

**National Competent Authorities for the implementation of Directive 2010/63/EU
on the protection of animals used for scientific purposes**

**A working document on Inspections and Enforcement to fulfil the requirements
under the Directive**

Brussels, 9-10 October 2014

The Commission established an Expert Working Group (EWG) to prepare guidance on inspections and enforcement to fulfil the requirements under Articles 34 and 60 of Directive 2010/63/EU on the protection of animals used for scientific purposes. All Member States and main stakeholder organisations were invited to nominate experts to participate in the work. The EWG met on 3-4 December 2013.

The objectives of the EWG were to develop guidance and principles of good practice with respect to the requirements of the Directive for inspection and enforcement to facilitate the implementation of the Directive.

This document is the result of the work of the EWG meetings, discussions with the Member States as well as legal input from the Commission. It was endorsed by the National Competent Authorities for the implementation of Directive 2010/63/EU at their meeting of 9-10 October 2014 with the exception of Appendix V¹.

Disclaimer:

The following is intended as guidance to assist the Member States and others affected by Directive 2010/63/EU on the protection of animals used for scientific purposes to arrive at a common understanding of the provisions contained in the Directive and to facilitate its implementation. All comments should be considered within the context of this Directive 2010/63/EU and the Commission Implementing Decision 2012/707/EU. It provides some suggestions on how the requirements of the Directive may be met. The content of the document does not impose additional obligations beyond those laid out in the Directive.

Only the Court of Justice of the European Union is entitled to interpret EU law with legally binding authority.

¹ Appendix V contains a list of suggestions to be considered for the development of a standard reporting template (discussed on page 17). However, this list was not discussed and, consequently, could not be endorsed by the Member State National Competent Authorities.

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Introduction

An effective inspection programme is a key component of the legislation, providing reassurance to all those involved or concerned with the care and use of animals in scientific procedures that compliance to the regulatory requirements is being achieved. Furthermore a well planned and executed inspection programme has many other benefits for all involved in the process, including the animals and the research community. Directive 2010/63/EU lays out a number of objectives for inspections, however, leaving the detailed implementation as to how to achieve these to the Member States.

Significantly differing processes are in place among Member States to meet the inspection and enforcement requirements contained within the Directive.

These range from inspection programmes directed primarily at assessing compliance, with inspection visits conducted at the minimum frequency set out in the Directive, to programmes involving more frequent inspection visits planned around a detailed risk assessment, with informed feedback to the establishments and the public, and promoting improved practices through education and advice on the implementation of the Three Rs.

Equally, across the EU, there are differences in the role and background of those undertaking the inspection visits. These differences are influenced by the overall number and size of establishments, geographical distribution and whether or not the inspectors are also involved in the project evaluation process. As a consequence, the inspection requirements under Directive 2010/63/EU are being implemented in a number of ways in practice, varying from a part-time inspector with a much wider inspection remit (for example, also covering farm animal welfare or meat hygiene) to full-time inspectors/inspectorate specifically dedicated to carrying out inspections and other duties under this Directive.

This guidance aims to promote a common understanding of, and approach to inspection and enforcement under the Directive. It should benefit those charged with inspection roles and responsibilities, establishments and individuals to whom the inspection programme is directed, the quality of science undertaken and standards of animal welfare. An effective inspection programme should promote improved compliance and public confidence in the regulatory framework.

Recital 36 states that *"To monitor compliance with this Directive, Member States should carry out regular inspections of breeders, suppliers and users on a risk basis. To ensure public confidence and promote transparency, an appropriate proportion of the inspections should be carried out without prior warning."*

Furthermore, a number of other recitals make reference to compliance and monitoring with regard to the Three Rs, severity classification, training and competence of staff and record keeping. These include

*"(11) The care and use of live animals for scientific purposes is governed by internationally established principles of replacement, reduction and refinement. To ensure that the way in which animals are bred, cared for and used in procedures within the Union is in line with that of the other international and national standards applicable outside the Union, **the principles of replacement, reduction and refinement should be considered systematically when implementing this Directive.**"*

*"(22) To enhance transparency, facilitate the project authorisation, **and provide tools for monitoring compliance, a severity classification of procedures should be introduced ..."***

*"(28) The welfare of the animals used in procedures is **highly dependent on the quality and professional competence of the personnel supervising procedures, as well as of those performing procedures or supervising those taking care of the animals on a daily basis ..."***

*"(32) In order to enable competent authorities to monitor compliance with this Directive, **each breeder, supplier and user should maintain accurate records of the numbers of animals, their origins and fate.**"*

Article 34 - Inspections by the Member State

1. *" Member States shall ensure that the competent authorities carry out regular inspections of all breeders, suppliers and users, including their establishments, to verify compliance with the requirements of this Directive.*
2. *The competent authority shall adapt the frequency of inspections on the basis of a risk analysis for each establishment, taking account of:*
 - (a) *the number and species of animals housed;*
 - (b) *the record of the breeder, supplier or user in complying with the requirements of this Directive;*

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32010L0063:EN:NOT>

- (c) *the number and types of projects carried out by the user in question; and*
- (d) *any information that might indicate non-compliance.*
- 3. *Inspections shall be carried out on at least one third of the users each year in accordance with the risk analysis referred to in paragraph 2. However, breeders, suppliers and users of non-human primates shall be inspected at least once a year.*
- 4. *An appropriate proportion of the inspections shall be carried out without prior warning.*
- 5. *Records of all inspections shall be kept for at least 5 years."*

Recital 52 states that *"Member States should lay down rules on penalties applicable to infringements of the provisions of this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive."*

Article 60 - Penalties

"Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive..."

Finally, on reporting requirements for inspections, Commission Implementing Decision 2012/707/EU provides in response to the obligations under Article 54(1) of the Directive that for the five-year report (the first is due in 2018), **quantitative and qualitative operational information** is reported, including the criteria applied under Article 34(2) of the Directive and the proportion of unannounced visits broken down by year."

Benefits of an effective inspection and enforcement programme

Considerable benefits can accrue from an effective inspection and enforcement programme. These benefits can extend beyond simple reassurances on compliance, with inspectors often in an ideal situation to promote improved practices, through their knowledge, including of good practices elsewhere in the Member States. However, care is needed that this does not result in an unnecessary additional bureaucratic burden for establishments e.g. imposition of unnecessary record keeping requirements.

The beneficiaries and their related benefits include:

The competent authority

- confidence that the inspection programme will appropriately monitor and promote compliance with the obligations under the Directive;
- confidence that the Three Rs are being applied in practice;
- facilitating public confidence that the enforcement mechanisms in place are effective;
- maintaining a current and accurate assessment of risk – through communications from inspectors and establishments, and understanding of local processes (to assist future risk analysis, inspection programme planning and promotion of common standards and practices).

Establishments

- Reassurance that appropriate standards of practice are being applied within the establishment– this has benefits for care staff, scientists and management (N.B. many stakeholder groups, including members of the user community are supportive of a higher inspection frequency than the minimum set out in Directive);
- Feedback received by establishments may facilitate improved resource distribution/allocation i.e. management may be persuaded that improvements and/or investment are needed;
- Reinforcement of good practice and promoting support for all levels of staff;
- Improves confidence of internal standards and practices – encourages promotion and sharing of good practice with other establishments and organisations, and facilitates an improved understanding of reputational risk;
- Harmonisation to establish and maintain a consistent approach within and between Member States.

