

Question VII.Aa.

Question text:

Introduction

VII.a) Current provisions of Directive 86/609/EEC

User establishments are subject to periodic inspections.

VII.b) Current situation in Member State

All Member States have an infrastructure for periodic inspections. The frequency of inspections varies significantly from one Member State to another.

VII.c) Trends and implications

Inspections are highlighted as one of the main tool for ensuring compliance with legislation and minimum requirements. Some Member States have over the recent years made specific investments to increase the training of inspectors and the frequency of visits. In UK, for example, same establishment can have multiple inspections over a period of one year many of which are unannounced.

VII.d) Problem dimension

The Directive does not specify any frequency of inspection apart from being periodic. Furthermore, the current requirement for inspections only covers user establishments leaving breeding and supplying establishments outside the requirement.

Since there is no EU wide requirement for inspections, it results in a low public perception of levels of compliance and its assurance by the authorities. Furthermore, if inspections are announced prior to the visit, it may result in providing an unrealistic picture of the day to day running of the establishment. In case full compliance is not assured, animal welfare may be compromised.

VII.e) Potential solutions

The revision of the Directive could harmonise the requirement for annual inspections at the level of two of which one could be unannounced. A system of EU inspections could be envisaged.

Do you support this analysis?

Statistics:

138 respondents stated that they support the preliminary analysis.

16 respondents stated that they have no opinion in relation to this question.

59 respondents stated that they do not support the preliminary analysis or components of it. To justify disagreement, they were asked to provide arguments, facts and figures and if possible indicate the source of information. However, a number of respondents opted for the "No" reply only to supply additional arguments in support of the preliminary analysis.

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII.Aa.
Dept. Laboratory Animal Science, Utrecht University, The Netherlands	User of animals - public sector	Worldwide	chair of lab. animal sci. recognized by national authorities/ responsible for national coordination education and training in lab. animal sci. / leading role in international laboratory animal science	Although a minimum requirement for inspections may be beneficial, a system of EU inspections would be costly and of doubtful value.
Gesellschaft zur Förderung der biomedizinischen Forschung	User of animals - public sector	National	The organisation is representative for the field at the respective activity level.	at VII.e) Potential solutions No Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !

Hannover Medical School	User of animals - public sector	Local; Regional; National	Hannover Medical School currently ranks highest with respect to research activities and acquired research grants	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work!
Hans J. Hedrich	User of animals - public sector	Local; Regional; National; European	I am currently President of the European College of Laboratory Animal Medicine (ECLAM) and Vicepresident Gesellschaft zur Förderung der Biomedizinischen Forschung	No. Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work!
Prof. Dr. R. Nobiling, University of Heidelberg	User of animals - public sector	Regional; National; European; Worldwide	Biomed research at Univ. Heidelberg is Top - ranked	" annual inspection "too rigid

Timo Nevalainen	User of animals - public sector	Local	Yes	EU inspections will not be efficient and cause high costs. It is far more productive to emphasize training and consequent competencies.
Torgny Jeneskog, Umeå University, Sweden	User of animals - public sector	Local; Regional; National	Yes, guess so ...	I agree to the proposal of 2 annual inspections, but not to a "system of EU inspections" if this means inspections from an EU (and not a national) authority. See Option 2.
(Name confidential - Respondent 001)	User of animals - public sector	National; European; Worldwide	yes	EU inspections cause high costs and give no real advantage over national or local inspections.
(Name confidential - Respondent 004)	User of animals - public sector	National	XXX are representative of our scientific activity (basic research)	It is not because an inspection is announced with a two-days notice that, all the sudden, bad practices disappear or can be hidden from the inspectors. Announcing inspections is a form of mutual respect. An example : in France, there are fixed radars on road sides which are clearly announced with large signs. This has been more efficient in reducing death toll than mobile, unannounced radars. Inspectors and actors of animal experimentation have to work together, not play a cat and mouse game.
(Name confidential - Respondent 005)	User of animals - public sector	Worldwide	there are others	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 006)	User of animals - public sector	National	representative	A system of EU inspections will be unrealistic in terms of costs and bureaucratic complexity.
(Name confidential - Respondent 010)	User of animals - public sector	Worldwide	One of several global pharmaceutical companies	I agree to the necessity to include breeding and supplying facilities, but do not understand the necessity for the high frequency and unannounced inspections which seem to be guided by considerable mistrust

(Name confidential - Respondent 018)	User of animals - public sector	Not applicable	we are a medical university.	We already have local government surprise inspections. I think that it is a waste of time and money to have EU inspections in addition to what we have already.
(Name confidential - Respondent 023)	User of animals - public sector	Local; National	There are several central laboratory animal facilities at Austrian universities	EU inspections would be certainly much more expensive with no additional value
(Name confidential - Respondent 032)	User of animals - public sector	Local	yes	No. EU inspections do not have a real value, will be not efficient and cause high costs.
(Name confidential - Respondent 036)	User of animals - public sector	Worldwide	Yes	Are the inspections supposed to control appliance or supposed to keep the standard up. the first will never be achieved in this way. For the second less inspections are sufficient.
(Name confidential - Respondent 042)	User of animals - public sector	National	yes	At the XXX University, we have continuous inspection by the local representative of the National Animal Experiment Ethics Review Committee. No costly EU commissary is needed.
(Name confidential - Respondent 051)	User of animals - public sector	National	yes	see below
(Name confidential - Respondent 054)	User of animals - public sector	National	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !

GlaxoSmithKline	User of animals - private sector	Worldwide	There are other international pharmaceutical companies. We produce 25% of the worlds vaccines	Some national inspection is warranted, but not a duplicative second tier of EU inspection
sanofi pasteur R&D	User of animals - private sector	Worldwide	Vaccine field	We definitely need inspections to prove research integrity and conducted efforts. But the communication to public opinion should be improved: public should be aware about the inspection process but not the outcomes are they are confidential. Inspections are expensive and member states should have to accept the twice-per-year inspection.
(Name confidential - Respondent 074)	User of animals - private sector	Worldwide	Yes	Paragraphs a)to d) are supportable. Paragraph e introduces the concept of 2 inspections per year, without any particular rationale.
(Name confidential - Respondent 075)	User of animals - private sector	Worldwide	Research and development	no comment
(Name confidential - Respondent 076)	User of animals - private sector	Worldwide	Yes	where inspections are also considered important (e.g. GLP inspections), the frequency is less than yearly. The benefit of unannounced inspections is questionable, since experimental and housing conditions will not be altered because of inspections, as loss of standardization would harm research results. Since access to animal housing facilities are often very restricted, announcement of inspection allows good preparation and time-saving for the inspector.
(Name confidential - Respondent 077)	User of animals - private sector	Worldwide	yes it's representative	Too specific country-based regulations and rules exists

(Name confidential - Respondent 081)	User of animals - private sector	Worldwide	other relevant organisations	no comment
(Name confidential - Respondent 084)	User of animals - private sector	Worldwide	yes	National inspections are enough and more effective
(Name confidential - Respondent 088)	User of animals - private sector	Worldwide	pharmaceutical	An inspection twice a year would generate a substantial additional cost for the national authorities, where once a year or even every 2-3 years should already be frequent enough to have a good idea about the compliance issues.
(Name confidential - Respondent 112)	User of animals - private sector	Worldwide	There are any other relevant organisations but we are making research with rodents	There are not enough inspectors for doing annual inspections. It is not a potential solutions (the differets membres will agree but It will be imposiple to do
(Name confidential - Respondent 198)	User of animals - private sector	Worldwide	Don't understand this question	Paragraphs a to d are supportable. Paragraph e introduces the concept of 2 inspections per year, without any particular rationale.

Animal Procedures Committee (APC)	Public authority	National	The APC provide independent advice to UK Government on the use of animals in scientific procedures. The APC consider science, industry and animal welfare. Members are from a variety of backgrounds.	The UK has a rigorous inspection process implemented by the Home Office. As the consultation states, there is the possibility of many inspections per year in the UK, some of which are unannounced. The inspections need to be risk based and proportionate. One or two a year might be suitable for some establishments but not for others. Clarification is required in the use of the terms 'facilities' and 'establishment'. One establishment may have multiple facilities playing host to a large number of experiments. Such subtleties need to be considered so that the resultant quantitative data can be interpreted correctly. Given the amount of inspection in the UK, we cannot see the justification for another layer of inspectorate at the European level.
Coordination group for laboratory animal activities	Public authority	National	Yes	EU inspections will not be efficient and cause high costs. It is far more productive to emphasize training and consequent competencies.
DR Achim Klug, Ludwig Maximilians University Munich	Public authority	Worldwide; Not applicable	Deutsche Forschungsgemeinschaft - DFG	We do need EU inspections. We are currently receiving plenty of inspections, some of them unannounced and there is no need for more.

MA 60- Veterinäramt, Wien/Vienna	Public authority	Local; Regional	yes	All inspections should be unannounced
MA 60- Veterinäramt, Wien/Vienna	Public authority	Local; Regional	yes	All inspections should be unannounced
(Name confidential - Respondent 115)	Public authority	Local	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 116)	Public authority	Local	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 122)	Public authority	National	We are the National Competent Authority	We do not support a system of EU inspections (which we would expected to be funded and delivered by the Commission), which, as your later analysis confirms, would entail very high resource and compliance costs and produce no meaningful benefits. Regarding the wider issue of inspection, in our view the focus must be on what inspection is intended to achieve, and not simply the frequency of inspection. For example, in the UK risk-based inspections are carried out to determine that procedures are performed as authorised; that the terms and conditions of authorised programmes are being adhered to; and to identify and spread best practice.
(Name confidential - Respondent 125)	Public authority	National	yes	In Italy, the option of two inspections per year is utopian and unrealistic.
(Name confidential - Respondent 127)	Public authority	National	Ministry of VWS is also involved	2 inspections might be enough for some. But in general it is not enough.

(Name confidential - Respondent 128)	Public authority	National; European; Worldwide	Although we are a smaller University, about half of the research groups involving animal experiments belong to leading institutions in their field.	Regulating/increasing the inspections through national authorities will mainly increase costs but might have little direct benefit on animal welfare. Qualified laboratory animal veterinarians (veterinary surgeons) are more suitable to attend the daily routine of an institution and to improve animal welfare.
(Name confidential - Respondent 129)	Public authority	National	representative	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
COST Action B24 “Laboratory Animal Science Welfare” - http://biomedicum.ut.ee/costb24	Other	European	No	No. EU inspections do not have a real value, will be not efficient and cause high costs. It is far more productive to emphasize training and consequent competencies.
Medical University of Vienna	Other	Local; Regional; National; European; Worldwide	Research in Medicine	EU inspections cause high costs and give no real advantage over national or local inspections

(Name confidential - Respondent 138)	Other	National	I am the chair of the Hungarian Scientific Ethical Committee on Animal Experimentation	VII.e. It is unjustified to generalize the British practice to the whole EU. Perhaps in Britain frequent and unannounced inspections are necessary to calm down the public, but in other countries there may be no reason to do this. Public perception of compliance does not depend on the number of inspection but it depends on the results of the inspections. In addition, state administration should act in a coherent way. If other authorities (tax, occupational, public health, fire, etc.) do not practice mandatory unannounced inspection the animal welfare authority should not do either (equal treatment). One mandatory inspection a year would be sufficient for the majority of member states and further, unannounced inspection would be at the discretion of national authorities.
(Name confidential - Respondent 141)	Other	Not applicable	other	EU inspections cause high costs and give no real advantage over national or local inspections.
(Name confidential - Respondent 143)	Other	National	Regulatory body	Inspection pattern and frequency should be based on risk and inspections should be conducted with particular clear objectives. Mandating the number of times places are visited provides very limited reassurance to the public however it is probably reasonable to mandate a minimum inspection requirement of once per year. Inspections should have a clear objective and public reassurance can be gained by providing a clear explanation of the purpose of inspection
Austrian Society of Toxicology (ASTOX)	Non-governmental organisation	National	Yes	EU inspections do not have a real value, will be not efficient and cause high costs.

FELASA (Federation of European Laboratory Animal Science Associations)	Non-governmental organisation	European	FELASA represents 13 European lab animal sci associations and therefore some 3-4000 members of those associations (scientists, veterinary surgeons, technicians etc.). See www.felasa.org	Although a minimum requirement for inspections may be beneficial, a system of EU inspections would be costly and of doubtful value.
Gesellschaft für Versuchstierkunde - Society for Laboratory Animal Science (GV-SOLAS)	Non-governmental organisation	National; European	Yes	No. EU inspections do not have a real value, will be not efficient and cause high costs.
Stichting EDEV - Een DIER Een VRIEND	Non-governmental organisation	National; European	We cooperate with animal organisations within the ECEAE	Annual inspections are not enough most lab animals are killed before the have been in the laboratoy one year.

(Name confidential - Respondent 164)	Non-governmental organisation	National	yes	EU inspections cause high costs and give no real advantage over national or local inspections.
(Name confidential - Respondent 166)	Non-governmental organisation	National	NO OTHER RELEVANT ORGANISATION	No need for unannounced inspections. Lack of efficiency and very high cost for European inspections.
(Name confidential - Respondent 169)	Non-governmental organisation	National	Represents all Finnish pharmacologists	Inspection system in Finland is good enough - no need to expand it
(Name confidential - Respondent 180)	Non-governmental organisation	Not applicable	yes	Absolutely no. An EU inspection is very costly and ineffective. National standards are sufficient
(Name confidential - Respondent 182)	Breeder of animals	Worldwide	Representative	In Germany there is already a strict compulsory monitoring by local government authorities. A local animal welfare officer (independent from research projects) in each research place would have more and effective impact on animal welfare (see regulations in germany).
(Name confidential - Respondent 187)		National; European; Worldwide	yes	EU inspections cause high costs and give no real advantage over national or local inspections.
(Name confidential - Respondent 192)		National; European; Worldwide	Yes	see below

Question VII.1.1.

Question text:

The overall preliminary assessment shows positive impacts in terms of increase in animal welfare, public perception and transparency. The costs for Member states would increase moderately, when intensifying the level of inspections.

Do you support this overall analysis? Yes/No/No opinion

Statistics:

132 respondents stated that they support the preliminary analysis.

33 respondents stated that they have no opinion in relation to this question.

62 respondents stated that they do not support the preliminary analysis or components of it. To justify disagreement, they were asked to provide arguments, facts and figures and if possible indicate the source of information. However, a number of respondents opted for the "No" reply only to supply additional arguments in support of the preliminary analysis.

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII.1.1a.

Gesellschaft zur Förderung der biomedizinischen Forschung	User of animals - public sector	National	The organisation is representative for the field at the respective activity level.	at 1.1. , 1.2 No Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
Hannover Medical School	User of animals - public sector	Local; Regional; National	Hannover Medical School currently ranks highest with respect to research activities and aquired research grants	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work!
Hans J. Hedrich	User of animals - public sector	Local; Regional; National; European	I am currently President of the European College of Laboratory Animal Medicine (ECLAM) and Vicepresident Gesellschaft zur Förderung der Biomedizinischen Forschung	No. Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work!

Prof. Dr. R. Nobiling, University of Heidelberg	User of animals - public sector	Regional; National; European; Worldwide	Biomed research at Univ. Heidelberg is Top - ranked	: cost für mthe memeber states will increase prop. To the number of inspections: qualified personnel is needed according to inspection demands
(Name confidential - Respondent 001)	User of animals - public sector	National; European; Worldwide	yes	Inspections have to approve the facility with regard to housing and care standards. If a facility has undergone this thorough procedure and thus obtained the license, it should be known to the authorities and one single control per year should be sufficient.
(Name confidential - Respondent 004)	User of animals - public sector	National	XXX are representative of our scientific activity (basic research)	The public does not suspect researchers from dishonesty. Mandatory need for unannounced inspection might induce lack of understanding and doubt.
(Name confidential - Respondent 005)	User of animals - public sector	Worldwide	there are others	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 010)	User of animals - public sector	Worldwide	One of several global pharmaceutical companies	The necessity for the high frequency and unannounced inspections is obviously guided by substantial but mostly unjustified mistrust. EU agencies should not further contribute to such unjustified mistrust which might have negative implications on public perception.
(Name confidential - Respondent 014)	User of animals - public sector	Local; Regional; National; European; Worldwide	Yes	see 1.6
(Name confidential - Respondent 017)	User of animals - public sector	National; European; Worldwide	Yes	The frequency is insufficient and would allow likely inspections to be calculated by individuals unless these were combined with frequent National inspections.

