. Available options might include: refusing all centres other than those that comply; setting a time limit (say 12 months) after which centres that do not comply are refused; setting some priority areas and making decisions on the basis of these – this immediately raises difficult questions since it is clearly difficult to

scrutinised by competent members of the national authority with appropriate background and experience in primate issues. Approved sources should be allowed to supply primates for a period of 2 years only, after which they are re-assessed – this is to ensure that standards are maintained and to promote improvements.



- **Inspections**

Questions (3 & 4):

- Should breeding and supplying establishments in 3rd countries be visited/inspected?
- If so, who should be responsible for this task?

Background

Visits/inspections are particularly valuable to the authorisation process because they allow for the following, all of which are integral to proper assessment of a source:

- observation of animal behaviour and assessment of animal welfare;
- observation of routine procedures, e.g. feeding and cleaning practices
- observation of socialisation, habituation and training (dogs and primates), and trapping methods (primates);
- information gathering from all areas of the establishment;
- examination of records;
- face-to-face questioning and discussion with senior and junior staff;
- gauging of attitudes.

Visits/inspections also give national authorities, and prospective users as customers, a visible presence to encourage improvements in animal welfare and to offer support and advice in this regard. Close communication between breeding/supplying establishments and user establishments is important in ensuring continuity of husbandry and care (e.g. for acclimatisation to conditions at the user establishment; to ensure that socialisation, habituation and training for dogs and primates begin early and continue in an appropriate manner at the user establishment) and in balancing supply and demand.

One practical problem re national competent authorities visiting establishments in 3rd countries might be the costs. Travelling costs are high so regular visits to several establishments are very expensive for the national authorities. Again this is an argument in favour of easy data sharing between member states.

Another practical problem is the visiting right itself. National or even EU authorities don't have a right of entrance in 3rd countries. Certificates of the authority of the 3rd country are helpful, but one can't help wondering if it would completely satisfy our demands.

Answer

weigh and trade-off disparate commodities such as the harms of early weaning, capture from the wild, inadequate husbandry or long-distance transport.

The national authority should encourage users to make visits to the animal facilities of 3rd countries sources.

In the case of primate supply, all sources should be visited by the national authority prior to acceptance. The purpose of the visit is to gather information to help decide whether to allow or disallow the source and to encourage improvements in standards where necessary. Once a source of primates has been accepted, it should be revisited by the national authority at intervals of 2 years to promote and monitor improvements in standards.

Members felt harmonising these inspections would be very helpful. The Commission could play a crucial role in this. The national authorities could provide experts, which could visit/inspect these suppliers on account of the Commission and the outcome could go into a central database, thus making the information available for all MS. See also 2.2.7 on the Central Database.

Additional information

In setting out clear criteria for acceptance of sources of primates, and in establishing a dialogue with these sources, the system of authorisation proposed here should encourage breeding and supplying establishments to improve their standards of animal welfare in order to achieve acceptance by the national authority.



Question (5):

Could visits by national authorities be used for common good, i.e. information gathered via these visits be shared on a voluntary basis?

Background

All those who use animals (or who create the demand for animal use) have a responsibility to understand all of the costs (harms) to animals that arise as a consequence. This is important for two reasons:

- in order to weigh the harms against the perceived benefits of the research, where harm-benefit assessment is done; and
- in order to reduce animal suffering to an absolute minimum. This includes acquiring animals from the source which has least impact on their welfare.

For both reasons there is a need for detailed information on breeding and supplying establishments to be easily available.

A database of information on sources in 3rd countries (e.g. answers to the questions on the issues listed in Section 3) would facilitate informed choices about how and from where animals are to be acquired. It would also enable better monitoring of standards at breeding and supplying establishments and provide a good source of information for responding to enquiries (e.g. parliamentary questions).

Answer

Each national authority should set up a database of information on breeding and supplying establishments in 3rd countries, using information from the authorisation

process (see Section 3). The aim is to facilitate comparisons and choices between breeding and supplying establishments and to continuously improve standards. The information from the national databases could be combined to create an international database, since trade in laboratory animals is a global issue – see also the comments of this Sub-Group in 2.2.7 on a central database.

The Commission should perform the management of the Central Database. The National Authorities will mainly supply the input for the Database.



Other actions that should be considered

• Ethical review and harm-benefit analysis

The full (lifetime) experience of animals, including the suffering experienced during breeding and supply, must be included in all decisions about whether their use is justified. This is essential for fair and proper harm-benefit assessment. If a system of authorisation of sources of animals similar to the outlined in this document was adopted, such that all sources meet the requirements of the national authority, there would still be some suffering caused to the animals involved through acquisition and transport. This suffering should be factored into any harm-benefit assessment for the authorisation under which the animals are acquired, and the ethical and welfare issues involved with breeding and supply should be considered by an appropriate ethical review process - we should refer these matters to the TEWGs considering cost-benefit analysis and ethical review. (The mechanism proposed for authorisation of sources could help with these processes if it is linked to the authorisation for procedures/experiments). The ethical review process could also help raise awareness of all the relevant ethical and welfare issues, devise criteria and policies for choosing sources of animals, and rationalise user's needs. Note that the SCAHAW recommends that use of primates in research and their maintenance for scientific purposes should be considered by an appropriate ethical review process.