Research workers

- Increases awareness of ethical, legal and animal welfare issues;
- Reinforces confidence that approaches towards use of animals are appropriate;
- Facilitates maintenance of the right attitudes and promotes the culture of care³ and compliance;
- Improves the quality of science undertaken through improved understanding and application of the Three Rs;
- Supports continuing improvements in the care and use of animals;
- Facilitates sharing of best practice and information exchange (within and between establishments) e.g. by Inspector;
- Facilitates links with other research groups;

³ Also referred to as a "climate of care". However, the term used subsequently in this document is "culture of care"

- Builds confidence in a level playing field (consistency in approach within and between Member States is important).

Support and care staff

- Promotes compliant culture and therefore helps prevent non-compliance;
- Supports communication and mediation between caretakers and researchers and management – helps to get care staff's voice heard and encourages more involvement of care staff;
- Supports improved welfare practices and application of the Three Rs.

Animals

- Supports and promotes optimisation of animal welfare practices and all Three Rs
 - Ensures animals are only used when justified, and all measures are taken to minimise suffering within the context of the scientific programme;
 - Offer advice on the implementation of environmental and social enrichment programmes;
 - Ensures species-specific needs are met.

The general public

- Reassurances on the appropriate and ethical care and use of animals;
- Where allied with appropriate communication – improved transparency
 - awareness and transparency on the inspections/controls in place and how these are enforced
 - information on the standards required and the legal obligations that must be met;
- Reassurance that animals are being respected as sentient beings and that they are afforded effective protection;
- Improved understanding and awareness of the situation at EU level as Member States provide summaries on the implementation of inspection and enforcement systems every 5 years⁴.

Designing an inspection programme
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Competent authorities should have a system in place for assigning and reviewing the risk status for each authorised and registered establishment breeding, supplying or using animals in their Member State.

⁴ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02012D0707-20140115&from=EN>

A level of risk rating (such as 'low', 'medium' or 'high' as the minimum differentiation) should be given to each establishment based on key factors listed below. A higher level of risk assigned to an establishment does not necessarily imply poorer performance or higher likelihood of non-compliance - it may be a result of the type of work being undertaken or the particular species being used.

An effective programme of inspection should be in place to monitor compliance and to enable the competent authority to determine whether the current level of risk rating for an establishment remains appropriate or needs to be increased or decreased.

Publication by the competent authority/EU of the commonly agreed criteria used to assign a risk rating will promote public understanding of, and confidence in, the robustness of the regulatory system.

The risk status assigned should be discussed with key individuals within the establishment - such as the person identified as responsible for ensuring compliance (Article 20(2)), the designated veterinarian⁵ (Article 25) and the persons referred to in Article 24(1). The factors which underlie the current rating should be included in the discussion, along with possible ways these can be managed to reduce, eliminate or prevent the risks, and if applicable, reduce the risk rating.

Although Member States are required to meet the minimum inspection frequency identified in Article 34, these minima are likely to be exceeded, in particular for establishments considered to be in a "high-risk" category.

An annual inspection programme (linking into a multi-annual rolling plan) is considered beneficial, as this can be helpful in securing the necessary resources and allows those resources to be properly focussed. The plan will be based on a risk analysis, having regard for availability of suitable personnel and geographical considerations. Such plans should be adapted as necessary throughout the period as risk factors may change significantly.

What is the aim of a risk based programme of inspection

The planning and delivery of a programme of inspection should be based on an identified set of risk criteria. This allows inspection resources to be targeted where there is a significant likelihood of non-compliance, and in particular, where there is a potential for a negative impact on animal welfare or loss of confidence in the regulatory system resulting from any non-compliance.

⁵ Term "designated veterinarian" when mentioned in this document refers to both "designated veterinarian" and "a suitably qualified expert where more appropriate" as per Article 25 of the Directive.

What are the factors to consider in a risk-analysis to determine frequency of inspections?

A common EU wide risk criteria has been developed (see Appendix I). However, the weighing of these different risk factors should remain at the level of Member States, or even at a regional level, as it may be influenced by the local environment and a number of other elements such as ethical concerns, past events and history of compliance. There is, however, a common understanding that the following elements should form the basis of the risk analysis. Risk factors may be separated into either objective (measurable) or subjective elements.

How should risk factors be weighed to determine frequency of inspections?

The risk-analysis is a key factor in helping to determine the frequency of inspection.

Individual Member States may choose to apply weighting to the different factors involved, as the relative importance of each factor will vary among Member States.

A regular risk management meeting with each establishment to review the “risk” factors pertinent to the establishment, and whether suitable measures are in place to effectively manage these risks has proved helpful for both the establishment and the regulator.

A review of the risk rating after each inspection should take place, and feedback to the establishment should include any action required to address any concerns raised and to consider any further actions which may be taken to reduce risk.

The application of a simple numerical allocation to risk factors allows a comparison to be made between establishments, and to set inspection frequency. Objective quantitative parameters are desirable (e.g. number of animals used, infringements) but are not always possible (e.g. management, communication structures) and knowledge of the local circumstances is required to allocate appropriate scores to such qualitative measures. An example is provided in Appendix IV.

Rating systems and allocations should be reviewed at a national level to promote a consistent approach.

Interval between inspections

The Directive sets out a minimum frequency of inspections of at least one third of the users each year, with breeders, suppliers and users of non-human primates to be inspected at least once a year. Furthermore, it requires that all breeders, suppliers and users are inspected regularly.

A number of principles could be considered when frequency of inspections is determined. These include the following:

- As the authorisation of an establishment can only be granted if compliance with the requirements of the Directive can be established, an initial inspection is necessary to confirm that suitable standards are in place.
- A structured rolling programme, spreading over more than one calendar year, should be established to ensure all active (i.e. those actively breeding, keeping or using animals) establishments are inspected regularly at an appropriate frequency.
- The “high-risk” establishments should be inspected more frequently than those considered to be of "moderate" or "low" risk.
- The longer the time between inspections, the more difficult it can become to be confident that the establishment remains compliant. This is likely to be a particular issue if there is little communication between visits, between the inspector and the establishment. These factors are likely to increase the risk rating.
- There should be oversight of the inspection programme to promote consistency in determining appropriate inspection frequency.

Examples of different inspection frequency regimes employed by Member States include:

- a minimum of annual inspections for “high” risk, with “moderate” risk establishments on a two-year cycle, and “low” risk on a three year cycle;
- an annual inspection visit of all “active” (breeding, supplying or using animals) establishments;
- a three-year rolling programme to ensure all establishments are inspected within a three-year period.

Types of inspection

Different types of inspection may be included in a programme of inspections. For example

- General inspection
- Targeted inspections such as
 - an initial inspection to consider an application for authorisation of a new user/breeder/supplier;
 - inspection of a new building or change of use of existing facilities;

- a follow up inspection on previous non-compliance incidents/pending issues from previous inspection;
- response to investigate third party claims;
- to assess new or innovative housing and care practices/techniques;
- to inspect new areas of work, or the use and care of new species.