(Name confidential - Respondent 018)	User of animals - public sector	Not applicable	we are a medical university.	we do not need more surprise inspections. The level of inspections seems appropriate. Cost- benefit ratio is low. We are aware of the standards and recognizing that we can be checked at any time, already keeps up good maintenance standards.
(Name confidential - Respondent 023)	User of animals - public sector	Local; National	There are several central laboratory animal facilities at Austrian universities	Increase in inspection frequency can have only little impact as the standards are high except in member states where it is not done yet.
(Name confidential - Respondent 032)	User of animals - public sector	Local	yes	No, because more inspections do not necessarily mean increase in animal welfare but it might increase cost and time loss, depending on the way how it is done. Animal welfare is particularly dependant on qualified persons (animal keepers, veterinary surgeons, experts for laboratory animal science) working in an establishment, their knowledge and appropriate equipment..
(Name confidential - Respondent 036)	User of animals - public sector	Worldwide	Yes	Are the inspections supposed to control appliance or supposed to keep the standard up. the first will never be achieved in this way. For the second less inspections are sufficient.
(Name confidential - Respondent 040)	User of animals - public sector	Local; Regional; National; European; Worldwide	Yes	The number of inspections should be targeted to size of facility and nature of work - not just a set amount!
(Name confidential - Respondent 043)	User of animals - public sector	Local; Regional; National; European; Worldwide	YES	See Section "Justification"

(Name confidential - Respondent 046)	User of animals - public sector	National	yes	Actually, we are inspected usually a year. Some inspections are unannounced. Doubling the number of inspections will induce a 100% increase of the cost of inspections for MS.
(Name confidential - Respondent 051)	User of animals - public sector	National	yes	there are already difficulties to perform one annual inspection, thus the proposed increase is unrealistic without a high cost
(Name confidential - Respondent 054)	User of animals - public sector	National	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 066)	User of animals - public sector	Worldwide	Yes, representative	My long experience disagrees with this analysis. Inspections have had on average a negative impact on the welfare of my animals.
sanofi pasteur R&D	User of animals - private sector	Worldwide	Vaccine field	We definitely need inspections to prove research integrity and conducted efforts. But the communication to public opinion should be improved: public should be aware about the inspection process but not the outcomes are they are confidential. Inspections are expensive and member states should have to accept the twice-per-year inspection.
(Name confidential - Respondent 074)	User of animals - private sector	Worldwide	Yes	Will more depend on quality of inspections and consequences of non-compliance.
(Name confidential - Respondent 075)	User of animals - private sector	Worldwide	Research and development	ok for visits and transparency but what is the interest of unannounced visits while in principle laws are respected. Is it necessary to suspect laboratories and to induce public distrust ?

(Name confidential - Respondent 076)	User of animals - private sector	Worldwide	Yes	See overall analysis: The impact on animal welfare is considered low since no sensible research site will change conditions because of announcement of an inspection, therefore the general benefit of an unannounced inspection not to allow special preparations at the inspected site is not expected. In addition, inspection is often not only related to a site visit, but also to a check of paper work, and there, preparation of the site is useful to allow an effective use of the time of the inspector.
(Name confidential - Respondent 081)	User of animals - private sector	Worldwide	other relevant organisations	no comment
(Name confidential - Respondent 084)	User of animals - private sector	Worldwide	yes	Animal welfare does not depend on a certain number of inspections, there are already high standards, standards will never be adjusted to the number of inspections, the costs would be higher
(Name confidential - Respondent 088)	User of animals - private sector	Worldwide	pharmaceutical	An formal inspection twice a year would generate a substantial additional cost for the national authorities, where once a year or even every 2-3 years should, already be frequent enough to have a good idea about the compliance issues. This would be enough if this is additional to the current participation of an inspector at all ethics committee meetings and subsequent informal visits of the animal research labs and the annual reports sent by the animal welfare officer to the inspectorate (like it currently is in Belgium). Currently, AAALAC international is already used more and more and may serve as a 'international calibration tool'. fyi: AAALAC assesses reports once a year and visits the facilities every 3 years.
(Name confidential - Respondent 091)	User of animals - private sector	Worldwide	YES (Safety Assessment)	The cost would increase significantly for Member states who have no regular inspection processes. The current frequency is less than a visit/year.
(Name confidential - Respondent 198)	User of animals - private sector	Worldwide	Don't understand this question	In the UK, for many establishments, 2 inspections per year would be a significant decrease, and might have a negative impact.

Bart Hoet	Public authority	National	Yes, representative	Associated with an elevated cost (personnel !).
Federal Public Service - Public Health (div. animal welfare & CITES)	Public authority	National	Yes, representative.	As for EU administration intensifying inspections at least twice a year per laboratory will highly and not moderately increase the costs and the administration for national authorities.
UK Medical Research Council	Public authority	Local; Regional; National; European; Worldwide	The MRC is the UK's leading publicly funded biomedical research organisation	Rather than fixing a standard to apply to all facilities, it would be better to target the number of visits according to the size of the facility and the nature of the procedures. This is current practice in the UK.
Universidad de Zaragoza	Public authority	European	yes	One yearly inspection by national authorities offers enough garaty. The inspections should be always announced. If the local inspection is made properly a twice yearly inspection by the national authorities is not considered compulsory.
(Name confidential - Respondent 115)	Public authority	Local	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 116)	Public authority	Local	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 120)	Public authority	National; European; Worldwide	Yes	It is good for inspectors to visit more frequently so that understanding of the work and supportive rather than policing relationships with research community can be encouraged.

(Name confidential - Respondent 122)	Public authority	National	We are the National Competent Authority	A formal risk-based and objective driven inspection programme is required. Option 1 would be much less effective than a risk-based assessment programme with specific performance objectives. From experience we know that the inspection frequency and the nature and outcome of the inspection programme must be tailored to the risks and objectives of inspection. These essential requirements are not captured by this option.
(Name confidential - Respondent 124)	Public authority	National	yes	In Italy, where there are approximately 300 animal user establishments, the option of two inspections for year is utopian and unrealistic; current personnel would have to be increased by twenty to cover all the establishments twice a year.
(Name confidential - Respondent 127)	Public authority	National	Ministry of VWS is also involved	In some countries it would not mean intensifying it would mean decreasing number of inspections
(Name confidential - Respondent 128)	Public authority	National; European; Worldwide	Although we are a smaller University, about half of the research groups involving animal experiments belong to leading institutions in their field.	Same as comment on analysis (above)
(Name confidential - Respondent 129)	Public authority	National	representative	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !

1. Animal Aid	Other	National	Other organisations do exist	Although extending the scope of the directive to include twice yearly inspections has the potential to improve animal welfare, experience in the UK indicates that this will not necessarily follow.
COST Action B24 “Laboratory Animal Science Welfare” - http://biomedicum.ut.ee/costb24	Other	European	No	No, because more inspections do not necessarily mean increase in animal welfare but it might increase cost and time loss, depending on the way how it is done. Animal welfare is particularly dependent on qualified persons (animal technicians, veterinary surgeons, experts in laboratory animal science) working in an establishment, their knowledge and appropriate equipment.
Medical University of Vienna	Other	Local; Regional; National; European; Worldwide	Research in Medicine	Inspections have to approve the facility with regard to housing and care standards. If a facility has undergone this thorough procedure and thus obtained the license, it should be known to the authorities and one single control per year should be sufficient.
The Association for the Study of Animal Behaviour	Other	Worldwide	yes	see 1.6 below
(Name confidential - Respondent 138)	Other	National	I am the chair of the Hungarian Scientific Ethical Committee on Animal Experimentation	In my country even the regular yearly inspection means a great job for the authority, they simply have not got enough personnel for doubling the number of inspections.

(Name confidential - Respondent 141)	Other	Not applicable	other	1 Inspections have to approve the facility with regard to housing and care standards. If a facility has undergone this thorough procedure and thus obtained the license, it should be known to the authorities and one single control per year should be sufficient.
(Name confidential - Respondent 143)	Other	National	Regulatory body	As above - inspection pattern should be based on risk, complexity of work, size of establishment etc. Also inspections should have clear objectives rather than fulfilling the sole requirement of having been on that particular premises on a mandated number of occasions.
(Name confidential - Respondent 153)	Other	National	Yes	Numbers of inspections may be better determined by the severity of the procedures being carried out at a particular site.
(Name confidential - Respondent 160)	Other	National	there are other relevant organisations	one unannounced inspection per year is enough according to me.
Gesellschaft für Versuchstierkunde - Society for Laboratory Animal Science (GV-SOLAS)	Non-governmental organisation	National; European	Yes	No, because more inspections do not necessarily mean increase in animal welfare but it might increase cost and time loss, depending on the way how it is done. Animal welfare is particularly dependant on qualified persons (animal keepers, veterinary surgeons, experts for laboratory animal science) working in an establishment, their knowledge and appropriate equipment.
Stichting EDEV - Een DIER Een VRIEND	Non-governmental organisation	National; European	We cooperate with animal organisations within the ECEAE	Only if all is public all reports and findings something might become more transparant

The National Anti-Vivisection Society	Non-governmental organisation	National; European; Worldwide	The NAVS is the leading and oldest anti-vivisection organisation in the world. There are a number of other relevant anti-vivisection organisations around the world with expertise in this field.	We do not agree that two inspections annually is sufficient. Establishments vary in size and number of animals and differing species vary. It is important that establishments expect inspections to occur regularly and unannounced in order to boost motivation to maintain standards and follow procedures. The NAVS reports Access Denied, Labs Unlocked, Vivisection in Britain and Inveresk have all highlighted problems with the UK inspection system. This has included certain animal rooms not being checked on visits, even though they may contain hundreds of animals. Series irregularities in killing procedures at one laboratory led to the licence being revoked following the NAVS investigation but the normal Home Office inspection process had failed to identify this (Access Denied, 1996). (http://www.navs.org.uk/publications/reports/).
(Name confidential - Respondent 164)	Non-governmental organisation	National	yes	Inspections have to approve the facility with regard to housing and care standards. If a facility has undergone this thorough procedure and thus obtained the license, it should be known to the authorities and one single control per year should be sufficient.
(Name confidential - Respondent 166)	Non-governmental organisation	National	NO OTHER RELEVANT ORGANISATION	The public does not suspect researchers from dishonesty. Mandatory need for unannounced inspection might induce lack of understanding and doubt.
(Name confidential - Respondent 167)	Non-governmental organisation	National	YES	This has to be left to the judgment of National Authorities.
(Name confidential - Respondent 169)	Non-governmental organisation	National	Represents all Finnish pharmacologists	Inspection system in Finland is good enough - no need to expand it

(Name confidential - Respondent 176)	Non-governmental organisation	Worldwide	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 180)	Non-governmental organisation	Not applicable	yes	The costs would largely increase and public perception is not a measured. Transparency should be gained nationally.
(Name confidential - Respondent 182)	Breeder of animals	Worldwide	Representative	The cost will arise dramatically because high qualified and experienced personel is indispensable in such a position.
giacomo Ri(olatti		National; European; Worldwide	it is represntative	The philosophy behind this point is that scientists and the veterinarian authorities controlling animal experiment do not care sufficiently about animal welfare. This is offensive to the people working on animals and especially to veterinarians that have as their duty to control the correct use of experimental procedures. Especially offensive is the non-announced visit that even more stress the lack of trust in people involved in research.
(Name confidential - Respondent 187)		National; European; Worldwide	yes	Inspections have to approve the facility with regard to housing and care standards. If a facility has undergone this thorough procedure and thus obtained the license, it should be known to the authorities and one single control per year should be sufficient.
(Name confidential - Respondent 192)		National; European; Worldwide	Yes	see below
(Name confidential - Respondent 193)		National	There are other relevant organisations	Inspections should be done at National levels, as they would be more effective.

Question VII.1.2.

Question text:

Impacts to establishments: 0

The costs for establishments would be very low and confined to a disruption of daily routines on the day of inspection.

Do you support the preliminary findings? Yes/No/ No opinion

Statistics:

151 respondents stated that they support the preliminary analysis.

25 respondents stated that they have no opinion in relation to this question.

47 respondents stated that they do not support the preliminary analysis or components of it. To justify disagreement, they were asked to provide arguments, facts and figures and if possible indicate the source of information. However, a number of respondents opted for the "No" reply only to supply additional arguments in support of the preliminary analysis.

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII. 1.2a.

Gesellschaft zur Förderung der biomedizinischen Forschung	User of animals - public sector	National	The organisation is representative for the field at the respective activity level.	at 1.1. , 1.2 No Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
Hannover Medical School	User of animals - public sector	Local; Regional; National	Hannover Medical School currently ranks highest with respect to research activities and aquired research grants	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work!
Hans J. Hedrich	User of animals - public sector	Local; Regional; National; European	I am currently President of the European College of Laboratory Animal Medicine (ECLAM) and Vicepresident Gesellschaft zur Förderung der Biomedizinischen Forschung	see 1.1

(Name confidential - Respondent 001)	User of animals - public sector	National; European; Worldwide	yes	If the inspection has to control the ongoing experiments, their compliance with the authority's permission, the number of animals used, etc. the working disruptions in central facilities will be enormous due to the large number of projects. Furthermore, unannounced inspections may cause problems, if the responsible people are occupied by clinical and other duties or are absent (e.g. international meetings, sick leave etc.). In the worst case, ongoing experiments with a sensitive time schedule may be totally ruined, associated with tremendous financial and intellectual damage to both society and the investigator.
(Name confidential - Respondent 004)	User of animals - public sector	National	XXX are representative of our scientific activity (basic research)	The cost could be enormous when experiments need to be interrupted on inspectors request. Unannounced inspections are already performed from time to time in France.
(Name confidential - Respondent 005)	User of animals - public sector	Worldwide	there are others	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 010)	User of animals - public sector	Worldwide	One of several global pharmaceutical companies	Such disruption of daily routines by repeated inspections every year causes at least moderate costs. The farer reaching impact of mistrust is more important and difficult to quantify.

(Name confidential - Respondent 011)	User of animals - public sector	National; European; Worldwide	Other organisations in Austria: Karl-Franzens-University; Medical University Vienna; Medical University Innsbruck	See 1.6
(Name confidential - Respondent 014)	User of animals - public sector	Local; Regional; National; European; Worldwide	Yes	see 1.6
(Name confidential - Respondent 018)	User of animals - public sector	Not applicable	we are a medical university.	disruption of daily routines may be very harmful. In fact, it may ruin ongoing experiments, leading to repeated experiments and higher animal requirements. It also interferes with the ongoing work.
(Name confidential - Respondent 021)	User of animals - public sector	Regional	yes	see 1.6
(Name confidential - Respondent 023)	User of animals - public sector	Local; National	There are several central laboratory animal facilities at Austrian universities	Unannounced inspections may cause problems if the people responsible are occupied by other duties or absent and in the worst case an experiment may be disturbed.

(Name confidential - Respondent 032)	User of animals - public sector	Local	yes	No, depending on the day disruption of the daily routines may cause considerable costs. Experiments/meetings have to be stopped because persons being responsible for the animal facility and the different experiments have to be on inspectors command to show things and of course to answer their questions.
(Name confidential - Respondent 048)	User of animals - public sector	Local	Not applicable, I am not an organisation	Agree in principle This depends on the impact of the inspection as failure to comply should result in possible closure etc.
(Name confidential - Respondent 050)	User of animals - public sector	Local; Regional; National; European; Worldwide	yes, we are a major EU HEI for biomedical research	The premises for 1.1 and 1.2 are logically incompatible.
(Name confidential - Respondent 054)	User of animals - public sector	National	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
GlaxoSmithKline	User of animals - private sector	Worldwide	There are other international pharmaceutical companies. We produce 25% of the worlds vaccines	The costs also include follow-up, reports and the costs of these inspections, which may be charged directly
sanofi pasteur R&D	User of animals - private sector	Worldwide	Vaccine field	Time-consuming, dedicated personel, more frequent reporting with limited benefits in term of animal welfare...

