Disclaimer:

The following is intended as guidance to assist the Member States and others affected by this Directive to arrive at a common understanding of the provisions contained in the Directive. All comments should be considered within the context of Directive 2010/63/EU on the protection of animals used for scientific purposes.

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

Article	The text of the related articles and paragraphs	Question and answer
1(3)(4)	***Article 1*** ***Subject matter and scope*** *..3. This Directive shall apply to the following animals:* *(a) live non-human vertebrate animals, including:* *(i) independently feeding larval forms; and* *(ii) foetal forms of mammals as from the last third of their normal development;* *(b) live cephalopods.* *4. This Directive shall apply to animals used in procedures, which are at an earlier stage of development than that referred to in point (a) of paragraph 3, if the animal is to be allowed to live beyond that stage of development and, as a result of the procedures performed, is likely to*	**<u>Question</u>:** **In connection with paragraph 3, do the terms in paragraph 4 "*earlier stage of development*" refer not only to points (i) and (ii) of paragraph 3, but also cover all vertebrate animals prior to birth or hatching, as well as live cephalopods, provided that the conditions referred to in paragraph 4 are met?** **<u>Answer</u>:** The extension of the scope to earlier stages in Article 1(3)(4) <u>covers *all* animals (vertebrates and cephalopods) within the scope of this Directive</u>, not only in reference to 1(3)(a)(i-ii). The extension of the scope of the Directive as defined in paragraph 4 makes reference to an earlier "*stage of development*" – including from hatching of a non-mammalian vertebrate species (e.g. bird) by the specific inclusion of an earlier foetal form of *mammalian species* under point 1(3)(a)(ii). Therefore, cephalopods are covered under paragraph 1(4) if a procedure is carried out before hatching and the animal is allowed

	experience pain, suffering, distress or lasting harm after it has reached that stage of development.	to live beyond that point and experience pain, suffering, distress or lasting harm.
1(5)	***Article 1*** ***Subject matter and scope*** *…5. This Directive shall not apply to the following:* *(a) non-experimental agricultural practices;* *(b) non-experimental clinical veterinary practices;* *(c) veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product;* *(d) practices undertaken for the purposes of recognised animal husbandry;* *(e) practices undertaken for the primary purpose of identification of an animal;* *(f) practices not likely to cause pain, suffering, distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice*.	**<u>Question</u>:** **What can be considered as "*recognised husbandry*" as referred to under Article 1(5)(d)?** **<u>Answer</u>:** The term "*husbandry*" is not defined in the Directive. Neither is there any established route by which different processes/techniques are "*recognised*" as being husbandry in the EU. According to the general principles of Law as established by the European Court of Justice (e.g. Joined Cases C 174/98 P and C 189/98 P, *Netherlands and van der Wal v Commission*) the exceptions shall be <u>interpreted narrowly</u>. When establishing a common definition of the term, the context and the way in which the term is used in this Directive, the purpose of the Directive as well as the structure in which the term is placed need to be analysed as well as the way the term is used in other EU legislation. This allows developing elements which can clarify what could be the principles defining "*animal husbandry*". The Directive mentions animal husbandry in connection with the end of procedures (Recital 26, Article 19). The Directive requires that, taking into account animal welfare considerations animals should be "*returned to a <u>suitable</u> habitat or <u>husbandry system</u>*". This indicates that husbandry shall be interpreted in connection with animal care and welfare. The remaining references are made in the context of housing and care of animals. Annex VIII specifically stating "*prevention from expressing natural behaviour <u>including restrictions on</u> the housing, <u>husbandry</u> and care <u>standards</u>*." References to the term "*husbandry*" in other EU legislation can be found in Regulation (EC) No 710/2009 laying down detailed rules for the implementation of

		Council Regulation (EC) No 834/2007, as regards laying down detailed rules on organic aquaculture animal and seaweed production. Its recital 10 provides that organic aquaculture animal production should ensure that species-specific needs of animals are met. In this regard husbandry practices, management systems and containment systems should satisfy the welfare needs of animals. Regulation (EC) No1698/2005 on support for rural development by the European Agricultural Fund for Rural Development establishes the condition that high animal welfare standards shall depend on standards for animal husbandry. Recital 36 provides that farmers should continue to be encouraged to adopt high standards of animal welfare by providing support for farmers who undertake to adopt standards of animal husbandry which go beyond the relevant mandatory standards. Directive 1999/22/EC relating to the keeping of wild animals in zoos provides that high standards of animal husbandry will satisfy the biological and conservation requirements of the individual species. It again stresses the element of animal welfare when mentioning animal husbandry and specifies moreover that husbandry shall benefit the animal. From the Directive itself and the above mentioned acts the following common criteria for animal husbandry may be suggested: • The term "*animal husbandry*" is repeatedly linked to animal welfare elements. Its purpose is the benefit of a particular animal or that of the group of animals. • Husbandry practices shall contribute to animal welfare standards. Animal welfare refers to the state of the animal (whether it is healthy, comfortable, well nourished, able to express its species specific behaviour, etc). Animal husbandry refers to the treatment and care that the animal receives to achieve this state. Animal husbandry may therefore be understood as the processes and activities during the caring, rearing and setting free or re-homing of animals with the aim of improving