Announced and unannounced inspections

The Directive requires (Article 34(4)) an appropriate proportion of inspections to be unannounced. In some cases, it is important that the inspection is announced in advance, for example where key staff need to be present, or where the inspector intends to inspect a particular piece of work (e.g. surgery). However, unannounced inspections have a number of other benefits.

There are benefits and challenges for both announced and unannounced visits which are discussed below.

Announced inspections

Benefits

- Key personnel within the establishment are available to meet the inspector, discuss work or to receive feedback;
- Enables the inspection of a particular work in progress e.g. surgery, work in the wild;
- Provides the opportunity for inspectors to promote educational role and disseminate good practice.

Challenges

- The establishment may prepare itself for inspection
 - Allows the possibility for potential non-compliance issues to be 'covered-up' before the inspection
 - Changing normal work practices e.g. to ensure that only simple procedures/techniques are in progress; no complex work being done;
- Reduced public confidence in the effectiveness of inspections.

The challenges can in part be addressed by minimising the period of notice that the establishment receives prior to the inspection.

Unannounced inspections

Benefits

- Inspection will be of “typical” standards, with no prior preparation by the establishment;
- Non-compliance is more likely to be detected;

- Assists in promotion of a compliant culture;
- Builds public confidence;
- Where senior staff/project leaders may be unavailable, there could be opportunities to meet more junior scientists/care staff.

Challenges

- Key staff may be absent or unavailable;
- There may be little or no animal work in progress;
- Potentially wasteful of limited resource e.g. it takes more time to find the right people and right documentation;
- Ensuring that biosecurity requirements and restrictions are met (however, information on general biosecurity needs should be available to inspector in advance e.g. in establishment file).

How is an “appropriate” proportion of unannounced visits determined?

Under the previous Directive, in a number of Member States, the majority of inspection visits made were as “announced”.

Although announced visits are likely to remain the majority in many Member States, the benefits of unannounced inspections are clear and the trend is towards increasing the numbers of these types of inspections.

The exact definition of what counts as “unannounced” is not always agreed upon. Ideally, no prior warning would be given. However, sometimes a short notification, generally by telephone, may be given to ensure that all necessary local establishment issues can be complied with e.g. security, biosecurity, health and safety, but there is considered insufficient time for the establishment to significantly modify its practices prior to the visit.

Many of the unannounced visits are often specifically targeted, whilst the announced visits tend to cover more general inspection issues.

Planning an inspection visit

Each inspection visit should have an identified purpose.

It is good practice to plan carefully for an inspection to ensure that all the objectives can be met and necessary background information has been collected and reviewed beforehand.

Some competent authorities maintain an “establishment file” which contains all relevant information on the establishment, such as compliance history, inspection

reports, and contacts for key personnel. This may include information on biosecurity and health and safety compliance requirements at the establishment.

Previous inspection reports should be reviewed to ensure that any necessary follow-ups can be included.

Where there is a history of non-compliance, it may be necessary to include in the inspection an assessment of whether or not the measures put in place by the establishment to prevent recurrence have been effective.

There is a clear change in focus of inspections under the new Directive. In contrast to 86/609/EU which focussed on inspection of establishments, the Directive 2010/63/EU now requires, in addition, inspections to verify general compliance with all other relevant requirements of the Directive.

Due to the size and complexity of many establishments, it is not often possible on every inspection to assess compliance with all areas of care and use. A structured and systematic approach to an inspection programme will ensure that, over the course of one or more inspections, all necessary elements will be checked. Visits should be structured on a risk basis - all areas should be covered in time, but not necessarily with the same frequency. Structured sampling may for example include a review of all procedures classified as severe, or a meeting with a selected proportion of project holders (Article 40(2)(b)) to review compliance with implementation of the Three Rs, or visiting selected animal holding areas.

Access to and overview of project authorisations is therefore helpful when a particular project work will be inspected.

Consideration needs to be given to whether or not the inspection can be unannounced. For announced visits, a preliminary questionnaire/request form can be sent to secure any necessary information, for example on ongoing project work prior to the visit, which can assist prioritisation, and efficiency, and to request presence of selected personnel.

Inspection programmes should include both general and targeted inspections

First time inspections (prior to establishment authorisation) tend to be general, including all relevant areas within the establishment.

A general inspection is also beneficial when a new inspector visits for the first time. The benefits of such a visit can be enhanced with visiting in the company of an inspector knowledgeable of the establishment (handover visit).

Targeted visits may be directed at particular projects, for example to observe new surgical procedures, follow-up on non-compliance issues identified on previous visits, consider the suitability of a new building for housing of animals, to attend an Animal

Welfare Body (AWB) meeting or to meet new personnel such as the designated veterinarian.

A structured sampling programme for inspection of *project work* is also considered helpful – again developed on a risk-basis. Over time, work on all projects may be observed, but this may not prove possible in establishments where large numbers of projects are authorised.

Prioritisation of what is inspected

Priorities should be aligned with risks for that establishment, but inspectors should ensure that they also sample “normal” work from across the full range of work carried out at the establishment. Follow-up when non-compliance issues have been identified will usually have relatively high priority. Priorities will change throughout the inspection cycle to ensure that all required elements of inspection are sampled. It is suggested that a full review of the establishment premises is completed in each inspection cycle.

Who conducts the inspection?

The majority of inspections within the EU are undertaken by veterinary trained inspectors, although, for example, trained animal welfare officers, biologists and medically-trained inspectors are also used. Depending on the size, nature and complexity of the establishment, and the reason for inspection, there are generally one or two persons involved. The second inspector can facilitate a more comprehensive inspection, and, for example overcome biosecurity issues restricting inspections of multiple animal units within the same establishment.

In some Member States, the persons involved in project evaluation are also responsible for inspection of the establishments where work under such project authorisations is undertaken.

This could have advantages in that the inspector is likely to have a good understanding of the scientific programme, the justification for the use of animals, the procedures involved and the application of the Three Rs within the programme of work in the projects.

Having the same inspector for a prolonged period can provide benefits, in that they will have a detailed knowledge of animal use and care practices within the establishment and a good understanding of local risks. However, if the relationship becomes (or even is perceived to become) “too friendly” (also known as regulatory capture), this can be detrimental. This issue may be addressed by moving and/or rotating inspectors, where possible, and/or occasional joint or exchange inspections. Joint inspections also promote consistency, and contribute to the continuing professional development (CPD) of inspectors.

Conducting an inspection visit

How the establishment is inspected is important. Inspectors need to know and understand what the expectations and standards against which they are inspecting are. Inspection manuals and guidance notes are considered helpful for both inspectors and those inspected, assisting all those involved to know what is expected and why, and to promote a consistent approach.

To ensure that both parties obtain maximum benefit from the inspection, it is important to have good communication between the establishment personnel and the inspector.

In some cases, inspectors are accompanied on their inspection visits by senior management from the establishment. Although this can have benefits in terms of them providing knowledge of the overall care and use practices in place, it is also often helpful to have direct interactions with scientists, care staff and other key persons such as the person responsible for overseeing welfare and care (Article 24(1)(a)), as this can provide a good insight into the overall attitudes and culture of care within the establishment. The presence of senior management can in some cases be intimidating to more junior staff.

Inspectors often have a pre-meeting on arrival with key personnel, to explain the purpose of the visit. This can facilitate the planned programme with regard to inspections of facilities (e.g. compliance with any health requirements between units) and personnel (ensuring requested individuals are on-site and available).