(Name confidential - Respondent 076)	User of animals - private sector	Worldwide	Yes	Actually yes but the costs for inspections are not negligible
(Name confidential - Respondent 084)	User of animals - private sector	Worldwide	yes	Depending on the dimension of a facility and the length and intensity of an inspection a disruption of daily routines is expensive
Animal Procedures Committee (APC)	Public authority	National	The APC provide independent advice to UK Government on the use of animals in scientific procedures. The APC consider science, industry and animal welfare. Members are from a variety of backgrounds.	The costs for establishments will be confined to a disruption of daily routines only if the costs of the inspection system are met centrally, i.e. by government. In the UK, the financial cost of inspections, and all other costs of the UK regulatory system, is recovered through licence fees.
(Name confidential - Respondent 115)	Public authority	Local	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !

(Name confidential - Respondent 116)	Public authority	Local	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 127)	Public authority	National	Ministry of VWS is also involved	depends on the system some countries might sent a bill after an inspection?
(Name confidential - Respondent 128)	Public authority	National; European; Worldwide	Although we are a smaller University, about half of the research groups involving animal experiments belong to leading institutions in their field.	Doubling inspections would more likely double costs per year for member states.
(Name confidential - Respondent 129)	Public authority	National	representative	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !

COST Action B24 “Laboratory Animal Science Welfare” - http://biomedicum.ut.ee/costb24	Other	European	No	No, depending on the day disruption of the daily routines may cause considerable costs. Experiments/meetings have to be stopped because persons being responsible for the animal facility and the different experiments have to be on inspectors command to show things and of course to answer their questions.
Medical University of Vienna	Other	Local; Regional; National; European; Worldwide	Research in Medicine	If the inspection has to control the ongoing experiments, their compliance with the authority’s permission, the number of animals used, etc. the working disruptions in central facilities will be enormous due to the large number of projects. Furthermore, unannounced inspections may cause problems, if the responsible people are occupied by clinical and other duties or are absent (e.g. international meetings, sick leave etc.). In the worst case, ongoing experiments with a sensitive time schedule may be totally ruined, associated with tremendous financial and intellectual damage to both society and the investigator.
National Centre for the Replacement, Refinement and Reduction of Animals in Research	Other	National	Representative	In the UK the cost of inspection are passed to the user indirectly through licence fees. Disruption to daily routines should be minimal.
The Association for the Study of Animal Behaviour	Other	Worldwide	yes	see 1.6 below

TNO Quality of Life (The Netherlands)	Other	National; Worldwide	Yes	The costs will be highly depending on the degree of compliance of institutes with the regulations.
(Name confidential - Respondent 138)	Other	National	I am the chair of the Hungarian Scientific Ethical Committee on Animal Experimentation	Disruption of daily routines may sometimes be vital for the establishment and may corrupt long term experimental activities. The impact is certainly negative (-).
(Name confidential - Respondent 141)	Other	Not applicable	other	If the inspection has to control the ongoing experiments, their compliance with the authority's permission, the number of animals used, etc. the working disruptions in central facilities will be enormous due to the large number of projects. Furthermore, unannounced inspections may cause problems, if the responsible people are occupied by clinical and other duties or are absent (e.g. international meetings, sick leave etc.). In the worst case, ongoing experiments with a sensitive time schedule may be totally ruined, associated with tremendous financial and intellectual damage to both society and the investigator.
(Name confidential - Respondent 157)	Other	Worldwide	pharmaceutical industry	The interruption of daily routines especially in long-term studies under GLP may be very expensive as it may ruin the whole experiment

Gesellschaft für Versuchstierkunde - Society for Laboratory Animal Science (GV-SOLAS)	Non-governmental organisation	National; European	Yes	No, depending on the day disruption of the daily routines may cause considerable costs. Experiments/meetings have to be stopped because persons being responsible for the animal facility and the different experiments have to be on inspectors command to show things and of course to answer their questions.
(Name confidential - Respondent 166)	Non-governmental organisation	National	NO OTHER RELEVANT ORGANISATION	The cost could be enormous when experiments need to be interrupted on inspectors' request
(Name confidential - Respondent 169)	Non-governmental organisation	National	Represents all Finnish pharmacologists	It would obviously increase, since more inspectors would be needed
(Name confidential - Respondent 170)	Non-governmental organisation	National	The Danish Society of Pharmacology and Toxicology represents Danish pharmacologists and toxicologists.	Costs are unlikely to be insignificant.
(Name confidential - Respondent 172)	Non-governmental organisation	Regional	Yes	see 1.6

(Name confidential - Respondent 176)	Non-governmental organisation	Worldwide	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 177)	Non-governmental organisation	Worldwide	Representative	There will be greater disruption than anticipated.
(Name confidential - Respondent 180)	Non-governmental organisation	Not applicable	yes	No. Certainly the user or the laboratory would at one point of time have to pay for the inspections.
(Name confidential - Respondent 182)	Breeder of animals	Worldwide	Representative	Disruption of routine and experimental work may cause high costs and experiments may have to be repeated. This is not a goal for animal welfare.
(Name confidential - Respondent 187)		National; European; Worldwide	yes	If the inspection has to control the ongoing experiments, their compliance with the authority's permission, the number of animals used, etc. the working disruptions in central facilities will be enormous due to the large number of projects. Furthermore, unannounced inspections may cause problems, if the responsible people are occupied by clinical and other duties or are absent (e.g. international meetings, sick leave etc.). In the worst case, ongoing experiments with a sensitive time schedule may be totally ruined, associated with tremendous financial and intellectual damage to both society and the investigator.
(Name confidential - Respondent 190)		Regional; Worldwide	also others	see 1.6

(Name confidential - Respondent 192)		National; European; Worldwide	Yes	see below
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Question VII.1.3.

Question text:

Impacts on animal welfare:

An increase of the frequency of inspections at Member State level would contribute to an increase in the welfare of the 10M or so animals used in experiments each year, as a result of a better and more systematic evaluation of compliance with legislation and standards.

Do you support the preliminary findings? Yes/No/ No opinion

Statistics:

146 respondents stated that they support the preliminary analysis.

20 respondents stated that they have no opinion in relation to this question.

61 respondents stated that they do not support the preliminary analysis or components of it. To justify disagreement, they were asked to provide arguments, facts and figures and if possible indicate the source of information. However, a number of respondents opted for the "No" reply only to supply additional arguments in support of the preliminary analysis.

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII. 1.3a.
Antal Maria Cristina	User of animals - public sector	Worldwide	yes	The frequency of the inspections will not have an impact on the animal welfare as any conscious institution watch over, without being forced, his animal welfare.

Dept. Laboratory Animal Science, Utrecht University, The Netherlands	User of animals - public sector	Worldwide	chair of lab. animal sci. recognized by national authorities/resp onsable for national coordination education and training in lab. animal sci./ leading role in international laboratory animal science	Inspections per se do not improve animal welfare, nor does the absence of them mean there is poor welfare
Gaertner	User of animals - public sector	Regional	representative for the field at the respective activity level.	at 1.3 No Qualified laboratory animal veterinarians (named veterinary surgeons) improve animal welfare instead of additional inspections.
Hannover Medical School	User of animals - public sector	Local; Regional; National	Hannover Medical School currently ranks highest with respect to research activities and aquired research grants	Qualified laboratory animal veterinarians (named veterinary surgeons) improve animal welfare instead of additional inspections.

Hans J. Hedrich	User of animals - public sector	Local; Regional; National; European	I am currently President of the European College of Laboratory Animal Medicine (ECLAM) and Vicepresident Gesellschaft zur Förderung der Biomedizinischen Forschung	Qualified laboratory animal veterinarians (named veterinary surgeons) improve animal welfare instead of additional inspections.
Prof. Dr. R. Nobiling, University of Heidelberg	User of animals - public sector	Regional; National; European; Worldwide	Biomed research at Univ. Heidelberg is Top - ranked	high scientific standards are required in most, if not all laboratories. This implies animal welfare in general. Scientific inspections by qualified laboratory animal veterinarians are already organised more frequently; this real situation keeps animal welfare levels already very high.
Prof. Manuela Baccarini, PhD	User of animals - public sector	Local	other relevant organisations	As expostulated already before, the welfare of experimental animals is already of the utmost importance for the scientist carrying out animal experiments, and I don't believe that more frequent controls will increase it.
Timo Nevalainen	User of animals - public sector	Local	Yes	It is the competent facility personnel (A_D), who will maintain high welfare, well above regulatory minimum requirements.
(Name confidential - Respondent 001)	User of animals - public sector	National; European; Worldwide	yes	Not the inspections per se but good infrastructure and qualified staff have the most relevant impact on animal welfare, which can be evaluated in the course of the license procedure. Increasing the frequency of inspections in institutions of high standard will therefore not be associated with any additional benefit to the animals.

(Name confidential - Respondent 004)	User of animals - public sector	National	XXX are representative of our scientific activity (basic research)	Welfare is the responsibility of all those involved in experiments, far better would be to ensure correct and continuous training of those people. Checking for the compliance to regulation through inspections refers most to a yearly basis (facilities, authorisations). Current control of animal use and animal welfare is checked by institutional committees and people in charge, something inspectors cannot do.
(Name confidential - Respondent 005)	User of animals - public sector	Worldwide	there are others	Qualified laboratory animal veterinarians (named veterinary surgeons) improve animal welfare instead of additional inspections.
(Name confidential - Respondent 010)	User of animals - public sector	Worldwide	One of several global pharmaceutical companies	Inspections once a year would be sufficient.
(Name confidential - Respondent 014)	User of animals - public sector	Local; Regional; National; European; Worldwide	Yes	see 1.6
(Name confidential - Respondent 018)	User of animals - public sector	Not applicable	we are a medical university.	the standards are currently high. animal welfare is dependant on qualified animal keepers, veterinary surgeons, experts for laboratory animal science and not by having more inspections.
(Name confidential - Respondent 023)	User of animals - public sector	Local; National	There are several central laboratory animal facilities at Austrian universities	The standards are already high.

(Name confidential - Respondent 032)	User of animals - public sector	Local	yes	No, there are already high standards. Public just believes if there are inspections then this will increase welfare of the animals. But animal welfare is particularly dependant on qualified persons (animal keepers, veterinary surgeons, experts for laboratory animal science) working in an establishment, their knowledge and appropriate equipment..
(Name confidential - Respondent 036)	User of animals - public sector	Worldwide	Yes	It assumes that animals are mistreated if the researcher are not controlled.
(Name confidential - Respondent 043)	User of animals - public sector	Local; Regional; National; European; Worldwide	YES	See Section "Justification"
(Name confidential - Respondent 046)	User of animals - public sector	National	yes	Unannounced inspections are conducted by inspectorate. The number of inspections is not defined (some of our installations had no inspections and the other 2 during the same period). It is too risky (and ethically unacceptable). The benefit will be low.
(Name confidential - Respondent 054)	User of animals - public sector	National	yes	Qualified laboratory animal veterinarians (named veterinary surgeons) improve animal welfare instead of additional inspections.
(Name confidential - Respondent 074)	User of animals - private sector	Worldwide	Yes	Lack of compliance and bad routines can be found with one inspection. It's nearly impossible to change way of working only to fulfil compliance during inspections.
(Name confidential - Respondent 075)	User of animals - private sector	Worldwide	Research and development	Researchers have already a legal individual authorization to do experiments.

(Name confidential - Respondent 076)	User of animals - private sector	Worldwide	Yes	Since experimental animals are housed under well defined standard conditions and experimental procedures have to be well defined to allow a successful experiment, inspections have a low impact on animal welfare for most of the animals, as there is good reason to believe that almost all animal researchers do work according to best practice, since animal experiments are expensive and are only valid, if performed properly. So, it is an economic necessity to follow state of the art and not promoted by inspections. Each Member State should have similar inspection systems so that there would not be competitive advantages in specific countries
(Name confidential - Respondent 081)	User of animals - private sector	Worldwide	other relevant organisations	no comment
(Name confidential - Respondent 084)	User of animals - private sector	Worldwide	yes	Animal welfare does not depend on a certain number of inspections, there are already high standards, standards will never be adjusted to the number of inspections, the costs would be higher
(Name confidential - Respondent 087)	User of animals - private sector	Worldwide	No	This assumes that inspection inevitably will find fault with regard to animal welfare, which can not be presupposed.
(Name confidential - Respondent 088)	User of animals - private sector	Worldwide	pharmaceutical	In Belgium, the research labs already have very close contacts with the national authorities through their participation in the local ethics committees.
Coordination group for laboratory animal activities	Public authority	National	Yes	It is the competent facility personnel (A-D), who will maintain high welfare, well above regulatory minimum requirements.

Francois Lachapelle INSERM	Public authority	National	BEA du CNRS, de l'INRA, du CEA	there are no clear eviednce that legislations always contribute to the animals welfare
(Name confidential - Respondent 115)	Public authority	Local	yes	Qualified laboratory animal veterinarians (named veterinary surgeons) improve animal welfare instead of additional inspections.
(Name confidential - Respondent 116)	Public authority	Local	yes	Qualified laboratory animal veterinarians (named veterinary surgeons) improve animal welfare instead of additional inspections.
(Name confidential - Respondent 119)	Public authority	Local; Regional	no	already now the requirements for animal caretaking are high. Annual or biannual inspections are sufficient
(Name confidential - Respondent 122)	Public authority	National	We are the National Competent Authority	The focus must be on what inspection is intended to achieve - not how often it is done.

(Name confidential - Respondent 128)	Public authority	National; European; Worldwide	Although we are a smaller University, about half of the research groups involving animal experiments belong to leading institutions in their field.	Qualified laboratory animal veterinarians (veterinary surgeons) improve animal welfare instead of additional inspections.
(Name confidential - Respondent 129)	Public authority	National	representative	Qualified laboratory animal veterinarians (named veterinary surgeons) improve animal welfare instead of additional inspections.
(Name confidential - Respondent 135)	Public authority	Worldwide	yes	somewhat overregulated: authorisation of single project, site and experimentator and more frequent inspections
1. Animal Aid	Other	National	Other organisations do exist	Leaked documents and undercover video footage have revealed horrific animal suffering and researcher incompetence, which Home Office inspectors failed to detect. This is despite the fact that 60% of inspections are purportedly unannounced.

COST Action B24 “Laboratory Animal Science Welfare” - http://biomedicum.ut.ee/costb24	Other	European	No	No, there are already high standards. Public just believes if there are inspections then this will increase welfare of the animals. But animal welfare is particularly dependant on qualified persons (animal technicians, veterinary surgeons, experts in laboratory animal science) working in an establishment, their knowledge and appropriate equipment.
Cris Iles-Wright	Other	Not applicable	Not applicable	Inspections have not led to action to prevent sub-standard conditions.
Medical University of Vienna	Other	Local; Regional; National; European; Worldwide	Research in Medicine	Not the inspections per se but good infrastructure and qualified staff have the most relevant impact on animal welfare, which can be evaluated in the course of the license procedure. Increasing the frequency of inspections in institutions of high standard will therefore not be associated with any additional benefit to the animals.
The Association for the Study of Animal Behaviour	Other	Worldwide	yes	see 1.6 below
(Name confidential - Respondent 138)	Other	National	I am the chair of the Hungarian Scientific Ethical Committee on Animal Experimentation	One additional inspection (even if unannounced) will have a minimal positive impact on animal welfare (+) but substantial administrative costs for the establishments and authorities.

(Name confidential - Respondent 141)	Other	Not applicable	other	Not the inspections per se but good infrastructure and qualified staff have the most relevant impact on animal welfare, which can be evaluated in the course of the license procedure. Increasing the frequency of inspections in institutions of high standard will therefore not be associated with any additional benefit to the animals.
(Name confidential - Respondent 143)	Other	National	Regulatory body	Conclusion is flawed. The potential to impact on animal welfare depend on clear criteria for inspection with clear objectives and outcomes rather than the number of visits conducted. Also depends on current standards and whether there is widespread non-compliance currently (which is unlikely)
(Name confidential - Respondent 157)	Other	Worldwide	pharmaceutical industry	With an in-house animal welfare officer in place, there is no need for inspections by out-house inspectors. The latter may see much less than an in-house officer can see and inspect.
FELASA (Federation of European Laboratory Animal Science Associations)	Non-governmental organisation	European	FELASA represents 13 European lab animal sci associations and therefore some 3-4000 members of those associations (scientists, veterinary surgeons, technicians etc.). See www.felasa.org	Inspections per se do not improve animal welfare, nor does the absence of them mean there is poor welfare. FELASA promotes good science and good welfare and has produced many recommendations and guidelines (see www.felasa.org) that are highly regarded within the scientific community and have been widely applied.