• Primate breeders accreditation scheme

In 1995, in view of the variation in standards for primates, the Federation of European Laboratory Animal Science Associations (FELASA) issued a statement of support for the establishment of a breeders accreditation scheme. No such scheme was established and consequently the onus is on individual countries to provide their own means of monitoring standards. Simply placing the onus on individual breeding and supplying establishments to ensure high standards of animal welfare permits conditions to exist and practices to occur which do not provide for the ethological, psychological and physiological wellbeing of the animals, despite international acknowledgement that restriction on these should be minimised. Proper accreditation is essential to ensure that adequate standards of housing, husbandry and care are achieved and maintained, to act as an incentive for suppliers to upgrade their facilities and to take control of trapping so that it is done in a humane manner while it continues. FELASA is currently exploring the possibility of establishing an accreditation system for breeders and suppliers of primates. The Commission could indicate its support for this initiative, if it believes it to be beneficial.

•Transport and sourcing of primates within the EU

For primates, transport can be extremely stressful, especially prolonged transport from overseas, and can result in very poor welfare (SCAHAW 2002b). In view of this, it is better for them to be captive-bred as close as possible to their place of use under conditions consistent with all their behavioural, social and physical needs. The SCAHAW has made a number of recommendations regarding minimising the adverse effects of transport on the welfare of primates. These should be considered as part of the review of Directive 86/609/EEC.

- In order to avoid poor welfare due to prolonged transport from overseas, the supply of primates for research within Europe should ideally be met from European breeding programmes, planned carefully to avoid surplus animals.
- If facilities using primates in research were located close to facilities where they were being bred and maintained in Europe this would reduce the adverse effects of transport on the animals.
- Importation and movements of primates should be co-ordinated between institutions to facilitate the sharing of facilities and to allow a number of smaller consignments to be synchronised and moved at the same time. This should reduce the total number of consignments and optimise the allocation of resources and expertise at the time of transport to safeguard animal welfare.
- Primates should only be transported when their welfare can be good and transport conditions optimised, e.g. direct flights by the shortest possible route, minimising waiting times, creating acceptable environmental conditions, good dietary care, and ensuring competence of those handling the crated animals.

Other members of the subgroup were not in favour of mentioning transport in the revised Directive. Transport is not in the scope of Directive 86/609 and this subject might be addressed by the revised transport Directive. Problem might be that the transport directive might focus on farm animals and lab animals will be left out. The Commission might be advised to approach the group working on the revision of the Animal Transport Directive to clear this. Also in the Council of Europe a separate transport convention exists. ETS 123 decided to refer transport issues to the transport convention.

• End to use of wild-caught primates

The SCAHAW (2002b) report notes that the breeding and export of macaques has become an important economic factor in many source countries and there is, therefore, a pressure to breed under economical conditions, which can ultimately impact upon the quality and welfare of animals. One aspect of this is that many primate breeding centres in 3rd countries are not self-sustaining and continue to draw heavily upon wild populations for replenishment and augmentation of breeding stock. Trapping primates from the wild causes a great deal of suffering and cannot be adequately monitored/controlled.

The SCAHAW recommends that for as long as use of primates continues, only purpose-bred animals should be used, and that furthermore, only animals of the second or subsequent generation bred in captivity should be accepted as being classified as 'purpose-bred'. This would help to prevent the use of wild-caught primates as breeding animals and support the effort to eliminate early weaning systems, as in general early-weaned primates do not become competent breeders. Furthermore, the SCAHAW believe that it should not be necessary to replace

breeding primates for research with wild-caught animals, as alternatives exist such as the exchange of animals between breeding colonies.

In view of the SCAHAW recommendation, and of the scientific benefits of purpose-bred animals and conservation status of primates, we should recommend that only purpose-bred primates of second or subsequent generation are used in research and testing in the EU and press for an end to trapping of wild-caught primates. Note that signatories to the Declaration of Intent agreed to encourage initiatives and measures to end the use of wild-caught primates.

Although everyone sympathises with the aim to use only purpose bred animals, several members of the subgroup felt it not (yet) possible and they were in favour of keeping the current wording: in general a ban on using wild-caught animals with specific exceptions for medical research. They were very strongly opposed an obligation to use only F2 animals. They felt exceptions should still be allowed.

An obligatory use of F2 animals might be acceptable in the long run, but in the short term it is not a realistic proposition.

In order to protect the interest of the lab animals, export of animal research to non-EU countries, due to highly impractical rules should be prevented. Especially because of the severe difference of standards.

Also it was felt by some that the discussion on acceptability of trapping of primates is not in the scope of this directive. It was felt like a duplication of the scope and objective of the CITES convention on endangered species.

The sensible way to deal with it seems to be to refer it to the scope subgroup of the TEWG. This subgroup was already asked by the Commission to give their pro and con arguments on this issue.

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Composition of the Sub-Group Authorisation:

Axel Kornerup Hansen/Jacob Nygaard Waage	(Denmark)
Ana Martins	(Portugal)
Sergio Papalia	(Italy)
Stefan Kasicki	(Poland)
Erwan Gicquel	(EuropaBio)
Roy Sutcliffe	(FELABA)
Bob Kemp	(EFAT)
Mark Prescott	(EFP)
Penny Hawkins	(Eurogroup)
Iris Arendzen (rapporteur)	(The Netherlands)
Mark Blainey (chair)	(DG Environment)

The Members of the TEWG were expected to act as individuals and not as representatives of the national authority or non-governmental organisation that nominated them.

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