Where compliance issues are uncovered, these will be brought to the attention of the establishment and appropriate action taken to prevent recurrence. In the case where animals during an inspection are found to be experiencing avoidable suffering, **immediate action should be taken** to avoid any further suffering.

What is inspected (e.g. facilities, animals, work in progress, personnel, records)?

Checklists are considered helpful, in particular, to ensure that all aspects of the inspection process are identified and to facilitate recording which of these have been addressed at each visit.

A comprehensive check list is attached as Appendix II.

Although each inspection should be planned, it is important also to be flexible and be able to amend plans in response to findings during the visit. This is especially important when tools such as check lists are used.

How to inspect?

Directive 2010/63/EU sets different inspection requirements from those under the previous Directive 86/609/EEC requiring verification of compliance with the requirements of the Directive, not only inspection of establishments.

Some further advice on specific elements of the inspection process may be helpful to promote a common understanding and consistent approach in these specific areas.

The first advice note on "Inspecting compliance with project authorisations" is attached as Appendix III.

Additional advice notes will be developed for other areas, should these be considered necessary.

Reporting on inspections

Initial Feedback to the establishments

Feedback from the inspector as soon as possible to the establishment should be encouraged. This should include positive feedback in addition to those aspects which may require action to be taken.

Addressing non-compliance

Non-compliance can vary from very minor (for example minor misunderstanding of project authorisation with no welfare or scientific consequences) to very serious (for example deliberate, avoidable animal suffering being caused), and the actions taken in these also vary considerably.

An escalating tariff is used as the severity of non-compliance increases. In many cases, trivial non-compliance can be dealt with in exchanges following the inspection. In more serious cases administrative (withdrawal or suspension of authorisations) or legal actions (fines, imprisonment) are available.

The occurrence of avoidable animal suffering is viewed most seriously. Similarly, incidents where individuals have knowingly breached their authorisations are viewed very seriously.

Actions should be directed at rectifying the problems and preventing recurrence.

Reporting

Inspection findings are generally recorded in a visit report, which may include a completed checklist of issues inspected. These are useful to monitor trends within and

across establishments, and are helpful in reviewing the risk profile and further risk analysis of the establishment.

All records of inspections must be held for at least five years (Article 34(5)). Many competent authorities also keep notes, pictures and copies of documents obtained during the course of the inspection.

Feedback should be provided where non-compliance is found. Depending on the seriousness of any non-compliance, a written record can be provided to ensure that the establishment has a record of the problem and of any corrective action which has to be taken (within an appropriate and specified timescale). Confirmation is needed that the issues have been satisfactorily addressed – this may necessitate a follow-up visit. In any case, the subsequent visit should confirm that identified problems have been rectified.

A number of competent authorities publish information on their inspection programme⁶, including summaries of compliance issues and action taken. In such publications, care is needed to safeguard confidentiality and intellectual property.

Feedback to authorities on inspection process

Establishments should be encouraged to provide feedback on their inspection process. This will provide useful information to inspectorates, which can help to inform further improvements to the process. Feedback should refer to the process, rather than the individuals involved.

EU Reporting on inspection and enforcement

The Commission Implementing Decision 2012/707/EU requires, by November 2018, and every five years thereafter, Member States provide information on inspections and enforcement:

- information on inspections, including quantitative and qualitative operational information including criteria applied to determine inspection frequency and the proportion of unannounced inspections broken down by year,
- information and reasons for the withdrawals of project authorisation during the reporting period and
- information on the nature of infringements as well as legal and administrative actions resulting from those infringements during the reporting period.

Member States agree that a common format for reporting would be helpful, and this will be developed. A number of elements, attached in Appendix V, were identified which could contribute to a common reporting framework. These were, however,

⁶ As an example, see: <https://www.gov.uk/government/publications/animals-in-science-regulation-unit-annual-report-2013>

neither discussed, nor endorsed by the Member State National Competent Authorities.

Other functions of an inspection programme

The inspection process should help to promote compliance within establishments, by disseminating information on the requirements of the legislation, and, (through the inspector/inspectorate's expert knowledge of use, husbandry and care practices in laboratory animals within the Member States and the EU), promoting positively the implementation of the Three Rs and improved animal care and use practices.

In a number of Member States, inspectors contribute to the AWB discussions, and also help to develop guidance on good practice in aspects of animal use and care, and consistency. Inspectors may also contribute to training e.g. providing update on legislation, the Three Rs and dissemination of good practice.

Inspections should also consider the attitudes and culture of care within the establishment.

Although an oversight by the competent authorities is an important factor, the development of an effective culture of care and responsibility critically relies on the internal processes, attitudes and practices in place within the establishments. Buy-in from all staff supported by effective leadership is essential. Each individual has to positively contribute. Inspectors can assist in identifying good practice and deficits in internal processes.

Factors to consider in determining the culture of care in an establishment

Indicators which may be positive or negative

- condition and care of animals;
- quality of project documentation;
- effectiveness of socialisation programmes (where appropriate);
- appropriateness and implementation of working practices and standard operating procedures (SOPs);
- first impressions such as on state (condition and tidiness) of support areas e.g. the cage washrooms (hardest work – respect to all levels);
- status including formal authority of key people – empowerment of staff;
- attitude of researchers towards the establishment AWB;
- knowledge of staff on their responsibilities;
- level of openness of staff and willingness to draw attention to problems.

Factors which are likely to be indicative of good culture of care

- openness of all staff: keen and able to answer questions;
- effective designated veterinarian whose input is respected by researchers and care staff;
- high quality, respected care staff;
- positive approach towards seeking and utilising external expertise;
- on-going education and training in animal care and welfare which is accessible to and encouraged for all levels of staff;
- effective communication between care staff and research workers e.g. regular meetings; experimental planning;
- knowledge and awareness of the Three Rs;
- demonstration of and commitment to Three Rs in practice, for example
 - strategy to minimise animal surplus
 - strategy for sharing of tissues
 - implementation and ongoing refinement of humane end-points for specific projects (e.g. trend of reduction in actual severities)
 - introduction of replacements
 - engagement with animal welfare science community, for example publications/presentations;
- involvement / use of biostatisticians;
- well-understood and clear procedure for 'whistle-blowing'.

Factors which are likely to be indicative of lack of culture of care

- poor attitude of staff e.g. no time, "talk to my deputy", how they judge the importance of inspection;
- unwillingness to contribute to discussions on animal care and use;
- too many people having access to restricted areas;
- project leader being too distant or removed from research workers and care staff;
- status of staff – not encouraged to contribute; not listened to;
- care staff/junior researchers not aware of the project details e.g. with regard to care, management of adverse effects;
- key people elusive;
- resistance to change/introduction of refinement and improvements;
- lack of acknowledgement that improvements are possible;
- failure to implement establishment practices; ineffective management;
- absence of or poor standard of working practices;
- lack of understanding of / poor engagement with animal welfare issues by scientists;
- poor communication between scientists and care staff.