Gesellschaft für Versuchstierkunde - Society for Laboratory Animal Science (GV-SOLAS)	Non-governmental organisation	National; European	Yes	No, there are already high standards. Public just believes if there are inspections then this will increase welfare of the animals. But animal welfare is particularly dependant on qualified persons (animal keepers, veterinary surgeons, experts for laboratory animal science) working in an establishment, their knowledge and appropriate equipment.
Stichting EDEV - Een DIER Een VRIEND	Non-governmental organisation	National; European	We cooperate with animal organisations within the ECEAE	Not when done by the same people as now. These need to be independent.
(Name confidential - Respondent 164)	Non-governmental organisation	National	yes	If the inspection has to control the ongoing experiments, their compliance with the authority's permission, the number of animals used, etc. the working disruptions in central facilities will be enormous due to the large number of projects. Furthermore, unannounced inspections may cause problems, if the responsible people are occupied by clinical and other duties or are absent (e.g. international meetings, sick leave etc.). In the worst case, ongoing experiments with a sensitive time schedule may be totally ruined, associated with tremendous financial and intellectual damage to both society and the investigator.
(Name confidential - Respondent 166)	Non-governmental organisation	National	NO OTHER RELEVANT ORGANISATION	Checking for the compliance to regulation through inspections refers most to a yearly basis (facilities, authorisations). Current control of animal use and animal welfare is checked by institutional committees and people in charge, something inspectors cannot do. Welfare is the responsibility of all those involved in experiments, far better would be to ensure correct and continuous training of those people
(Name confidential - Respondent 167)	Non-governmental organisation	National	YES	Inspections do not improve animal welfare, no does the absence of them mean there is poor welfare. Animal welfare is particularly dependant on qualification and competence of personnel (animal technicians, veterinary surgeons, experts in laboratory animal science, etc.) and appropriate equipment.

(Name confidential - Respondent 169)	Non-governmental organisation	National	Represents all Finnish pharmacologists	Inspection system in Finland is good enough - no need to expand it
(Name confidential - Respondent 175)	Non-governmental organisation	National	yes	An EU regulation would harmonize the procedure.
(Name confidential - Respondent 176)	Non-governmental organisation	Worldwide	yes	Qualified laboratory animal veterinarians (named veterinary surgeons) improve animal welfare instead of additional inspections.
(Name confidential - Respondent 180)	Non-governmental organisation	Not applicable	yes	At the national level. but not at the EU level.
(Name confidential - Respondent 182)	Breeder of animals	Worldwide	Representative	Because there is a high standard in animal experiments concerning the animal welfare aspect in Germany anyway, further inspections would only pretend a stricter regulation to the public.
(Name confidential - Respondent 187)		National; European; Worldwide	yes	Not the inspections per se but good infrastructure and qualified staff have the most relevant impact on animal welfare, which can be evaluated in the course of the license procedure. Increasing the frequency of inspections in institutions of high standard will therefore not be associated with any additional benefit to the animals.
(Name confidential - Respondent 192)		National; European; Worldwide	Yes	see below

(Name confidential - Respondent 194)		Local	representative	An EU regulation will harmonize the procedure.
(Name confidential - Respondent 195)		National; European; Worldwide	Yes, we are representative for the field	An EU regulation would harmonize the procedure.

Question VII.1.4.

Question text:

Public accountability and transparency:

More inspections at Member State level would significantly contribute to the enhancement of public accountability and transparency, due to a more effective compliance check of the authorisation criteria, which can result in the withdrawal of licences, if the criteria and standards are not met by the respective establishments.

Do you support the preliminary findings? Yes/No/ No opinion

Statistics:

166 respondents stated that they support the preliminary analysis.

26 respondents stated that they have no opinion in relation to this question.

34 respondents stated that they do not support the preliminary analysis or components of it. To justify disagreement, they were asked to provide arguments, facts and figures and if possible indicate the source of information. However, a number of respondents opted for the "No" reply only to supply additional arguments in support of the preliminary analysis.

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII.1.4a.

Gesellschaft zur Förderung der biomedizinischen Forschung	User of animals - public sector	National	The organisation is representative for the field at the respective activity level.	At 1.4, 1.5 No see at VII.e) Potential solutions and 1.1. , 1.2
Hannover Medical School	User of animals - public sector	Local; Regional; National	Hannover Medical School currently ranks highest with respect to research activities and aquired research grants	see VII.e) Potential solutions and 1.1. , 1.2
Hans J. Hedrich	User of animals - public sector	Local; Regional; National; European	I am currently President of the European College of Laboratory Animal Medicine (ECLAM) and Vicepresident Gesellschaft zur Förderung der Biomedizinischen Forschung	No see VII.e) Potential solutions and 1.1. , 1.2

Prof. Dr. R. Nobiling, University of Heidelberg	User of animals - public sector	Regional; National; European; Worldwide	Biomed research at Univ. Heidelberg is Top - ranked	: high scientific standards are required in most, if not all laboratories. This implies animal welfare in general. Scientific inspections by qualified laboratory animal veterinarians are already organised more frequently; this real situation keeps animal welfare levels already very high.
(Name confidential - Respondent 004)	User of animals - public sector	National	XXX are representative of our scientific activity (basic research)	The public does not suspect researchers from dishonesty. Mandatory need for unannounced inspection might induce lack of understanding and doubt.
(Name confidential - Respondent 005)	User of animals - public sector	Worldwide	there are others	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 010)	User of animals - public sector	Worldwide	One of several global pharmaceutical companies	Current written information together with yearly inspections or an inspection every 2 years would be sufficient to reach the same objective and reduce mistrust and administrative burden.
(Name confidential - Respondent 014)	User of animals - public sector	Local; Regional; National; European; Worldwide	Yes	see 1.6
(Name confidential - Respondent 018)	User of animals - public sector	Not applicable	we are a medical university.	this inspections are already implemented. I do not believe that the public will gain a level of comfort knowing that more tax money is being spent on more inspections that are unnecessary.

(Name confidential - Respondent 023)	User of animals - public sector	Local; National	There are several central laboratory animal facilities at Austrian universities	This is already the situation in most of the member states. Most critics in animal experimentation is ideologically not rationally motivated. More inspections will not change this.
(Name confidential - Respondent 043)	User of animals - public sector	Local; Regional; National; European; Worldwide	YES	See Section "Justification"
(Name confidential - Respondent 054)	User of animals - public sector	National	yes	see at VII.e) Potential solutions and 1.1. , 1.2
(Name confidential - Respondent 074)	User of animals - private sector	Worldwide	Yes	Would depend on the quality of the inspection and the consequences of non- compliance and the juridical process (appealing, second opinion?)
(Name confidential - Respondent 075)	User of animals - private sector	Worldwide	Research and development	no comment
(Name confidential - Respondent 076)	User of animals - private sector	Worldwide	Yes	There is no evidence for this statement

(Name confidential - Respondent 084)	User of animals - private sector	Worldwide	yes	Because there will not be a more effective compliance check of the authorisation criteria, you cannot be less compliant with the law if there are less inspections
(Name confidential - Respondent 115)	Public authority	Local	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 116)	Public authority	Local	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 119)	Public authority	Local; Regional	no	this does not depend on the number of inspections
(Name confidential - Respondent 122)	Public authority	National	We are the National Competent Authority	This assumes that there is significant non-compliance and that is not currently being identified and remedied.
(Name confidential - Respondent 127)	Public authority	National	Ministry of VWS is also involved	Some countries with higher inspection freq. also have complaining general publics
(Name confidential - Respondent 129)	Public authority	National	representative	see at VII.e) Potential solutions and 1.1. , 1.2

(Name confidential - Respondent 135)	Public authority	Worldwide	yes	they cannot be made public
1. Animal Aid	Other	National	Other organisations do exist	Experience in the UK indicates that this will not necessarily follow
Cris Iles-Wright	Other	Not applicable	Not applicable	The statement does not make it clear whether withdrawal of licences is proposed or exists. It exists in theory in the UK but is purely a public-relations exercise. Inspections have not led to action to prevent sub-standard conditions.
(Name confidential - Respondent 138)	Other	National	I am the chair of the Hungarian Scientific Ethical Committee on Animal Experimentation	Only minimal increase can be expected in public accountability and transparency (+) as the public is not aware of the inspections. The withdrawal of licences is an existing option of the authority in my country even along the present practice (one inspection a year).
(Name confidential - Respondent 143)	Other	National	Regulatory body	Number of inspections is not the issue. It is the quality of inspection and clear indication of what inspection should achieve that would provide reassurance to the public.

PETA Europe Ltd.	Non-governmental organisation	Worldwide	both	More inspections will only lead to the enhancement of public accountability if non-confidential information about inspections is made available to the public, and if there are systems in place to ensure accuracy and honesty in reporting. Specifically, regular reporting on the number of breaches in legislative requirements must be compulsory, as must reporting of categories of breaches, ie: failure to accurately report statistical information, failure to accurately assess severity bandings, failure to ensure expected severity matches actual severity, failure to apply humane endpoints, failure to ensure appropriate housing and care, and failure to keep proper records. Public accountability cannot exist when rigid confidentiality precludes public access to current and specific information regarding animal experiments. A new system would need to be demonstrably different through being more open to scrutiny, and involving regular, accurate, reporting to the public.
Stichting EDEV - Een DIER Een VRIEND	Non-governmental organisation	National; European	We cooperate with animal organisations within the ECEAE	No license has ever been revoked.... Covance can abuse animals (as to be seen on hidden camera) nothing happens. The EU public knows and there for doesn't trust animal testers any more.

The National Anti-Vivisection Society	Non-governmental organisation	National; European; Worldwide	The NAVS is the leading and oldest anti-vivisection organisation in the world. There are a number of other relevant anti-vivisection organisations around the world with expertise in this field.	Inspections in themselves do not increase accountability and transparency. However they could be a step towards this through publication of inspection data.
(Name confidential - Respondent 166)	Non-governmental organisation	National	NO OTHER RELEVANT ORGANISATION	Checking authorisations refers most to a yearly basis.
(Name confidential - Respondent 169)	Non-governmental organisation	National	Represents all Finnish pharmacologists	Inspection system in Finland is good enough - no need to expand it
(Name confidential - Respondent 176)	Non-governmental organisation	Worldwide	yes	Potential solutions and 1.1. , 1.2
(Name confidential - Respondent 192)		National; European; Worldwide	Yes	see below

Question VII.1.5.

Question text:

Regulatory compliance to Member States:

More inspections at Member State level would lead to a moderate increase in administrative costs to Member States, because the enhancement of administrative capacity for inspections would require additional qualified personnel. Member States with centralised systems of authorisation and high numbers of animals used per year (such as France, UK, Italy) would be particularly concerned because of the high share of travelling time involved.

Do you support the preliminary findings? Yes/No/ No opinion

Statistics:

111 respondents stated that they support the preliminary analysis.

81 respondents stated that they have no opinion in relation to this question.

33 respondents stated that they do not support the preliminary analysis or components of it. To justify disagreement, they were asked to provide arguments, facts and figures and if possible indicate the source of information. However, a number of respondents opted for the "No" reply only to supply additional arguments in support of the preliminary analysis.

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII.1.5a.

Gesellschaft zur Förderung der biomedizinischen Forschung	User of animals - public sector	National	The organisation is representative for the field at the respective activity level.	At 1.4, 1.5 No see at VII.e) Potential solutions and 1.1. , 1.2
Hannover Medical School	User of animals - public sector	Local; Regional; National	Hannover Medical School currently ranks highest with respect to research activities and aquired research grants	see VII.e) Potential solutions and 1.1. , 1.2
Hans J. Hedrich	User of animals - public sector	Local; Regional; National; European	I am currently President of the European College of Laboratory Animal Medicine (ECLAM) and Vicepresident Gesellschaft zur Förderung der Biomedizinischen Forschung	No see VII.e) Potential solutions and 1.1. , 1.2

Prof. Dr. R. Nobiling, University of Heidelberg	User of animals - public sector	Regional; National; European; Worldwide	Biomed research at Univ. Heidelberg is Top - ranked	Unannounced inspections might not work in institutions like medical schools, where animal research activities are mixed with other types of research, student education, and clinical activities.
(Name confidential - Respondent 005)	User of animals - public sector	Worldwide	there are others	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 006)	User of animals - public sector	National	representative	The increase in administrative costs will be not moderate but high.
(Name confidential - Respondent 010)	User of animals - public sector	Worldwide	One of several global pharmaceutical companies	Inspections are necessary to assure compliance with regulations. These should, however, be restricted to a minimum, since better education and training of research and animal holding personnel rather than repeated inspections would enhance animal welfare. The bureaucratic burden of inspections and the impact on loss of effective working hours and loss of results due to this burden is underestimated. The tendency of certain EU authorities to further increase inspections contributes significantly to the level of public mistrust in the necessity of animal experiments.
(Name confidential - Respondent 014)	User of animals - public sector	Local; Regional; National; European; Worldwide	Yes	see 1.6
(Name confidential - Respondent 046)	User of animals - public sector	National	yes	Actually, we are inspected usually a year. Some inspections are unannounced. Doubling the number of inspections will induce an increase of the cost of inspections for MS (maybe doubling the cost).

(Name confidential - Respondent 051)	User of animals - public sector	National	yes	there are already difficulties to perform one annual inspection, thus the proposed increase is unrealistic without a high cost
(Name confidential - Respondent 054)	User of animals - public sector	National	yes	see at VII.e) Potential solutions and 1.1. , 1.2
GlaxoSmithKline	User of animals - private sector	Worldwide	There are other international pharmaceutical companies. We produce 25% of the worlds vaccines	The UK already inspects many more times than 1-2, whereas in other is it usually less, often once a year. Therefore the analysis is incorrect
sanofi pasteur R&D	User of animals - private sector	Worldwide	Vaccine field	See above section 1.1
(Name confidential - Respondent 072)	User of animals - private sector	European	Yes	It is clear that additional costs may arise but if the impact of transparency in public and increased confidence to scientific community is considered, the cost will be moderate. Especially the amount of monthly cost of a medium sized lab is taken into account, the additional expected increase will remain unnoticed.
(Name confidential - Respondent 086)	User of animals - private sector	Worldwide	There are many other such organisations in Europe	The costs could be very high for member states if inspectors with the specific technical expertise have to be recruited. It is very important that the inspections are conducted rigorously and to a consistent standard using appropriately trained inspectors.

(Name confidential - Respondent 088)	User of animals - private sector	Worldwide	pharmaceutical	A formal inspection twice a year would generate a substantial additional cost for the national authorities, where once a year or even every 2-3 years should, already be frequent enough to have a good idea about the compliance issues.
(Name confidential - Respondent 098)	User of animals - private sector	Worldwide	Representative	Although a moderate increase in administrative costs to Member States might arise to get additional qualified personnel, travelling time has already been addressed in some of the quoted Country (ie Italy), involving the "peripheral" (local) offices.
Animal Procedures Committee (APC)	Public authority	National	The APC provide independent advice to UK Government on the use of animals in scientific procedures. The APC consider science, industry and animal welfare. Members are from a variety of backgrounds.	Although the UK has a centralised system, the offices are regional. Cost issues related to travelling time can therefore be minimised by a system of regional offices such as is the case with the UK.
Bart Hoet	Public authority	National	Yes, representative	High increase in administrative costs.

Federal Public Service - Public Health (div. animal welfare & CITES)	Public authority	National	Yes, representative.	As for EU administration intensifying inspections at least twice a year per laboratory will highly and not moderately increase the costs and the administration for national authorities.
Francois Lachapelle INSERM	Public authority	National	BEA du CNRS, de l'INRA, du CEA	please there is no more centralised system in France since 1997, I hope that all the informations of the commission are more up to date!!! The cots will not be so moderated
(Name confidential - Respondent 115)	Public authority	Local	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 116)	Public authority	Local	yes	Increase of costs with 2 inspections per year for member states. Doubling of costs and impact to establishments by 2 inspections per year. Unannounced inspections might not work !
(Name confidential - Respondent 122)	Public authority	National	We are the National Competent Authority	The analysis of the UK position is wrong as are some other assumptions. In the UK already have a national inspection programme - with 230 approved places subject to >2500 annual inspections. More than 50% of inspections of animal facilities are without notice. In addition inspection costs/time depends on the number and distribution of establishments to be inspected, and how the inspection system is authorised - not whether decision making is centralised. The UK inspection programme is effected from 5 locations.

(Name confidential - Respondent 128)	Public authority	National; European; Worldwide	Although we are a smaller University, about half of the research groups involving animal experiments belong to leading institutions in their field.	Administrative costs are likely more than moderate.
(Name confidential - Respondent 129)	Public authority	National	representative	see at VII.e) Potential solutions and 1.1. , 1.2
National Centre for the Replacement, Refinement and Reduction of Animals in Research	Other	National	Representative	Although the UK has a centralised system, the offices are regional. Regional offices, such as those in the UK, can offset travel costs.
(Name confidential - Respondent 143)	Other	National	Regulatory body	Many countries already have a comprehensive inspection programme in place therefore impact would be low (impact is overestimated)

(Name confidential - Respondent 175)	Non-governmental organisation	National	yes	Costs would increase for the administration; but only in those member states where regular inspections are not in place yet. In Germany institutes are fully controlled and inspected by the respective authorities.
(Name confidential - Respondent 176)	Non-governmental organisation	Worldwide	yes	Potential solutions and 1.1. , 1.2
(Name confidential - Respondent 192)		National; European; Worldwide	Yes	see below
(Name confidential - Respondent 194)		Local	representative	Costs will increase for the administration; but only in those member states where regular inspections are not in place yet. In Germany institutes are fully controlled and inspected by the regular authorities.
(Name confidential - Respondent 195)		National; European; Worldwide	Yes, we are representative for the field	Costs would increase for the administration; but only in those member states where regular inspections are not in place yet. In Germany institutes are fully controlled and inspected by the respective authorities.

Question VII.1.6.**Question text:**

Justification (open text box)

Statistics:

(no numbers registered as this was not a closed question)

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII.1.6. Justification
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Dept. Laboratory Animal Science, Utrecht University, The Netherlands	User of animals - public sector	Worldwide	chair of lab. animal sci. recognized by national authorities/resp onsable for national coordination education and training in lab. animal sci./ leading role in international laboratory animal science	Regarding twice yearly inspections, this should be the minimum required, so that national authorities may determine the appropriate level of inspection on a case by case basis.
(Name confidential - Respondent 001)	User of animals - public sector	National; European; Worldwide	yes	Ad 1.4 Yes, if inspections serve to falsify the horror stories from animal rightists by which the public is overrun and misinformed (see Chapter XII).
(Name confidential - Respondent 002)	User of animals - public sector	Local; Regional; National; European; Worldwide	XXX	Some level of inspection is warranted to provide public accountability, but there should be a major effort towards standardisation between member states, the lack of which is currently highly unsatisfactory. The twice yearly rate proposed seems appropriate. If there are to be inspections then de facto there need to be sanctions if the inspections are to generate public confidence. The document provides no insight into what such sanctions might be and how they might be implemented. This requires consultation. There should be discussion of an EU-wide inspection framework.

(Name confidential - Respondent 009)	User of animals - public sector	National	Yes, we are representing all physiological researchers in the Netherlands; we have about 300 members	Good inspections are more important for good animal care than retrospective analysis or publication of information to the public. The inspection and the authorization by experts is really where account is given to the public as well.
(Name confidential - Respondent 010)	User of animals - public sector	Worldwide	One of several global pharmaceutical companies	Inspections are necessary to assure compliance with regulations. These should, however, be restricted to a minimum, since better education and training of research and animal holding personnel rather than repeated inspections would enhance animal welfare. The bureaucratic burden of inspections and the impact on loss of effective working hours and loss of results due to this burden is underestimated. The tendency of certain EU authorities to further increase inspections contributes significantly to the level of public mistrust in the necessity of animal experiments.
(Name confidential - Respondent 011)	User of animals - public sector	National; European; Worldwide	Other organisations in Austria: Karl-Franzens-University; Medical University Vienna; Medical University Innsbruck	It should be anticipated that raising the number of inspections will require national bodies to increase their staff and therefore the associated costs will not be minimal. The corollary of increasing the number of inspections must be that there is an increase in the number of inspectors and costs must rise proportionately. However, the benefits probably outweigh the costs

(Name confidential - Respondent 014)	User of animals - public sector	Local; Regional; National; European; Worldwide	Yes	The only practical requirement shall be that there is one (announced or non-announced) inspection at member state level per year. Unannounced inspections can in some instances be a severe problem, namely if chronic neurobehavioural experiments are carried out. Perturbation of the daily routine by an inspection (exposure to non-familiar persons) could make the whole experiment useless.
(Name confidential - Respondent 016)	User of animals - public sector	European	Yes	These recommendations would bring other member states into line with practices already established in the UK.
(Name confidential - Respondent 018)	User of animals - public sector	Not applicable	we are a medical university.	probably increasing the inspections will increase the number of inspectors and will end up costing more to do science.
(Name confidential - Respondent 021)	User of animals - public sector	Regional	yes	It should be anticipated that raising the number of inspections will require national bodies to increase their staff and therefore the associated costs will not be minimal.
(Name confidential - Respondent 025)	User of animals - public sector	Local	representative	Introducing EU-Inspections would result in an expensive bureaucracy. Instead of asking for ever more inspections animal welfare would be served better, if qualified laboratory personal was engaged. This is why biomedical research studies should include education and training in animal experimentation
(Name confidential - Respondent 028)	User of animals - public sector	National	yes. There are other academic medical centres	The inspectorate responsible for these inspections should be well positioned within the central government. In the Netherlands, this is not the case. Here, the inspectorate responsible is that of food and safety. The context of animal experimentation is more complex than an inspectorate, that is known to work with checklists based on absolute numbers and facts, can deal with. A central inspectorate for animal experimentation should be set up in such a way to allow for specific expertise and knowledge to be the guiding principle.

(Name confidential - Respondent 032)	User of animals - public sector	Local	yes	At 1.4 Yes, but only because public just believes if there are more inspections then standards are better met. Animal welfare is particularly dependant on qualified persons (animal keepers, veterinary surgeons, experts for laboratory animal science) working in an establishment, their knowledge and appropriate equipment.
(Name confidential - Respondent 043)	User of animals - public sector	Local; Regional; National; European; Worldwide	YES	The philosophy behind Option 1 is that scientists and the veterinarian authorities controlling animal experiment do not care about animal welfare. This is offensive to the people working on animals and especially to veterinarians that have as their duty to control the correct use of experimental procedures. Especially offensive is the non-announced visit that even more stress the lack of trust in people involved in research
(Name confidential - Respondent 044)	User of animals - public sector	National; Worldwide	yes, major UK research organisation for aquatic organisms and environment	Twice a year is minimal.
(Name confidential - Respondent 047)	User of animals - public sector	Regional; National	yes	In my opinion, more inspections by officials not employed by the institutions to be inspected is probably the cheapest and most efficient way to improve animal welfare, animal care taker performance and job satisfaction, and researchers awareness of their responsibility towards the welfare of their animals. More inspections will have a greater impact on improvements and are much less labor intensive and by far more efficient than other instruments such as harm-benefit and retrospective analyses.
(Name confidential - Respondent 048)	User of animals - public sector	Local	Not applicable, I am not an organisation	Already subject to this
Bayer HealthCare	User of animals - private sector	Worldwide	organisation is representative for the field	In Germany there are more than two inspections in companies per year (sometimes as frequent as 1 per month).

GlaxoSmithKline	User of animals - private sector	Worldwide	There are other international pharmaceutical companies. We produce 25% of the world's vaccines	Whilst a certain level of inspection seems warranted as above there should be a risk based approach. It is unclear why some countries have 10 times the amount of inspection than others.
Protherics Medicines Development Ltd.	User of animals - private sector	Worldwide	No - ABPI and EFPIA represent the pharmaceutical industry in UK/EU	In many countries there are more than two inspections in companies per year (sometimes as frequent as 1 per month). Pharmaceutical industry would support increasing the number of inspections.
(Name confidential - Respondent 073)	User of animals - private sector	National; European; Worldwide	Sanofi aventis is the largest pharmaceutical company in Europe and ranks third worldwide	The number of inspections varies. Industry would however support an increase. Industry would also support the use of an independent accreditation agency as an adjunct to Inspection. Currently AAALAC fills this role.
(Name confidential - Respondent 074)	User of animals - private sector	Worldwide	Yes	Inspection schedules might be done by requirement; good establishments might be enough to inspect once yearly and could be unannounced. Establishments with findings - several inspections depending of grade of non-compliance. Put the efforts where it's needed.
(Name confidential - Respondent 075)	User of animals - private sector	Worldwide	Research and development	no comment

(Name confidential - Respondent 076)	User of animals - private sector	Worldwide	Yes	In many countries there are more than two inspections in companies per year, in some even one every month The pharmaceutical industry would not support increasing the number of inspections
(Name confidential - Respondent 079)	User of animals - private sector	National; Worldwide	yes	More than 2 inspections or visits are already carried out in some countries or regions. An increased number of inspections can only be beneficial but the frequency should be adapted on a case per case basis, focusing on sites having to improve their standards and taking into account more "positive" situation such as the site AAALAC accreditation? This would allow a much better use of the inspection resources
(Name confidential - Respondent 081)	User of animals - private sector	Worldwide	other relevant organisations	The number of yearly official inspection should not improve animal-welfare. This should increase administrative burden and costs with the preparation of inspection, reporting and answer to the inspection. Administrative burden should not be more time-consuming than time used to take care of animals In some countries, inspection should be performed by non-centralised authorities and questions/requests should be very inspector-dependent taking into account the sensitivity of the subject.
(Name confidential - Respondent 085)	User of animals - private sector	Not applicable	Also other biotech companies have similar animal facilities	Feedback on inspection to establishments should also be mandatory
(Name confidential - Respondent 087)	User of animals - private sector	Worldwide	No	This is about establishing and maintaining an open culture with the national authority, and increasing public confidence that it is not just self-regulation. I don't think that two visit per years is enough though for many sites. I would rather have more regular, informal, potentially unannounced visits, than occasional, very formal visits, such as those for GLP compliance which does not foster the same degree of openness.
(Name confidential - Respondent 088)	User of animals - private sector	Worldwide	pharmaceutical	It is indeed important to have regular inspections, combined with regular reports of changes. But the high cost of frequent inspections should be balanced with the added value. A formal inspection every 2-3 years, combined with the participation in the local ethics committees or with regular reports from the facilities seems to be an affordable alternative.

(Name confidential - Respondent 092)	User of animals - private sector	Worldwide	Global pharmaceutical research and development	we already have more than 2 inspections per year !
(Name confidential - Respondent 093)	User of animals - private sector	Worldwide	yes	In many countries there are more than two inspections in companies per year. Frequency and unannounced inspections should be an option but not mandatory. We propose to have a system where one or two visits per year should be the minimum, and more and/ or unannounced additional inspections should be based on trust. If there are any deviations from the guidelines frequency should be increased. We would not support the mandatory increasing of inspections.
(Name confidential - Respondent 096)	User of animals - private sector	National; European; Worldwide	there are multiple independent Contract Research Organisations in UK and EU	No comments
(Name confidential - Respondent 097)	User of animals - private sector	National	Yes	If more frequent inspections did add to true improved animal welfare, it would be OK
(Name confidential - Respondent 101)	User of animals - private sector	Worldwide	yes	In many countries there are more than two inspections in companies per year (sometimes as frequent as 1 per month). Pharmaceutical industry would support increasing the number of inspections.

(Name confidential - Respondent 103)	User of animals - private sector	Worldwide	The questionnaire will be completed for the German sites. Other site head in other countries will reply individually	In Germany at our site we are used to authority inspections every 3 weeks. We have learned to cope with it as we regard inspections (also the ones we perform ourselves internally) as effective and necessary. Especially, if findings are followed by intensified training of staff in certain areas.
(Name confidential - Respondent 104)	User of animals - private sector	Worldwide	Many organisations	In many countries there are more than two inspections in companies per year (sometimes as frequent as 1 per month). Pharmaceutical industry would support increasing the number of inspections.
(Name confidential - Respondent 110)	User of animals - private sector	National	representative	In Germany there are more than two inspections in companies per year (sometimes as frequent as 1 per month).
(Name confidential - Respondent 198)	User of animals - private sector	Worldwide	Don't understand this question	Where there are less than 2 inspections per year, then the increase would be positive. In the UK, we currently receive around 10 to 12 inspections per year - we are unclear if the proposal is to reduce the number of annual inspections in cases like this?

Animal Procedures Committee (APC)	Public authority	National	The APC provide independent advice to UK Government on the use of animals in scientific procedures. The APC consider science, industry and animal welfare. Members are from a variety of backgrounds.	These proposals are a suitable start line for those states which currently have little or no inspection. For states with no current minimum level, this would presumably be an improvement but the APC has no evidence to contribute on what occurs outside the UK.
Swedish Animal Welfare Agency	Public authority	National	yes	In Sweden, responsibility for ensuring animal welfare is divided between central, regional and local competent authorities. At the regional level, the County Administrative Board is responsible for animal welfare. Sweden is divided into 21 Counties and in each of these the County Administrative Board coordinates the local authorities within the region. In each of Sweden's 290 municipalities, an Environmental and Public Health Service is responsible for animal welfare on local level. To ensure that animal welfare legislation is followed, an Animal Welfare Inspector from the Environmental and Public Health Service conducts inspections of laboratory animal facilities twice a year. According to the Animal Welfare Act, the municipality is obliged to employ personnel trained in animal welfare in order to carry out this task in a satisfactory manner.

(Name confidential - Respondent 117)	Public authority	National; European; Worldwide	yes	Consistency across European inspectorates is essential.
(Name confidential - Respondent 118)	Public authority	National	Yes	The questions are impossible to answer without knowing the suggested quality level/standard of the inspection. That also includes the qualifications and skill of the inspectors.
(Name confidential - Respondent 122)	Public authority	National	We are the National Competent Authority	We do not support a system of EU inspections (which we would expect to be funded and delivered by the Commission), which, as your later analysis suggests, would entail very high resource and compliance costs and produce no meaningful benefits. Regarding the wider issue of inspection, in our view the focus must be on what inspection is intended to achieve, and not simply the frequency of inspection. For example, in the UK inspections are carried out to determine that procedures are performed as authorised; that the terms and conditions of authorised programmes are being adhered to; and to identify and spread best practice.
(Name confidential - Respondent 123)	Public authority	National	yes	Breeding and supplying establishments should also be submitted to regular inspections (min 1/year; compare Österr. Tierversuchsgesetz)
(Name confidential - Respondent 126)	Public authority	National	Regulatory authority in UK	Focus should be on the inspection process and what it should achieve rather than on numbers of inspections. Flexibility should be maintained to ensure that an appropriate inspection system is in place determined by the size of the places and the complexity and extent of work. For some small places a minimum of one visit per year is reasonable and insisting on 2 visits per year would be a waste of resource. Frequency of inspection should be based on a size and risk basis. Inspection should not be about places only but should include assessment of the quality of science and include discussion on programmes and ongoing work.

(Name confidential - Respondent 135)	Public authority	Worldwide	yes	this is quite some effort in our (small) country. It is now done annually or biannually
Biosciences Federation	Other	National; European	There are other relevant organisations	Some level of inspection is warranted to provide public accountability, but there should be a major effort towards standardisation between member states, the lack of which is currently highly unsatisfactory. The twice yearly rate proposed seems appropriate. If there are to be inspections then de facto there need to be sanctions if the inspections are to generate public confidence. The document provides no insight into what such sanctions might be and how they might be implemented. This requires consultation.
COST Action B24 "Laboratory Animal Science Welfare" - http://biomedicum.ut.ee/costb24	Other	European	No	At 1.4 Yes, but only because public just believes if there are more inspections then standards are better met. Animal welfare is particularly dependant on qualified persons (animal keepers, veterinary surgeons, experts for laboratory animal science) working in an establishment, their knowledge and appropriate equipment.
Medical University of Vienna	Other	Local; Regional; National; European; Worldwide	Research in Medicine	Ad 1.4 Yes, if inspections serve to falsify the horror stories from some animal rightists by which the public is overrun and misinformed (see Chapter XII).