Inspectors and inspections as means to promote a good culture of care

- provide links and encouragement towards good practice – point staff in right direction;
- communication between 'inspectorate' and establishments improves understanding of expectations and prevents problems;
- constructive approach and open dialogue;
- help empower key staff - care staff/designated veterinarian should be encouraged to engage with scientists;
- provide (including immediate) positive feedback – not only emphasis on negative;
- educational role outside the inspection situation;
- provide advice outside the inspection situation;
- work in partnership;
- explaining reasons behind different requirements and/or changes e.g. impact on animal welfare and science;
- demonstrate practical experience to enforce message;
- being able to identify good practice;
- promoting consistency and good practices e.g. use of SOPs, work instructions, development of severity assessment framework, clearly defined humane endpoints;
- available to resolve issues after the visit and as a 'source of information' at all times;
- provide feedback specifically in relation to resource issues;
- re-enforce message that good science goes hand in hand with good welfare – where applicable, promote a shift in the balance from 'only' research focus to embrace care and animal welfare;
- engaging scientific and care staff to work together in problem identification and problem solving to gain ownership of the solution;
- promote importance of staff in understanding, promoting and implementing the Three Rs;
- promote open communication and transparency within and outside establishment.

Raising awareness and improving culture of care in a wider context by the Member States

- Communication with funding authorities;
- Communication between different government departments especially if there may be differences in priorities and policies between science and welfare;
- Communication between those assessing projects and those inspecting where authorisation and inspection are separate responsibilities;
- Role of National Committees to raise profile of welfare and care practices;

- Reduction in bureaucracy, allowing focus on animal use and care;
- Communication with general public – scientific needs/benefits and welfare and care practices.

Profile, skills and training of inspectors

The guidance document endorsed by Member States on the Education and Training Framework for personnel under Directive 2010/63/EU includes, in Appendix III, advice on the profile, skills and training of inspectors.

In order to verify that research establishments and relevant personnel are meeting the requirements of the Directive, inspectors must have a detailed knowledge and a good understanding of the relevant legislation and any relevant national policies. They should understand the different roles and responsibilities of personnel involved, and the basis of and detail required within authorisations for establishments.

Inspectors should have a good understanding of animal welfare, animal breeding and accommodation and care practices.

For inspections within user establishments, to enable verification that the Three Rs are implemented as far as possible within the projects being inspected, inspectors should have a good understanding of project and experimental design, and the content of project authorisations for the establishments being inspected.

This role can be fulfilled by persons with a good understanding of the care and use of animals in scientific procedures, in particular the application of the Three Rs. These can be veterinarians, biologists or other personnel with appropriate training and expertise in medical, biomedical or biological sciences. Inspectors should have broad, detailed experience in science and scientific methods, experimental design and expertise in, and / or a keen interest in optimising, animal health and welfare.

Inspectors should be proactive and promote improved practice in animal care and use and development and maintenance of a good culture of care. Inspectors may be able to encourage collaboration among key players working within establishments. Team-working among inspectors will facilitate the dissemination of knowledge and sharing of experiences and will promote consistency.

Inspectors should have “personal authority” deriving from their background, experience and knowledge. Effective interpersonal skills, including oral and written communication is beneficial. Inspectors should be trained to identify conflicts of interest and how to avoid these. This will allow inspections to be independent and increase public confidence in the regulatory oversight.

Initial training

Training programmes for inspectors should be devised for each individual taking into account the required role, the previous education, training and experience of the inspector and having regard for the way in which the Directive is implemented in the Member State in question.

Full details can be found at

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_E-T.pdf

Promoting consistency

Consistency of approach from those involved in the inspection process is important to promote confidence and understanding within the scientific community and the general public that the regulatory requirements are being applied equitably and to an appropriate standard.

Appropriate training and CPD are considered key components.

A number of methods and tools can be used to promote consistency. These include

- effective communications among inspectors;
- development, sharing and maintenance of common standards and practices e.g. agreed inspection criteria;
- joint inspections (within and among Member States);
- meetings of inspectors (at regional, Member State and EU level);
- the use of case studies in on-going training;
- maintenance of a database on advice given;
- a common format and style for reporting inspection visits;
- encouragement of feedback on the process from those being inspected;
- consideration for a restricted inspector “chat-room” e.g. European Commission on CIRCABC;
- sharing of reports among Member States, as available.

Efficient inspection programmes

The views on the main difficulties and challenges in delivering an efficient inspection programme differ between those carrying out the inspections and those being inspected. An improved understanding of these different views will hopefully

encourage and promote improvements in the future construction and delivery of effective inspection programmes.

Views from some inspectors

- insufficient resources (both inspectors and support staff);
- inadequate training and CPD;
- new systems of inspection to meet the requirements of the Directive ;
- poor internal communications within establishments, in particular, between scientific and care staff;
- lack of clarity on powers/authority of inspectors within legal framework; turnover of personnel (inspectors and of key staff within the establishment);
- financial constraints/ability of establishments to deliver prompt and effective improvements;
- biosecurity restrictions;
- attitudes of establishment, in particular, of management to deliver improvements.

Views from various other interested parties including a number of those being inspected

- inconsistency;
- insufficient proportion of unannounced visits;
- lack of transparency on process of inspection and enforcement, including sanctions;
- lack of expertise;
- maintaining confidentiality (personal information, intellectual property);
- sanctions considered not proportionate;
- delays in dealing with issues impacting negatively on science and welfare.

Defining a good and effective inspection programme

A good and effective inspection programme is one which provides positive support to establishments, encouraging compliance and preventing non-compliance, and actively facilitating good practice and communication. It should report key findings relating to legislative requirements to establishments and to the public, whilst maintaining confidentiality. The inspection programme should be sufficiently resourced with trained and experienced personnel, and with good administrative support.

Consistency in the application of the inspection programme is important. This can be promoted through initial training for inspectors using standard inspection practices and guidance. Joint inspections within and between Member States will promote consistency. Relevant CPD should ensure inspectors remain up to date with current good practice.

Measurable outcomes could include

- The number (incidences) of non-compliance and the severity of these (this includes, for example, the nature and level of impact on the animal, whether non-compliance was deliberate, whether non-compliance was self-reported or whether attempts were made to conceal non-compliance);
- The effectiveness of the risk-based approach being operated can be reviewed by comparing the non-compliances within an establishment with the inspection programme being operated (e.g. the frequency and nature of inspection visits) as well as the level of risk rating assigned to the establishment;
- A change in risk profile of establishments;
- The competent authority is meeting the targets set for the planned inspection programme including visiting frequency, timeliness of reporting and the handling of non-compliance;
- Improvements in care and use practices (including the implementation of the Three Rs) generated as a direct consequence of input at inspections.

However, these measures do not always provide a direct indication of the effectiveness of an inspection programme with respect to animal welfare. This requires a different set of outcome measures which are much harder to evaluate, but critically important with respect to understanding how the letter and spirit of the legislation are being implemented.

Some suggestions include:

- (i) Demonstration of continuous improvements in social/environmental enrichment provision and in housing practices;
- (ii) Demonstration of continuous improvements in animal monitoring and welfare assessment, taking new knowledge and approaches into account;
- (iii) Demonstration of year on year improvements in reduction of surplus/wastage of animals, e.g. humane killing of 'surplus stock';
- (iv) Demonstration of improvements in the promotion and application of the Three Rs.

Inspection is an important element of the Directive to ensure that the requirements for breeding, care and use of animals in scientific procedures are met.

An effective inspection programme should deliver discernible benefits – to the authorities, stakeholder groups, including the general public, to the scientific research community and to the animals being used or bred for use in scientific procedures.

A well-trained and effective inspectorate is essential if these benefits are to be realised.

Appendix I

Inspection risk analysis criteria

- **Type and complexity of an establishment** - when an establishment has a complex internal structure or is spread across several sites, the risk rating could be affected. In large or complex establishments it could be justified to assign a different risk rating for individual units or departments, and plan separately for inspections (e.g. for a large establishment using multiple species such as non-human primates, dogs and rodents).
- **New establishments** - an initially higher risk rating should be given to establishments that have little or no experience of demonstrating that they meet the requirements of the Directive.
- **Number of animals** - when large numbers of animals are involved, this may raise the likely incidence of any errors or lapses occurring, or might mean that more animals could be affected should non-compliance occur.
- **Species involved** - those receiving special protection (such as stray or feral animals of a domestic species, endangered species, animals taken from the wild, non-human primates), either due to perceived increased capacity to experience suffering, or because they are focus of other particular public concerns, could result in a higher risk rating.
- **Severity of procedures** - higher prospective assigned levels of severity classification, and higher levels of actual severity of procedures, may increase the risk rating. This is because the consequences of any errors or lapses occurring might result in a higher level of animal suffering.
- **Type and complexity of projects, and procedures involved** - when the procedures involved are more complex, or require a significant level of expertise, skill or personnel training, the risk rating could be higher as the potential for error or any lapses may be increased.
- **Compliance history** - a higher risk rating should generally be assigned to an establishment with a record or history of non-compliance as they may be more likely to have current or future incidents of non-compliance. It is however necessary to understand the nature of the non-compliance (range from minor, with no welfare or scientific consequences, to deliberate avoidable welfare impact on animals), and the responsiveness of the establishment to deal with non-compliance.
- **Time elapsed since previous inspection** - where an establishment has not been inspected for a longer period of time, the risk rating is likely to be higher as there

can be less confidence that standards are being maintained, that the establishment is compliant and that the current risk rating in place is still appropriate.

- A higher risk rating should be assigned where it is known that the **personnel** involved may lack significant experience or where there is a known high turnover of staff. A higher rating should also be given if there is concern about the adequacy of staff numbers in place at an establishment.

Some Member States may decide to include **additional risk factors** in their consideration:

- It may be appropriate to reduce the assigned risk rating where an establishment is, on the basis of past inspections, reported to have in place a good ‘**culture of care**’ which promotes positive attitudes of personnel towards issues of ethics, animal welfare and good research conduct.
- It may be appropriate to reduce the assigned risk rating where an establishment is deemed to have in place good **management and communication structures** and other mechanisms (including an effective AWB) to ensure appropriate training, supervision and competence, and to encourage compliance and rigorous implementation of the Three Rs.
- Where an establishment is a member of a well-recognised **third party specialised accreditation scheme** (e.g. AAALAC International,) this might be considered appropriate for reducing the risk rating. This is because there may be additional oversight of some of the activities within an establishment or that those within the establishment already have some experience of operating to meet specified standards of practice. This would be dependent on the competent authority being aware of the standards being applied and knowledge of the outcomes for the establishment.
- A higher risk rating should be assigned where it has been identified that individual staff working within an establishment, whose primary responsibility is for the welfare of the animals, may have a **conflict of interest** (e.g. financial, scientific) in the outcome of the work. This would generally only be the case in small establishments where individuals may by necessity have multiple roles.
- A small establishment with no AWB (i.e. fulfilling the tasks of Article 27 by other means) may pose a higher risk of non-compliance and may therefore impact on the frequency of inspections.
- Where there is particular **public concern** in a specific establishment, for example following specific allegations of non-compliance.

Appendix II

Inspection *Aide Memoire*

The use of an *Aide Memoire* or a check list can be helpful in ensuring all aspects of compliance are inspected and to facilitate reporting to both the establishment and competent authorities, and to promote consistency between inspectors. These can also inform the handover of establishments to new inspectors. However, inspectors **should not be limited by check lists and should, on the day, use their expertise, skills and experience** to revise the planned inspection as appropriate to investigate and assess compliance.

The below *Aide Memoire* is established to facilitate the development of national check lists, where appropriate. The content is especially useful in ensuring that the change in focus with the new Directive, from the previous user establishment centred inspection to an all-encompassing compliance inspection, is appropriately addressed during inspection visits.

Components which may form an inspection

1. *Animals*

- Health and wellbeing of stock animals;
- Health, wellbeing of breeding animals and efficiency of breeding programmes;
- Health and well-being of animals undergoing procedures and choice of methods being used;
- Quality and frequency of clinical monitoring – e.g. use and suitability of clinical score sheets to record signs such as behaviour, posture, coat, injuries; application of authorised endpoints;
- Enrichment/ socialisation / training programmes for animals;
- How physiological and ethological needs are satisfied;
- Ensure suitable identification methods are used. Check that dogs, cats and non-human primates have been marked with permanent individual identification mark in the least painful manner;
- Source – e.g. taken from the wild.

2. *Environmental stability and suitability to meet welfare and scientific needs*

- Temperature;
- Humidity;
- Light;
- Ventilation;
- Noise;

- Environmental conditions checked daily, defects dealt with as soon as possible.

3. *Animal Enclosure suitability*

- Food;
- Water;
- Bedding / nesting material;
- Flooring;
- Dimensions;
- Stocking densities;
- Cleanliness and cleaning regimes;
- Environmental complexity and enrichment;
- Labelling / identification

4. *Establishment*

- Alarms - fire / power/ pressures / backups;
- Equipment – function / maintenance;
- Suitability for purpose of animal holding areas;
- Maintenance and cleanliness of units, e.g. surgical facilities.

5. *Records*

- Source of animals;
- Use – breeding, authorised scientific use;
- Disposal – e.g. killed as part of procedure, surplus to requirements, rehomed;
- Health status – ensure suitability for scientific work;
- Health records – morbidity / mortality rate and cause;
- Production (breeding) records and analysis of efficiency and any welfare concerns;
- Welfare assessments of genetically altered animals – harmful / non-harmful lines;
- Individual history files for each dog, cat and non-human primate which includes relevant reproductive, veterinary and social information for each animal and details of projects in which it has been used;
- Records of veterinary medicines used;
- Records for use of animals taken from or used in wild (ensure other legislative requirements in place).

6. *Personnel (general)*

- Attitudes towards use and care of animals.

7. *Scientific staff*

- Existence and quality of animal use records;
- Clarity and completeness of training and competence records;
- Compliance with project authorisation, including progress towards achieving objectives on scientific programmes;
- Up to date implementation of each of the Three Rs including use of anaesthesia and analgesia;
- Adverse effects as expected from authorisations and efforts being made to minimise severity;
- Severity assessments at the end of the study or life of animals;
- Records of animal use and check that annual statistical reports have been submitted appropriately.

8. *Animal care staff*

- Suitability of numbers and experience available to perform all required tasks at all required times;
- Knowledge of species requirements and attention to animals;
- Oversight monitoring of animals undergoing procedures and actions to take – knowledge of interventions and humane end-points;
- Quality of handling of animals;
- Clarity and completeness of training and competence records.