The Association for the Study of Animal Behaviour	Other	Worldwide	yes	The reason for 'No' in several cases above is that inspections may certainly serve the 'accountability', 'transparency' and 'public image' issues, but their effect on animal welfare is much more questionable. Thus the points 1.2-1.5 have too many issues within them to allow a simple Yes/No response. Experience with current national systems of inspection is that their impact is highly dependent on individual inspectors, with considerable variation in the requirements and restrictions applied, and in the form of information provided within licence applications. The higher the level of bureaucracy driving the inspections, the greater the potential for over-generalized decisions. This is a particular problem with fundamental research. In the UK, many Home Office inspectors have a veterinary background and bring a simplistic clinical perspective to welfare decisions. Again, current regulation is too tramlined by a biomedical/commercial perspective
(Name confidential - Respondent 143)	Other	National	Regulatory body	Focus should be on the inspection process and what it should achieve rather than on numbers of inspections. Flexibility should be maintained to ensure that an appropriate inspection system is in place determined by the size of the places and the complexity and extent of work. For some small places a minimum of one visit per year is reasonable and insisting on 2 visits per year would be a waste of resource. Frequency of inspection should be based on a size and risk basis. Inspection should not be about places only but should include assessment of the quality of science and include discussion on programmes and ongoing work.
(Name confidential - Respondent 147)	Other	Not applicable	not applicable	In many countries there are more than two inspections in companies per year (sometimes as frequent as 1 per month). I would support increasing the number of inspections.

(Name confidential - Respondent 154)	Other	National	representative	It is very naive to think that an Inspector can get a good idea of how an establishment functions on a single unannounced inspection, or to think that there are significant changes between announced and unannounced inspections. Care must be taken not to focus on the process of inspection - how often, how long, but to focus on the function of inspection and describe criteria for what an inspection is supposed to achieve. A single, announced detailed inspection may be of more value than several unannounced short visits. There is a balance here between what is necessary to make a proper audit of compliance, and public expectation, which may be that inspections will be unannounced to 'catch people out'.
Eurogroup for Animal Welfare/EWLA	Non-governmental organisation	European	Eurogroup/EWLA is made up of animal welfare Member Organisations and Observers in all Member States	Minimum requirements for the inspection of breeding, supply and user establishments, should be laid down in the revised Directive to ensure inspection processes and minimum levels of supervision are harmonised for all types of establishment. The proposed level of two inspections should be the absolute minimum. The requirement for two inspections per year, one of which is unannounced, provides a reasonable balance between the need for a manageable administrative burden and the need to ensure a reliable system that will be able to take into account and, for example, advise on changing scientific procedures or breeding needs). Regular inspections at defined intervals are essential in order to ensure: a) that there is a 'level playing field' with respect to implementation of the Directive and competitiveness throughout the European Union; and b) that the animal welfare provisions of the Directive are met and properly monitored in all establishments.

European Coalition to End Animal Experiments (ECEAE)	Non-governmental organisation	Worldwide	Representative (the only EU coalition focusing on animal experiments)	To ensure harmonisation of supervision of breeding, supply and user establishments, minimum requirements for the inspection of all of these types of establishments should be laid down in the revised Directive. The proposal of requesting two inspections per year, of which one unannounced, provides a reasonable balance between the need not to create too high administrative burden and to ensure a reliable system (that for example is sufficiently closely meshed to register changing scientific procedures or changing breeding needs). Even if the inspection frequency proposed by the Commission would lead to a moderate increase in administrative costs, especially for those Member States with centralized systems of authorisation, regular inspections with concrete defined periods are inevitable to ensure that there is level playing competitiveness throughout the European Union and that animal welfare provisions are met in the establishments and are adequately monitored on a continuous basis.
FELASA (Federation of European Laboratory Animal Science Associations)	Non-governmental organisation	European	FELASA represents 13 European lab animal sci associations and therefore some 3-4000 members of those associations (scientists, veterinary surgeons, technicians etc.). See www.felasa.org	Regarding twice yearly inspections, this should be the minimum required, so that national authorities may determine the appropriate level of inspection on a case by case basis.

Gesellschaft für Versuchstierkunde - Society for Laboratory Animal Science (GV-SOLAS)	Non-governmental organisation	National; European	Yes	At 1.4 Yes, but only because public just believes if there are more inspections then standards are better met. Animal welfare is particularly dependant on qualified persons (animal keepers, veterinary surgeons, experts for laboratory animal science) working in an establishment, their knowledge and appropriate equipment.
Nuffield Council on Bioethics	Non-governmental organisation	National; Worldwide	There any other relevant organisations	See para 13.20 for information on inspections in the UK, half of which are unannounced, in Nuffield Council on Bioethics (2005) The ethics of research involving animals (London: Nuffield Council on Bioethics) Available at: http://www.nuffieldbioethics.org/go/ourwork/animalresearch/publication_178.html
PETA Europe Ltd.	Non-governmental organisation	Worldwide	both	A harmonized and efficiently administered system could reduce the administrative burden in some MSs at the same time as improving animal welfare and public accountability. Public confidence is low and the effectiveness of inspections must be questioned in view of information obtained through investigations carried out by animal protection organisations. Lack of compliance detailed in the European Parliament Resolution on Directive 86/609 [TA(2002)0594] provides further justification for changes to inspection practice and reporting. Unannounced inspections are essential. In the BUAV's 2002 report: An Investigation by the BUAV into Primate Research at Cambridge University (http://www.buav.org/zerooption/news.html) the investigator noted that ' . . . on the morning of the visit . . . staff and researchers were given instructions to make sure that all animals including experimental ones had an identification tag and that records were correct.' Also, staff prepared in other ways
PROFESSOR RD COMBES - FRAME	Non-governmental organisation	Worldwide	THERE ARE OTHERS	The key to good welfare, and therefore, good science is a culture of care at each establishment - the more inspections and control, to balance human nature and pressures of work to generate data, the better.

The National Anti-Vivisection Society	Non-governmental organisation	National; European; Worldwide	The NAVS is the leading and oldest anti-vivisection organisation in the world. There are a number of other relevant anti-vivisection organisations around the world with expertise in this field.	Our undercover investigations have raised issues of concern regarding inspections. When laboratories are made aware of visits in advance, staff are warned to take extra care, clean up and hide problems, thus giving a false impression on the day of inspection. Inspections are not thorough and do not include every area; in 20 months spent in two laboratories our investigator did not meet a Home Office inspector although the visits took place on his working days, this is because inspectors failed to inspect the areas in which he was working (1). There is added concern that inspections may be biased when individual inspectors are known to establishments and have a long standing working relationship with them. There is a clear need for inspections to be more frequent and for frequency to be specified but this is unlikely to improve animal welfare unless the majority of these inspections are unannounced. (1) Access denied 1996. NAVS report http://www.navs.org.uk/publications/reports/c=1
The Physiological Society	Non-governmental organisation	Worldwide	Many other Learned Societies are also representative	Some level of inspection is warranted to provide public accountability, but there should be a major effort towards standardisation between member states, the lack of which is currently highly unsatisfactory. The twice yearly rate proposed seems appropriate. If there are to be inspections then de facto there need to be sanctions if the inspections are to generate public confidence. The document provides no insight into what such sanctions might be and how they might be implemented. This requires consultation.
UK Laboratory Animal Science Association (LASA)	Non-governmental organisation	National	LASA represents animal user community in academic, government & industry sectors.	In the UK there are considerably more than 2 inspections per year and a number of these are unannounced.

(Name confidential - Respondent 163)	Non-governmental organisation	National; European; Worldwide	both	please refer to statements given by ECEAE and PETA
(Name confidential - Respondent 165)	Non-governmental organisation	Worldwide	Yes	As with many of the proposals discussed here, the authorities conducting inspection must prove that they are being effective in order to gain the trust of the public and in order to have an impact on animal welfare. If the inspections show no problems and no enforcement, especially if problems are uncovered by whistleblowers or through audits, for example, animal will suffer and the public will not trust the system—not to mention the waste of money in conducting such inspections if they are not effective and not taken seriously.
(Name confidential - Respondent 166)	Non-governmental organisation	National	NO OTHER RELEVANT ORGANISATION	Inspections are not centralized in France. Notwithstanding, it remains that the cost is directly linked to the number of inspections.
(Name confidential - Respondent 169)	Non-governmental organisation	National	Represents all Finnish pharmacologists	Increasing the number of inspections will have no impact on the welfare of laboratory animals but will disrupt the routines of workers in animal facilities and researchers
(Name confidential - Respondent 170)	Non-governmental organisation	National	The Danish Society of Pharmacology and Toxicology represents Danish pharmacologists and toxicologists.	No further comment.

(Name confidential - Respondent 172)	Non-governmental organisation	Regional	Yes	It should be anticipated that raising the number of inspections will require national bodies to increase their staff and therefore the associated costs will not be minimal.
(Name confidential - Respondent 174)	Non-governmental organisation	Worldwide	-	In many countries there are more than two inspections in companies per year (sometimes as frequent as 1 per month). Pharmaceutical industry would support increasing the number of inspections.
(Name confidential - Respondent 177)	Non-governmental organisation	Worldwide	Representative	The corollary of increasing the number of inspections must be that there is an increase in the number of inspectors and costs must rise proportionately. However, the benefits probably outweigh the costs.
(Name confidential - Respondent 178)	Non-governmental organisation	Worldwide	yes	Since from a German point of perspective we are nationally inspected every 2 weeks, often unannounced. Since care, handling and housing of animals is done with the respect it should be done, and according to law unannounced inspections shouldn't be a thing to have fear of. It is very effective and necessary.
(Name confidential - Respondent 179)	Non-governmental organisation	Worldwide	The field at the respective activity level	Is very important to implement inspections
(Name confidential - Respondent 183)	Breeder of animals	Worldwide	We are representative for the field and constitute about 50 percent of the activity	No justification required.

Biotechnology and Biological Sciences Research Council		National	Representative	BBSRC supports the principle of inspections but suggests that the number of inspections per year should reflect the size of facility and nature of procedures.
(Name confidential - Respondent 188)		Regional; National	Not applicable: response is based on personal expertise	The specification should be for a minimum of 2 annual inspections per year rather than for 2, since more inspections are justified for some establishments and some circumstances. The importance of inspections is what they achieve rather than how often they occur. Inspections can have positive impacts on science as well as welfare. For the UK and some other MS there will be no or minimal increase in administrative costs.
(Name confidential - Respondent 190)		Regional; Worldwide	also others	It should be anticipated that raising the number of inspections will require national bodies to increase their staff and therefore the associated costs will not be minimal. However it should be taken into account that unannounced inspections can in some instances be a severe problem, e.g. when long-term behavioural experiments are carried out. Perturbation of the daily routine by an inspection (= exposure to non-familiar persons) could ruin a whole series of experiments.
(Name confidential - Respondent 192)		National; European; Worldwide	Yes	While inspections are important, a frequency of once in two years instead of twice a year seems more appropriate, unless one is convinced that research institutes and animal facilities are inhabited by irresponsible persons.

Question VII.2.1.

Question text:

The overall preliminary assessment shows, that EU inspections would not result in a significant increase in animal welfare unless disproportionately high resources were be invested to render these inspections efficient and sufficiently frequent.

Do you support this overall analysis? Yes/No/No opinion

Statistics:

185 respondents stated that they support the preliminary analysis.

17 respondents stated that they have no opinion in relation to this question.

20 respondents stated that they do not support the preliminary analysis or components of it. To justify disagreement, they were asked to provide arguments, facts and figures and if possible indicate the source of information. However, a number of respondents opted for the "No" reply only to supply additional arguments in support of the preliminary analysis.

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII.2.1A.
(Name confidential - Respondent 008)	User of animals - public sector	Local; National; European; Worldwide	representative of a research university	Animal welfare can be improved simply because an inspection is going to take place and help ensure compliance.

(Name confidential - Respondent 017)	User of animals - public sector	National; European; Worldwide	Yes	I feel that they would increase animal welfare as inspections underpin animal welfare and the work of reputable scientists and professional animal care staff, therefore a system of rigorous national inspections is required to feed into the European system..
(Name confidential - Respondent 036)	User of animals - public sector	Worldwide	Yes	I disagree
(Name confidential - Respondent 072)	User of animals - private sector	European	Yes	As long as the inspections are unannounced, the efficiency will noticeably increase. Unannounced inspections will reduce the required number of inspection per year and will give a more objective picture of the condition of animals there.
(Name confidential - Respondent 107)	User of animals - private sector	Worldwide	yes	---
(Name confidential - Respondent 114)	Public authority	National	XXX is central competent authority for approval for the experiments and inspections animal protection	EU inspections are carried out on implementation of EU rules by competent authorities. These inspections are actually carried in other issues of veterinary field. These inspections lead to uniform application of the same provisions, which lead to increase of welfare of used animals indirectly, by providing the effective pressure on these competent authorities. It also makes the field of interest transparent.
(Name confidential - Respondent 117)	Public authority	National; European; Worldwide	yes	There may need to be a relatively high input, but there could be a huge increase in animal welfare and a better equalisation of competitiveness.

(Name confidential - Respondent 126)	Public authority	National	Regulatory authority in UK	see 2.5
(Name confidential - Respondent 127)	Public authority	National	Ministry of VWS is also involved	it would harmonise everything on a higher level. Look at positive effects of FVO
(Name confidential - Respondent 133)	Public authority	National; European	Yes, together with the National Food and Product safety Authority	EU- inspections will contribute to create harmonized standards about animal experimentation with the EU. FVO is a very clear example to this purpose. FVO inspects also animal welfare issues at this moment, which would be the basis for EU -inspections under the animal experiment directive. This combination could reduce the economical disadvantages due to the setting up of a totally new inspection infrastructure.
1. Animal Aid	Other	National	Other organisations do exist	Spend what is necessary to properly supervise experiments and to protect animals.
(Name confidential - Respondent 149)	Other	Worldwide	The Institute of Animal Technology is the professional body representing animal technologists	Inspections are an essential part of promoting animal welfare and member states should make funding available.

Eurogroup for Animal Welfare/EWLA	Non-governmental organisation	European	Eurogroup/EWLA is made up of animal welfare Member Organisations and Observers in all Member States	Without knowing what sort of system is proposed, how this would relate to the system in Member States, and the level of resources that would be required, it is not possible to agree that the required level of investment is disproportionately high. It is nevertheless necessary to establish some type of EU surveillance of the Member State inspection system to ensure that the harmonisation and enforcement envisaged is achieved.
European Coalition to End Animal Experiments (ECEAE)	Non-governmental organisation	Worldwide	Representative (the only EU coalition focusing on animal experiments)	While the introduction of a general obligation to perform specific EU inspections in individual establishments in the Member States might result in disproportionately high resources to be invested, it is nevertheless necessary to establish some type of EU surveillance of the Member State inspection system to ensure that the harmonisation envisaged is truly met (see below).
Norwegian Animal Welfare Alliance	Non-governmental organisation	National	2 other relevant organisations	Experience from other areas (i. e. abattoirs) indicates that EU inspections can have a positive impact on national compliance and priorities.
PETA Europe Ltd.	Non-governmental organisation	Worldwide	both	Resources must be made available for EU inspections because of low public confidence in MS inspections; the frequency of breaches in the law identified through animal protection investigations and the grave consequences of non-compliance in terms of increased animal suffering. The EU level of inspections, coupled with systems to ensure dialogue between national inspection teams and competent authorities in different MSs, is also essential in ensuring consistent application of rules and systems such as ethical review and severity classifications, as well as compliance. It could be envisaged that senior inspectors from MSs also take a role as EU inspectors, reducing costs of training and ensuring consistency. Ultimately, as stated, the additional resources should be made available because of the importance of compliance and the consequences of non-compliance.