9. *Articles 24/25 persons*

- Adequacy of education and training, and of supervision, where required, of scientists and care staff and provision of information to them;
- With designated veterinarian
 - Review quality of assessment and activity relating to health/welfare issues;
 - Review role and effectiveness in promotion of refinements – for example evaluate quality and uptake of advice on aseptic technique, anaesthesia/analgesia/peri-operative care.

10. *Re-use*

Have all aspects of reuse been taken into account?

- Evaluate whether appropriate severity of previous procedure has been allocated;
- Determine whether it is likely or apparent that the animal's general state of health and well-being have been restored;
- Determine whether veterinary advice was obtained and whether it took into account the lifetime experience of the animal.

11. *Setting free and Re-homing*

Are appropriate mechanisms in place and have these been applied correctly?

Factors to be considered include

- Check that the Member State allows re-homing or setting free. If so, determine whether
 - (a) the state of animal's health has been (likely to have been) evaluated correctly;
 - (b) any danger to public health, animal health or the environment has been duly considered, and there is considered to be no danger;
 - (c) appropriate measures taken to safeguard health of the animal.
- Review existence and quality of AWB advice on rehoming scheme, including appropriate socialisation.

12. *Projects (work in progress)*

- Projects checked to ensure compliance with authorisations;
- Appropriate planning and design of studies in progress. Evaluation of experiments to assess compliance with use of minimum numbers and achievement of objectives;
- Inspection of procedures being conducted to ensure procedure is appropriate and most refined (particular attention may be needed for new procedures e.g. new surgical procedure, where the procedure is new to the establishment and not yet standardised);
- Replacements are used where possible;
- Existence and quality of record keeping;
- Training, supervision and competence of staff carrying out work on the project;
- Records – source, use, fate of animals; staff training.

13. *Implementation of the Three Rs*

- Check approach to maintaining up to date information on the Three Rs and how this is disseminated within the establishment;
- Check that the Three Rs are being implemented in the use and care of animals within the establishment (e.g. long term projects, genotyping, breeding practices).

14. *Killing*

- Competency of staff;
- Compliance with Annex IV or other approved methods;
- Records – includes fate of animals; training records.

15. *Others*

- Evaluate whether AWB required tasks are being completed;
- Is the advice of the AWB properly documented;
- Assess whether the structure and function of the AWB is appropriate (e.g. by attendance at an AWB meeting).

Feedback should be provided to the establishment

- Identifying any issues that require correcting (e.g. non-compliance).
- Identifying areas for preventing non-compliance. Inspectors should report details of any non-compliance found to relevant competent authority.
- Provision of the timescale for any remedial actions to be completed (e.g. a Corrective and Preventive Action Plan (CAPA)).

Appendix III
Collection of guidance notes

Guidance Note 1

Inspecting compliance with Project Authorisations

Article 34 requires Member States to ensure that the competent authorities carry out regular inspections of all breeders, suppliers and users, including their establishments, to verify compliance with the requirements of this Directive. One such requirement is to ensure that projects are carried out in accordance with the authorisation from the competent authority or decision taken by the competent authority (Article 36).

The purpose of this advice note is to suggest ways that this can be achieved.

Inspection of project authorisation can be considered in three categories:

1. Planning and preparation for studies
2. Performance of procedures
3. Review of results and severity

1. Planning and preparation for studies

Items which may be assessed during inspection to ensure appropriate design and implementation of the three Rs

Appropriateness of experimental design

Evidence of seeking professional statistical advice on experimental design and planning of individual experiments, when these are not detailed in the project authorisation. Are experiments being done in a manner that will ensure robust results (e.g. random allocation of weight, sex, and aged matched animals, appropriate design)? This can be inspected by looking at numbers of animals in cages, layout of cages on cage racks, discussion of experimental design with project holders.

Use of specialist advice

Has advice from experts within the establishment or from other sources been sought before starting procedures, if appropriate? For example, input from designated veterinarian on anaesthesia or aseptic technique for surgical procedures.

Input from Animal Welfare Body

Evidence of AWB involvement/advice in refining procedures. Records of AWB decisions can be inspected and information gathered about the AWB involvement through discussions with scientists and care staff.

Staffing, training and competence

Is there evidence of adequate training and supervision of people carrying out procedures? Records of training of those carrying out procedures on animals can be assessed during inspection?

Are people carrying out procedures aware of the content of project authorisations and any limitations/restrictions that may have been imposed by the competent authority? This can be assessed during inspection through discussion with people carrying out procedures, and those with responsibilities for the care of the animal following procedures.

Animal care and accommodation; environment and equipment.

Is the accommodation suitable for the procedures being done – e.g. do metabolism cages meet minimum enclosure sizes for the species and if not is there a scientific or other acceptable reason why this is the case? Have metabolism cages been designed to minimise the effects of a barren environment on the animals?

2. Performance of procedures

Performance of procedures can be inspected by observing procedures, inspecting animals after procedures and inspecting records relating to the procedures.

Observing procedures

Are procedures being done included in the project authorisation? Procedures observed during inspection can be checked against those in project authorisations.

Are procedures seen being done in an appropriately refined manner e.g. surgery is being done aseptically; are animals being restrained in the most refined manner?

Is an appropriate anaesthetic regime being used? Where neuromuscular blocking agents are used are there suitable monitoring regimes in place (Article 14(3))?

Inspecting animals after procedures

Animals can be checked at appropriate times following procedures to observe clinical signs and look at records of any treatments provided. Are animals being monitored at sufficient frequency to detect adverse effects resulting from procedures? If unexpected adverse effects have occurred, has appropriate action been taken e.g. is

adequate treatment or other actions being taken to minimise any pain, suffering, distress or lasting harm, has consideration been given to ending the experiment? Has advice been sought regarding amendment to authorisation to increase severity classification if unexpected adverse effects have been seen?

Are anaesthetics and analgesics being given at appropriate times (e.g. are analgesics given both before and after surgery)?

If non Annex IV methods of killing are being used, are they consistent with the project authorisation and are they done competently?

3. Review of results and severity

Consistency with project authorisations

Are records of the procedures done consistent with project authorisations?

Are end points detailed in project authorisations being adhered to?

Mortality and morbidity records can be assessed against expected numbers and compared with the actual severity recorded.

Actual severity of procedures

Are records of actual severity consistent with procedures observed and/or clinical signs seen during inspection?

Re-use

Are adequate records of animals being re-used kept demonstrating compliance with Article 16?

Rehoming/setting free

Are the schemes for setting free/rehoming animals at the end of procedure meeting Article 19 requirements?

Appendix IV

Example of a numerical scoring system to assist in risk analysis (provided by Ireland)

Guideline	
Title	Risk assessment for frequency of conducting inspections relating to scientific animal protection
Scope	The establishment inspection schedule for the inspection of scientific animal establishments.

INTRODUCTION

National and EU legislation requires the competent authority to adapt the inspection schedule for the inspection of establishments breeding, supplying or using animals intended for scientific purposes on the basis of a risk analysis. This guide sets out the parameters for that analysis.

The competent authority is also required to conduct a number of unannounced inspections.

In addition to routine inspections, follow-up inspections may also be required to ensure that any remedial measures identified in earlier inspections have been completed.

Inspections shall be carried out on at least one third of the users each year in accordance with the risk analysis. An appropriate proportion of the inspections are carried out without prior warning.