Stichting EDEV - Een DIER Een VRIEND	Non- governmental organisation	National; European	We cooperate with animal organisations within the ECEAE	The more independent and transparant inspections the better it will be for the animals welfare
The National Anti-Vivisection Society	Non- governmental organisation	National; European; Worldwide	The NAVS is the leading and oldest anti- vivisection organisation in the world. There are a number of other relevant anti- vivisection organisations around the world with expertise in this field.	All of the NAVS reports (1-4) have highlighted problems with the UK inspection system. There are many aspects which should be harmonised under this Directive and inspection would be step towards this. It is vital that there be inspection and accountability. We would question the sentiment that the cost of a significant increase in animal welfare could be disproportionately high. (1) Access denied 1996. NAVS report http://www.navs.org.uk/publications/reports/c=1 (2) Labs unlocked (1994) NAVS report (3) Vivisection in Britain (1992) NAVS report. (4) Animal experiments at Inveresk (2005) ADI report http://www.navs.org.uk/downloads/invereskreport.pdf
(Name confidential - Respondent 163)	Non- governmental organisation	National; European; Worldwide	both	Resources must be made available for EU inspections because of low public confidence in MS inspections; the frequency of breaches in the law identified through animal protection investigations and the grave consequences of non-compliance in terms of increased animal suffering. The EU level of inspections, coupled with systems to ensure dialogue between national inspection teams and competent authorities in different MSs, is also essential in ensuring consistent application of rules and systems such as ethical review and severity classifications, as well as compliance. It could be envisaged that senior inspectors from MSs also take a role as EU inspectors, reducing costs of training and ensuring consistency. Ultimately, as stated, the additional resources should be made available because of the importance of compliance and the consequences of non-compliance.

(Name confidential - Respondent 188)		Regional; National	Not applicable: response is personal opinion based on personal expertise	There may need to be a relatively high input, but there could be a huge increase in animal welfare and a better equalisation of competitiveness.
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Question VII.2.2.

Question text:

Resource requirements:

Establishment of an EU-Inspectorate on animal welfare would require unrealistically high personnel and financial resources to ensure an effective level of inspections of all establishments in all 25 Member States.

Do you support this overall analysis? Yes/No/No opinion

Statistics:

171 respondents stated that they support the preliminary analysis.

21 respondents stated that they have no opinion in relation to this question.

22 respondents stated that they do not support the preliminary analysis or components of it. To justify disagreement, they were asked to provide arguments, facts and figures and if possible indicate the source of information. However, a number of respondents opted for the "No" reply only to supply additional arguments in support of the preliminary analysis.

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII.2.2a.
(Name confidential - Respondent 007)	User of animals - public sector	National	yes	-

(Name confidential - Respondent 008)	User of animals - public sector	Local; National; European; Worldwide	representative of a research university	It could be the equivalent of the FVO
(Name confidential - Respondent 036)	User of animals - public sector	Worldwide	Yes	I disagree
(Name confidential - Respondent 045)	User of animals - public sector	National; European; Worldwide	Our organisation is representative within the field of cancer research but we have many collaborations with other like organisations.	As a charitable organisation, we would not welcome additional financial burden of increased costs.
GlaxoSmithKline	User of animals - private sector	Worldwide	There are other international pharmaceutical companies. We produce 25% of the world's vaccines	The costs of an EU inspection would, it could be expected, have to be borne primarily by EU government institutions. It would be unreasonable for the EU to impose both a second tier of inspection AND expect national authorities or institutions to pay for this second tier of inspection.
(Name confidential - Respondent 072)	User of animals - private sector	European	Yes	Unrealistically high is only exaggeration since such a system is already in use. Modifications in that system as personnel and paper work can not bring such a high load as if creating the system from zero.

(Name confidential - Respondent 107)	User of animals - private sector	Worldwide	yes	---
(Name confidential - Respondent 114)	Public authority	National	XXX is central competent authority for approval for the experiments and inspections animal protection	The European Commission has already established such body - FVO. The new may be a part of FVO, which will need relatively low increases of costs.
(Name confidential - Respondent 117)	Public authority	National; European; Worldwide	yes	Experienced member state inspectors could be used as a quality control / training facility across other countries without major resource implications..
(Name confidential - Respondent 126)	Public authority	National	Regulatory authority in UK	see 2.5
(Name confidential - Respondent 127)	Public authority	National	Ministry of VWS is also involved	cooperation with FVO might cut the costs considerably

(Name confidential - Respondent 133)	Public authority	National; European	Yes, together with the National Food and Product safety Authority	See argumentation under 2.1.a
1.Animal Aid	Other	National	Other organisations do exist	An EU inspectorate has potentially more independence - which would lead to greater transparency. An EU system of inspections at slaughter houses already exists and produces benefits.
Cris Iles-Wright	Other	Not applicable	Not applicable	There is a desire among the industry to present at least an illusion of laboratory activity being monitored. Most people realise this is not practical given current staffing levels. If the claim is being made, appointment methods and staff levels need to be improved radically.
The Association for the Study of Animal Behaviour	Other	Worldwide	yes	see 2.5 below
Eurogroup for Animal Welfare/EWLA	Non-governmental organisation	European	Eurogroup/EWLA is made up of animal welfare Member Organisations and Observers in all Member States	The task of an EU inspectorate would be in line with the Commission's obligation to ensure that as outlined in Treaty article 211, the measures foreseen in the Directive are being applied by all Member States. As with other inspectorates such as the Food and Veterinary office, the Inspectorate checks if at Member States level the necessary systems, ethical review process and authorisations are in place to ensure that the competent authorities can effectively control the enforcement of the Directive. In case of doubt, spot checks of some establishments are foreseen.

European Coalition to End Animal Experiments (ECEAE)	Non-governmental organisation	Worldwide	Representative (the only EU coalition focusing on animal experiments)	See below justification
PETA Europe Ltd.	Non-governmental organisation	Worldwide	both	As stated above, it is possible to envisage senior inspectors from MSs taking a role in EU inspections. This will improve expertise within MSs and dialogue between MSs and the European Commission. The additional resources must be made available to ensure maximum animal welfare advantages and to improve public accountability. The European Union has resources available, so this is a matter of prioritization, not scarcity of resources. Because EU citizens demand a high level of animal protection, it is appropriate that funding is made available. Research facilities using animals should also contribute a proportion of the cost, as an effective inspection system could benefit their public image.
Stichting EDEV - Een DIER Een VRIEND	Non-governmental organisation	National; European	We cooperate with animal organisations within the ECEAE	This is the price we have to pay.

The National Anti-Vivisection Society	Non-governmental organisation	National; European; Worldwide	The NAVS is the leading and oldest anti-vivisection organisation in the world. There are a number of other relevant anti-vivisection organisations around the world with expertise in this field.	An EU inspectorate could work in tandem with national inspection systems, utilising what is already in existence.
(Name confidential - Respondent 163)	Non-governmental organisation	National; European; Worldwide	both	As stated above, it is possible to envisage senior inspectors from MSs taking a role in EU inspections. This will improve expertise within MSs and dialogue between MSs and the European Commission. The additional resources must be made available to ensure maximum animal welfare advantages and to improve public accountability. The European Union has resources available, so this is a matter of prioritization, not scarcity of resources. Because EU citizens demand a high level of animal protection, it is appropriate that funding is made available. Research facilities using animals should also contribute a proportion of the cost, as an effective inspection system could benefit their public image.
(Name confidential - Respondent 188)		Regional; National	Not applicable: response is personal opinion based on personal expertise	Experienced member state inspectors could be used as a quality control / training facility across other countries without major resource implications.

Question VII.2.3.

Question text:

Efficiency:

An EU inspectorate on animal welfare would not contribute to a more efficient control of compliance, because the differences in authorisation and ethical review systems in the Member States would require different approaches at a decentralized level.

Do you support this overall analysis? Yes/No/No opinion

Statistics:

178 respondents stated that they support the preliminary analysis.

18 respondents stated that they have no opinion in relation to this question.

23 respondents stated that they do not support the preliminary analysis or components of it. To justify disagreement, they were asked to provide arguments, facts and figures and if possible indicate the source of information. However, a number of respondents opted for the "No" reply only to supply additional arguments in support of the preliminary analysis.

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII.2.3a.

(Name confidential - Respondent 007)	User of animals - public sector	National	jes	-
(Name confidential - Respondent 008)	User of animals - public sector	Local; National; European; Worldwide	representative of a research university	But it would give some confidence in a level playing field
(Name confidential - Respondent 024)	User of animals - public sector	Worldwide	Representative	Most important items are the same in all States.
(Name confidential - Respondent 029)	User of animals - public sector	Local; Regional; National; European; Worldwide	No	One of the goals of the revised directive is to equalize the authorisation and ethical review systems for all member states and from that point of view it wouldn't require different approaches!
(Name confidential - Respondent 036)	User of animals - public sector	Worldwide	Yes	This directive will harmonize them more. The difference are of no major importance.
(Name confidential - Respondent 056)	User of animals - public sector	Local	organisation is representative	this question was not in the questionnaire when I printed it out
(Name confidential - Respondent 059)	User of animals - public sector	Not applicable	No	I still think that the inspections should be performed by those not living in the same country, that is, Portugal should be inspected by swedish inspectors and vice-versa. In our country many conflict of interests arise and possibility of corruption is high

(Name confidential - Respondent 072)	User of animals - private sector	European	Yes	The efficiency will gradually increase as the centralization among member states increase. However, doing something is always better than doing nothing.
(Name confidential - Respondent 080)	User of animals - private sector	European	Representative	The legislation should there for be standardised.
(Name confidential - Respondent 114)	Public authority	National	XXX is central competent authority for approval for the experiments and inspections animal protection	The new Directive has to harmonised the procedures, therefore your these preliminary findings are not correct.
(Name confidential - Respondent 117)	Public authority	National; European; Worldwide	yes	The new directive instills significant similarities and it would be these which would be used in "European" evaluations. It would need to account for local processes, but in for example standards of housing and care, these should be the same minimum standards across Europe.
(Name confidential - Respondent 127)	Public authority	National	Ministry of VWS is also involved	different systems should lead to the same results. this could be inspected by the EU inspections

(Name confidential - Respondent 133)	Public authority	National; European	Yes, together with the National Food and Product safety Authority	If there is a total harmonization of the legislation (for example a regulation instead of a directive) this problem should be reduced. But even in the case of a directive EU-inspection result could be very positive to follow the developments at national and EU-level and to facilitate policy decision based on real data.
1. Animal Aid	Other	National	Other organisations do exist	Most EU proposals call for harmonisation and transparency, therefore an EU inspectorate could be efficient.
Eurogroup for Animal Welfare/EWLA	Non-governmental organisation	European	Eurogroup/EWLA is made up of animal welfare Member Organisations and Observers in all Member States	The inspections would cover national implementation systems to enforce all requirements of the Directive and this can be achieved with due consideration of differences in approach. The inspections are intended to ensure that the provisions foreseen in the National law transposing the Directive can be properly controlled.
European Coalition to End Animal Experiments (ECEAE)	Non-governmental organisation	Worldwide	Representative (the only EU coalition focusing on animal experiments)	See below justification

PETA Europe Ltd.	Non-governmental organisation	Worldwide	both	As stated above, it is possible to envisage senior inspectors from MSs taking a role in EU inspections. This will improve expertise within MSs and dialogue between MSs and the European Commission. The additional resources must be made available to ensure maximum animal welfare advantages and to improve public accountability. The European Union has resources available, so this is a matter of prioritization, not scarcity of resources. Because EU citizens demand a high level of animal protection, it is appropriate that funding is made available. Research facilities using animals should also contribute a proportion of the cost, as an effective inspection system could benefit their public image.
Stichting EDEV - Een DIER Een VRIEND	Non-governmental organisation	National; European	We cooperate with animal organisations within the ECEAE	Why not harmonise to the highest possible standard: no more problem on this
The National Anti-Vivisection Society	Non-governmental organisation	National; European; Worldwide	The NAVS is the leading and oldest anti-vivisection organisation in the world. There are a number of other relevant anti-vivisection organisations around the world with expertise in this field.	Not necessarily, An EU inspectorate could work in tandem with national inspection systems, utilising what is already in existence.

(Name confidential - Respondent 163)	Non-governmental organisation	National; European; Worldwide	both	The revised directive is expected impose certain minimum standards relating to ethical review and authorization systems in MSs, and it is consistency in application of these systems, as well as ensuring compliance in general, that will most benefit from the establishment of EU inspections. Where there are differences between rules applied in MSs, these are expected to arise from higher national standards being applied, whereas the purpose of the EU inspectorate is primarily to identify lower standards, where research facilities fail to meet the minimum standards imposed by the directive. If inspectors find higher standards due to national differences, there could be positive advantages in spreading best-practice
(Name confidential - Respondent 173)	Non-governmental organisation	Local; Regional; National; European	One other	Why
(Name confidential - Respondent 188)		Regional; National	Not applicable: response is personal opinion based on personal expertise	The new directive instils significant similarities and it would be these which would be used in “European” evaluations. It would need to account for local processes, but in for example standards of housing and care, these should be the same minimum standards across Europe.
(Name confidential - Respondent 192)		National; European; Worldwide	Yes	see below

Question VII.2.4.

Question text:

Regulatory compliance in Member States:

To be effective and efficient, an EU inspectorate would require harmonised regulatory standards throughout Europe, which would presuppose unrealistic high regulatory compliance costs for all Member States.

Do you support this overall analysis? Yes/No/No opinion

Statistics:

172 respondents stated that they support the preliminary analysis.

23 respondents stated that they have no opinion in relation to this question.

20 respondents stated that they do not support the preliminary analysis or components of it. To justify disagreement, they were asked to provide arguments, facts and figures and if possible indicate the source of information. However, a number of respondents opted for the "No" reply only to supply additional arguments in support of the preliminary analysis.

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII.2.5a.

(Name confidential - Respondent 007)	User of animals - public sector	National	jes	-
(Name confidential - Respondent 008)	User of animals - public sector	Local; National; European; Worldwide	representative of a research university	Not necessarily too costly by the side of real costings for animal research
(Name confidential - Respondent 045)	User of animals - public sector	National; European; Worldwide	Our organisation is representative within the field of cancer research but we have many collaborations with other like organisations.	As a charitable organisation, we would not welcome additional financial burden of increased costs.
(Name confidential - Respondent 056)	User of animals - public sector	Local	organisation is representative	this question was not in the questionnaire when I printed it out
(Name confidential - Respondent 072)	User of animals - private sector	European	Yes	Unrealistically high is only exaggation since such a system is already in use. Modifications in that system as personnel and paper work can not bring such a high load as if creating the system from zero.
(Name confidential - Respondent 080)	User of animals - private sector	European	Representative	It would achieve the level playing field that everyone wants

(Name confidential - Respondent 114)	Public authority	National	XXX is central competent authority for approval for the experiments and inspections animal protection	Approval of each animal experiment is compulsory according the current Directive. The same we expect to be in the new one. Only this system allows prevent use of unnecessary animals and perform the experiments by the most gently methods. The cost/benefit assessment according our opinion is on the side of regulated experimentation (harmonised regulatory standards).
(Name confidential - Respondent 117)	Public authority	National; European; Worldwide	yes	The regulatory standards set in the European legislation could be used with reference to local legislation and compliance with these should already be in place in most member states. The additional costs would not be high.
(Name confidential - Respondent 127)	Public authority	National	Ministry of VWS is also involved	See FVO examples
(Name confidential - Respondent 133)	Public authority	National; European	Yes, together with the National Food and Product safety Authority	A regulation with a clearly defined standars should be the legislative basis. I can't imagine this means mote costs for teh MS than the transposition/implementation of a directive
1.Animal Aid	Other	National	Other organisations do exist	A key idea embodied in this consultation is to achieve harmonisation across the EU. Thus, in order to accomplish anything, an EU Directive must achieve harmonisation.

Eurogroup for Animal Welfare/EWLA	Non-governmental organisation	European	Eurogroup/EWLA is made up of animal welfare Member Organisations and Observers in all Member States	To be effective and efficient, an EU inspectorate would indeed require harmonised regulatory standards throughout the Member States. However, while the standards would have to be comparable, they would not have to be identical. Therefore, the regulatory compliance costs need not be unrealistically high.
European Coalition to End Animal Experiments (ECEAE)	Non-governmental organisation	Worldwide	Representative (the only EU coalition focusing on animal experiments)	See below justification
PETA Europe Ltd.	Non-governmental organisation	Worldwide	both	See above. Minimum standards will be established through the directive, and it is breaches in these that will be of interest to the EU inspectors. Where/if higher standards exist in some MSs, sharing of best practice by spreading knowledge through EU inspection teams can only serve to enhance animal protection.
PROFESSOR RD COMBES - FRAME	Non-governmental organisation	Worldwide	THERE ARE OTHERS	I do not agree with the presupposition.
Stichting EDEV - Een DIER Een VRIEND	Non-governmental organisation	National; European	We cooperate with animal organisations within the ECEAE	Is not unrealistic. The money to build million euro expensive labs and pay huge salaries always seems to be there so.... why not for this?

The National Anti-Vivisection Society	Non-governmental organisation	National; European; Worldwide	The NAVS is the leading and oldest anti-vivisection organisation in the world. There are a number of other relevant anti-vivisection organisations around the world with expertise in this field.	There seems no logical reason not to make inspection part of a wider harmonisation of the authorisation processes.
(Name confidential - Respondent 163)	Non-governmental organisation	National; European; Worldwide	both	See above. Minimum standards will be established through the directive, and it is breaches in these that will be of interest to the EU inspectors. Where/if higher standards exist in some MSs, sharing of best practice by spreading knowledge through EU inspection teams can only serve to enhance animal protection.
(Name confidential - Respondent 188)		Regional; National	Not applicable: response is personal opinion based on personal expertise	The regulatory standards set in the European legislation could be used with reference to local legislation and compliance with these should already be in place in most member states. The additional costs would not be high.
(Name confidential - Respondent 192)		National; European; Worldwide	Yes	see below

Question VII.2.5.

Question text:

Justification (open text box)

Statistics:

(no numbers registered as this was not a closed question)

Comments received:

Name of the expert or organisation	Type of organisation	Activity level of the organisation	Representativeness	VII.2.5. Justification
(Name confidential - Respondent 008)	User of animals - public sector	Local; National; European; Worldwide	representative of a research university	I believe it is quite important that compliance with EU legislation is seen to be enforced at the EU level. Simply being auditable is an awareness call, and institutions will be more likely to comply, especially if the penalties are proportionate. It also cross-checks on competent authorities. It works to some extent with farming and their experience would be valuable (FVO).

(Name confidential - Respondent 011)	User of animals - public sector	National; European; Worldwide	Other organisations in Austria: Karl-Franzens-University; Medical University Vienna; Medical University Innsbruck	Given the enormous costs associated with implementing a European inspectorate, which certainly would not in any way be more effective than national inspectors, this option does not seem to offer any real advantage. A European inspectorate would create a hugely costly, cumbersome and, probably, minimally effective structure and this should be resisted. Each member country should develop its own which should operate according to some agreed protocols
(Name confidential - Respondent 012)	User of animals - public sector	National	yes, competitive in the field of small animal research	Keep things as local as possible, with only a minimal national overhead.
(Name confidential - Respondent 014)	User of animals - public sector	Local; Regional; National; European; Worldwide	Yes	The idea of inspections at EU levels should be abandoned. Unless the EU is intended to become a police state, such inspections are non-realistic in terms of administration and cost and would represent a useless replication of inspections at member state level. The EU should define minimal standards, their implementation and enforcement should be a task of the member states. A European inspectorate would create a hugely costly, cumbersome and, probably, minimally effective structure and this should be resisted. Each member country should develop its own which should operate according to some agreed protocols.
(Name confidential - Respondent 021)	User of animals - public sector	Regional	yes	Given the enormous costs associated with implementing a European inspectorate, which certainly would not in any way be more effective than national inspectors, this option does not seem to offer any real advantage.

(Name confidential - Respondent 036)	User of animals - public sector	Worldwide	Yes	It would insure that experts are controlling the facilities which smaller countries could not achieve. Corruption and different cultural differences would not play a role in animal welfare issues.
(Name confidential - Respondent 037)	User of animals - public sector	National; European; Worldwide	Yes	A harmonised EU approach is to be strongly encouraged.
(Name confidential - Respondent 046)	User of animals - public sector	National	yes	The revision propose (chap III B option 1) to avoid “losing the flexibility of MS to take national differences into account” which seems very difficult to achieve with centralisation of inspectorate at EU level.
(Name confidential - Respondent 048)	User of animals - public sector	Local	Not applicable, I am not an organisation	The rules and inspections must also be considered fair and worthwhile.
(Name confidential - Respondent 069)	User of animals - public sector	Local; Regional; National; European; Worldwide	It is a University, the question is meaningless	On balance, individual MS should establish and maintain an Inspectorate which keeps their individual animal users aware and compliant with the legislation which applies - while the legislation may be generalised to the EU, there is no necessity for a formal link between the Inspectorates of the individual MS - but, much like the Police forces and Health Services, collaboration should be actively encouraged.
GlaxoSmithKline	User of animals - private sector	Worldwide	There are other international pharmaceutical companies. We produce 25% of the worlds vaccines	The Commission itself has been ineffective in implementing Article 22.3 of the current Directive, which would at the moment allow sharing of good practice on inspection

(Name confidential - Respondent 073)	User of animals - private sector	National; European; Worldwide	Sanofi aventis is the largest pharmaceutical company in Europe and ranks third worldwide	The EU should give strong consideration to using AAALAC accreditation as an adjunct to inspection. Institutions that are AAALAC accredited could be inspected less frequently. Personal experience with AAALAC has shown that AAALAC is much more rigorous than state or local inspectors.
(Name confidential - Respondent 075)	User of animals - private sector	Worldwide	Research and development	no comment
(Name confidential - Respondent 082)	User of animals - private sector	Worldwide	There are other relevant organisations	We think that inspections should also be applicable to breeders and suppliers as they should also be compliant with the Directive.
(Name confidential - Respondent 087)	User of animals - private sector	Worldwide	No	Far too much difference across the EU in terms of culture, language etc fort this to be a sensible or valuable option.
(Name confidential - Respondent 088)	User of animals - private sector	Worldwide	pharmaceutical	Currently, AAALAC is already used more and more and may serve as a 'international calibration tool'. They take the different national legislation into account in their assessment.
(Name confidential - Respondent 093)	User of animals - private sector	Worldwide	yes	-

(Name confidential - Respondent 096)	User of animals - private sector	National; European; Worldwide	there are multiple independent Contract Research Organisations in UK and EU	No comments
(Name confidential - Respondent 102)	User of animals - private sector	Worldwide	no	The national authorities should be aware, that there are other inspections from national and international authorities (like e.g. GLP-inspections and AAALAC inspections from USA, MAFF inspections from Japan) which are in general comparable. These inspections consider animal welfare during experimental procedures too.
Animal Procedures Committee (APC)	Public authority	National	The APC provide independent advice to UK Government on the use of animals in scientific procedures. The APC consider science, industry and animal welfare. Members are from a variety of backgrounds.	The APC cannot see the justification for another layer of inspectorate at the European level.

Coenraad F.M.Hendriksen	Public authority	National	at the national level: yes	An EU-inspectorate could be a stimulus to increase harmonisation of housing and care standards. However, it is too early to implement such a system due to the diversity of standards in Europe. The next Council Directive revision might be a better occasion.
(Name confidential - Respondent 122)	Public authority	National	We are the National Competent Authority	We do not support the proposal that there be an EU inspection programme - even assuming it was funded and delivered by the Commission. As your analysis tends to confirm this would involve high resource and compliance costs and produce no meaningful benefits. These and other benefits could largely be achieved by regular meetings of the National Competent Authorities and/or national inspectorates.
(Name confidential - Respondent 126)	Public authority	National	Regulatory authority in UK	Within Europe there are already a number of experienced inspectors and establishment of a new resource seems unnecessary. Could be achieved by national authorities nominating some of their inspectors to work on quality control across Europe and provide input into a central training facility. Overall using current national inspectors conducting joint visits to other countries could progress towards harmonisation of standards, exchange of information, promotion of best practice and ensure good welfare standards and science. This would contribute to improving standards across Europe and help towards providing a level playing field for animal users.
1.Animal Aid	Other	National	Other organisations do exist	An EU inspectorate has potentially more independence - which would lead to greater transparency. An EU system of inspections at slaughter houses already exists and produces benefits.
National Centre for the Replacement, Refinement and Reduction of Animals in Research	Other	National	Representative	The NC3Rs cannot see the justification for inspection at the EU level.
The Association for the Study of Animal Behaviour	Other	Worldwide	yes	The effectiveness of inspections in terms of improving welfare is not just a matter of resourcing and frequency, but of education of the inspectorate, particularly in the needs of hypothesis-testing fundamental research and the fact that animal welfare science is in its infancy and needs vastly more research in its own right

(Name confidential - Respondent 144)	Other	National	Yes	It is our view that an EU inspectorate would create significant economic costs for the European Commission.
(Name confidential - Respondent 154)	Other	National	representative	An EU Inspectorate would be unworkable because of differences in national legislation, however there is scope for a forum for national inspectorates to share experiences and best practice.
(Name confidential - Respondent 161)	Other	National	There are other similar organisations	Inspections made by local authorities should be enough. However, I cannot see why EU inspections would require different approaches in different states even there are differences in ethical review systems.
Eurogroup for Animal Welfare/EWLA	Non-governmental organisation	European	Eurogroup/EWLA is made up of animal welfare Member Organisations and Observers in all Member States	In order to ensure that national authorities in all Member States work according to comparable standards, some kind of EU surveillance system and a framework for cooperation between the national authorities should be established. For example, national authorities could meet annually specifically to present and discuss inspection issues, such as the performance and outcome of their activities. Re. 2.3.+2.4.: The revision of the Directive may result in greater harmonisation of approaches to authorisation and ethical review systems, and to regulatory standards. In that case an EU inspectorate would be able to adopt a standard approach across the different Member States. Additionally, the surveillance system should cover not only research and testing establishments, but also breeding and supplying facilities.

European Coalition to End Animal Experiments (ECEAE)	Non-governmental organisation	Worldwide	Representative (the only EU coalition focusing on animal experiments)	In order to ensure that national authorities in all Member States work according to comparable standards, some kind of EU surveillance system and a framework for cooperation between the national authorities should be established, for example by requesting annual meetings of the national authorities specifically dedicated to presenting and discussing inspection issues, such as the performance and outcome of their activities. Re. 2.3.+2.4.: Since the authorisation and ethical review process are to be harmonised in the course of the revision of the Directive, an EU inspectorate would not necessarily require fundamentally different approaches on the Member State level. Additionally, since the inspection's system should address all types of establishments, breeders, suppliers and users, the questions of authorisation and ethical review process would not apply to all establishments in the first case and moreover need not be the central focus of such supervision measures.
PETA Europe Ltd.	Non-governmental organisation	Worldwide	both	In addition to points made above, an EU inspectorate, with training provided at EU level and some personnel only functioning at EU level, has potentially more independence - which would lead to greater transparency and public confidence. European citizens demand high animal protection standards and the need for additional resources should be seen as an appropriate expression of the value attached by citizens to maintaining high standards of animal welfare.
PROFESSOR RD COMBES - FRAME	Non-governmental organisation	Worldwide	THERE ARE OTHERS	There is no need for a centralised inspectorate - but information should be shared between the different inspectorates electronically and regularly, to indicate the types of projects being proposed/undertaken with a view to indicating overlaps and trends etc. and highlighting different approaches to cost benefit analysis across the EU. Any inspection system must also be operated in conjunction with one that penalised offenders and should work hand in hand with a revoking system. All establishments should be inspected regularly as far as is practicable by unannounced visits. The roles/criteria of inspectorates must be concise, clear and practicable, and be based on facilitating best scientific practice and animal welfare. The work of the inspectorates should be reported annually and discussed on a regular basis (e.g. every 3-5 years) at an international forum and reported annually.

The National Anti-Vivisection Society	Non-governmental organisation	National; European; Worldwide	The NAVS is the leading and oldest anti-vivisection organisation in the world. There are a number of other relevant anti-vivisection organisations around the world with expertise in this field.	We agree that frequency of inspections should be specified and that a minimum of half such inspections should be unannounced. However we do not agree that two inspections annually is enough, especially when establishments vary in size and number of animals they contain and this is likely to have an effect on how thorough one inspection can be. Also as an announced inspection is likely to comprise of discussions and meetings as well as the actual inspection, additional inspections may need to take place to ensure all areas of a lab are thoroughly checked. Also if there is only one unannounced inspection, this could result in a lapse in standards once the inspection has taken place as they will not be expecting another one until the following year. One announced and at least two unannounced would be more sufficient. It is important that establishments expect inspections to occur regularly and unannounced in order to boost motivation to maintain standards and follow procedures.
(Name confidential - Respondent 163)	Non-governmental organisation	National; European; Worldwide	both	In addition to points made above, an EU inspectorate, with training provided at EU level and some personnel only functioning at EU level, has potentially more independence - which would lead to greater transparency and public confidence. European citizens demand high animal protection standards and the need for additional resources should be seen as an appropriate expression of the value
(Name confidential - Respondent 165)	Non-governmental organisation	Worldwide	Yes	Efficiency does not necessarily require high resources, but inspections at the MS level seems more realistic. Perhaps an EU committee to oversee the individual MS inspection systems would be appropriate instead of the EU inspectorate being responsible for conducting all inspections. This body could also respond to public inquiry about the MS inspections.
(Name confidential - Respondent 169)	Non-governmental organisation	National	Represents all Finnish pharmacologists	Establishment of some supra-national body would simply enormously increase the costs since much documentation is written in national languages which would require translation to be understandable to the EU office.

(Name confidential - Respondent 170)	Non-governmental organisation	National	The Danish Society of Pharmacology and Toxicology represents Danish pharmacologists and toxicologists.	A European inspectorate should at most provide overall guidelines for member countries.
(Name confidential - Respondent 172)	Non-governmental organisation	Regional	Yes	Given the enormous costs associated with implementing a European inspectorate, which certainly would not in any way be more effective than national inspectors, this option does not seem to offer any real advantage.
(Name confidential - Respondent 174)	Non-governmental organisation	Worldwide	-	-
(Name confidential - Respondent 177)	Non-governmental organisation	Worldwide	Representative	A European inspectorate would create a hugely costly, cumbersome and, probably, minimally effective structure and this should be resisted. Each member country should develop its own which should operate according to some agreed protocols.
(Name confidential - Respondent 183)	Breeder of animals	Worldwide	We are representative for the field and constitute about 50 percent of the activity	No justification required.

giacomo Ri(olatti		National; European; Worldwide	it is represntative	A further proof that the philosophy behind this document (most part of it) is not that animal experiments are higly beneficial for the progress of bio-medical resesrch, but something that must be redereded so difficult in Europe that Europe should step out of this field.
(Name confidential - Respondent 188)		Regional; National	Not applicable: response is personal opinion based on personal expertise	There appears to be the assumption that this would be a separate Inspectorate. It seems feasible to use personnel from within regulatory bodies in the MS. The importance to improving animal welfare and ensuring comparable standards and harmonisation across all MS by the inspectorates of the MS getting together in some form should not be underestimated. This might be more efficiently performed as meetings and joint inspections between MS with Inspectors that will already be performing routine inspection of facilities.
(Name confidential - Respondent 190)		Regional; Worldwide	also others	The idea of inspections at EU levels should be abandoned. Such inspections are non-realistic in terms of administration and cost and would represent a useless replication of inspections at member state level. The EU should define minimal standards, their implementation and enforcement should be a task of the member states.
(Name confidential - Respondent 192)		National; European; Worldwide	Yes	Inspections by an EU panel would have the advantage that implementation of inspecting bodies by the single member states is unnecessary. Furthermore, an EU panel is likely to be less biased and more knowledgeable than panels in especially the smaller member states where inspection of the different animal housings is not a full time job (and therefore assigned to less specialized panels). Similarity in regulatory standards between member countries should not be a prerequisite - the panel should be sophisticated enough to be able to discern which rules are essential and which allow alternative interpretations.
(Name confidential - Respondent 193)		National	There are other relevant organisations	Centralised inspection will be unworkable