APPROACH

The model is based on an analysis of the components, based on the legal parameters and other relevant considerations. A weighting is given to these components in the score range in order to calculate an overall risk level. The range of values takes into consideration the prior inspection or regulatory compliance history of the breeder, supplier or user establishment i.e. those with previous non-compliance histories receive enhanced (more penal) scores, thereby triggering more frequent future monitoring. Within each category, if more than one parameter applies, that assigned the highest risk level of any category is taken. These are then summed together to give an estimated risk ranking.

The risk analysis should be conducted on an annual basis and the rating used throughout the following year (save in exceptional cases where new information comes to light).

Animal species, scale 1-20 (1= lowest risk, 20 = highest risk)

Non-human primate	20
Cats, dogs, equidae	4
Farm animals	3
Rabbits, guinea pigs, ferrets	3
Wild animals	3
Rats, mice, fish, birds	2
Invertebrates (including cephalopods)	1

Number of animals kept in breeder, supplier or user establishment, scale 1-5 (1= lowest risk, 5 = highest)

> 30,000	5
> 20,000 but < 30,000	4
> 10,000 but < 20,000	3
> 3,000 but < 10,000	2
<3,000	1
Procedures involving any number of fish or cephalopods	1

Compliance record of breeder, supplier or user establishment, scale 1-10 (1 = lowest risk, 10 = highest)

Critical non-compliances detected within past year	10
Critical non-compliances detected between one and three years ago	8
Major non-compliances detected within the past year	6
Major non-compliances detected between one and three years ago	4
No major or critical non-compliances detected within the last three years	1
Newly authorised (in past 12 months) establishment	5

Regulatory actions taken against breeder, supplier or user establishment, including personnel and projects, scale 1-10 (10 = highest)

Court convictions within past year	10
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Court convictions within past three years	8
Financial penalty within past year	7
Financial penalty within past three years	6
Revocation or suspension of authorisation(s) within past year	2-10
Revocation or suspension of authorisation(s) within past three years	2-8
Compliance notice issued within past year	5
Compliance notice issued within past three years	3
Animal welfare notice(s) issued within past 3 years	2-8
No regulatory action has been taken in past three years	1

Profile of staff conducting procedures/euthanasia in breeder, supplier or user establishment, scale 1-5 (5 = highest)

> 30% of staff or researchers have been recruited in last year	5
> 20 but < 30% of staff or researchers have been recruited in last year	4
> 10 but < 20% of staff or researchers have been recruited in last year	3
All other cases	1

Types of projects and procedures conducted at the breeder, supplier or user establishment, scale 1-5 (5=highest)

>30% of projects have a severity classification of severe	5
>30% of projects have a severity classification of moderate	4
Majority of procedures have a severity classification of mild or non-recovery	3
Breeding of genetically altered animals (only)	2
Breeding animals for their tissues or organs (only)	1

Other considerations on case-by-case basis, scale -10 to +10 (-10 = most favourable level)

Non-scientific animal protection inspections being carried out at the breeder, supplier or user establishment (e.g. Good Laboratory Practice (GLP) inspections):	-5
Personnel, facilities or premises undergoing significant change	5
Breeder, supplier or user establishment has multiple sites	3
Other (indicate and justify)	x (-10 to +20)

SAMPLE SCENARIOS AND RISK ASSESSMENT CALCULATIONS

Refer to Table below for sample scenarios and their risk assessment calculations.

REVIEW OF RISK RATINGS

On the basis of the above model, all breeder, supplier or user establishments are scored and a spreadsheet created to record the individual establishment risk scores.

The breeder, supplier or user establishments are ranked from highest score (highest risk) to lowest score (lowest risk). The highest scoring establishment(s) will be inspected at least once annually, with the lowest scoring establishment(s) inspected at least once every three years. If breeder, supplier or user establishments have the same risk ratings, priority for inspection should be given to those establishments with the greatest number of project authorisations. This risk scoring should only be used as a general guide.

The competent authority will review the inspection targets each year, as part of its normal planning cycle.

TABLE 1 SAMPLE SCENARIOS AND RISK ASSESSMENT CALCULATIONS

Some fictitious examples of how to calculate a risk score for various types of establishments are given below:

1. Very large contract research facility, 24,000 animals, houses rodents and dogs, long-serving staff, regulatory tests classified as ‘severe’ GLP facility, regulatory compliant: 11.
2. Large university facility, multiple sites, keeps 6,000 rodents, high student turnover, non-recovery research, compliant: 17.
3. Small higher-level facility, 15% of staff are new recruits, currently building new premises keeps 500 rodents for organs only, previous major non-compliance detected within past year: 19.
4. Small contract research facility, keeps 22,000 fish, long-serving staff, regulatory tests classified as ‘severe’, compliant: 11.
5. Government farm, keeps 250 wild animals, long-serving staff, research studies classified as ‘moderate’, compliant: 11.
6. Government farms located in different provinces, keep 900 livestock, long-serving staff, research trials classified as ‘mild’, compliant: 13.

	Species	No. of animals	Compliance record	Regulatory action record	Profile of personnel	Project/ procedure type	Other considerations	Score total
Score range/ Scenario	1-20	1-5	1-10	1-10	1-5	1-5	-10 - +20	
1	4	4	1	1	1	5	-5	11
2	2	2	1	1	5	3	3	17
3	2	1	6	1	3	1	5	19
4	2	1	1	1	1	5	0	11
5	3	1	1	1	1	4	0	11
6	3	1	1	1	1	3	3	13

Appendix V

Suggestions for the development of an inspection reporting template

This Appendix contains a list of suggestions developed by the Expert Working Group on Inspection and Enforcement that could be considered when developing a standard template for reporting on inspections to contribute to the Article 54(1) report on implementation of the Directive as detailed in Section E "Enforcement" of Annex I of Commission Implementing Decision 2012/707/EU.

Depending on how the inspection requirements are met within each Member State, there may be some of these suggestions which would be difficult to meet within a common EU reporting format. The suggestions below were not discussed by the Member States and could therefore not be endorsed as part of this guidance document. However, the suggestions are reproduced here in full for consideration.

- factors included in the risk analysis (standard EU list); description of the inspection process;
- description of inspectorate including inspector qualifications and structure (general animal welfare inspectors versus specialised inspectors for laboratory animal science);
- description of the inspection process— who and how, planning;
- rationale for announced versus unannounced visits;
- the number of planned versus actual inspection numbers with explanation if targets not met;
- the number of establishments versus those inspected (absolute and proportion);
- type of establishments (broken down by users, breeders and suppliers);
- number of visits (announced versus unannounced);
- number of inspectors (Full Time Equivalents – FTEs);
- total time devoted to inspection process (hours on inspection, preparation and reporting);
- risk rating of establishments and relative frequency of inspections (high, medium, low); description (qualitative) of type of inspections e.g. general, housing and care, specific projects/persons, assessing education and training/supervision and competence;
- report maximum period between visits for establishments which are breeding, using or holding animals;
- summary/assessment of inspection results including impact on the Three Rs - benefits, trends (improvements);
- description of infringement handling practices;
- description of penalties for non-compliance;
- summary of non-compliance, infringements and actions taken;

- quantitative (numbers) and qualitative information on non-compliance, in particular their impact on animals;
- to consider potential links with inspection report to statistical reports on animal use.