		the health and welfare of animals i.e. carried out for the benefit of animals and / or animal welfare. The term "*recognised*" also requires clarification. Since no formal method of recognition exist in the Directive, "*recognised husbandry*" is to be understood in the context of practices considered as fulfilling the criteria and purposes of animal husbandry i.e. an activity/treatment carried out in the framework of breeding and keeping animals and done for the benefit of the animal(s) and/or animal welfare. **Question:** **Can tissue sampling for the purposes of genetic characterisation (genotyping) of genetically altered animals be considered as "*recognised husbandry*" as referred to under Article 1(5)(d)?** **Answer:** In the context of the use of genetically altered (GA) animals in scientific procedures, genotyping is required for two separate purposes: • During the creation of new genetically altered line, samples are taken for genetic characterisation to determine whether and to what extent the genetic manipulation has been successful. This sampling is required solely for a scientific purpose to determine a scientific unknown. • In an established GA breeding colony, samples are occasionally taken to verify that the genotype has not varied from the intended genetic background. This can occasionally happen due to random mutations during normal breeding practices or by errors in the breeding programme. Sampling is necessary to verify that the established gene alteration for scientific purposes is maintained and that there has been no genetic drift from this. Sampling is therefore necessary to confirm the continued

		conformity of the animals of a given line with the intended scientific characteristics. In reference to the term "*recognised animal husbandry*" above, in neither of the above cases animal health / welfare is the primary purpose of genetic characterisation. Its primary purpose is to either fulfil scientific needs or confirm scientific suitability. Thus, in light of the above, genetic characterisation of GA animals cannot be seen as a recognised husbandry practice. This conclusion is supported by the Guideline on xenogeneic cell-based medicinal products for Directive 2001/83/EC issued by the European Medicines Agency which is the only applicable text making reference to "*genetic characterisation*" and "*husbandry*". This Guideline follows the principles established in other EU legislation in which husbandry is considered in relation to the health and welfare of an animal/animal group. It specifies the main elements of husbandry under section "*Animal husbandry*" detailing those of housing and care, veterinary controls and quarantine which relate to welfare and benefit of the animal(s)/animal group. Genetic characterisation is considered separately from "Animal husbandry" under a section "*Genetically modified*" animals. **Question:** **Do procedures, other than radio-collaring or non-invasive identification, carried out on *free ranging wildlife* (i.e. the animals are not kept in captivity in an establishment or, if so, only during a very short period of time) fall within the scope of the Directive?** **Answer:** Yes, if the procedure that is carried out on wild animals a) is above the minimum threshold i.e. *"practices likely to cause pain suffering,*

		distress or lasting harm equivalent to, or higher than, that caused by the introduction of a needle in accordance with good veterinary practice" and b) it is not explicitly exempted from the scope under Article 1(5)(a) to (f). If the procedure is under the scope of the Directive, all relevant provisions, including those on project evaluation and authorisation, need to be respected.. Furthermore, the capture as such, even if above the threshold would not bring the animal under the scope of the Directive, unless combined with a scientific procedure above the threshold. In the case of latter, the distress caused by capture should be considered during project evaluation. **Question:** **Why does the Directive not apply to veterinary clinical trials required for the marketing authorisation of a veterinary medicinal product, while experimental purposes under Article 5(c) includes (veterinary) drug trials?** **Answer:** Clinical veterinary practices are covered by another piece of EU legislation. Directive 2001/82/EC on the Community code relating to veterinary medicinal products details the requirements for veterinary clinical trials. Animals used in such trials are under veterinary care and appropriate clinical care, including alternative treatments, is provided should the test product prove ineffective or animal welfare is compromised.
2	***Article 2*** ***Stricter national measures*** *1. Member States may, while observing the general rules laid down in the TFEU, maintain provisions in force on 9 November 2010, aimed*	**Question:** **Is the inventory of existing, stricter national measures merely for the information of Member States or will it be published on the Commission website? Could it also be considered as an incentive and/or a future legal**

	at ensuring more extensive protection of animals falling within the scope of this Directive than those contained in this Directive. *Before 1 January 2013 Member States shall inform the Commission about such national provisions. The Commission shall bring them to the attention of other Member States.* *2. When acting pursuant to paragraph 1, a Member State shall not prohibit or impede the supply or use of animals bred or kept in another Member State in accordance with this Directive, nor shall it prohibit or impede the placing on the market of products developed with the use of such animals in accordance with this Directive.*	**possibility for a Member State to adapt stricter measures other than those in place before 9 November 2010?** **<u>Answer</u>**: The stricter national measures will be published on the Commission web-site to improve transparency as well as to assist in answering queries. Furthermore, Article 2 requires that these are brought to the attention of other Member States. Publication of stricter measures does not alter the legal provision in Article 2 which only allows the maintenance of those stricter measures that were duly notified and in force prior to the entry into force of Directive 2010/63/EU. **<u>Question</u>:** **Is the notification to the Commission within the given deadline mandatory in order for the Member State to be able to maintain the stricter measure?** **<u>Answer</u>**: One of the objectives of the Directive is to harmonise the legislation concerning the use of animals for scientific purposes and to ensure the proper functioning of the internal market. Member States are obliged to properly transpose Directives. Article 2 provides for an exemption from harmonisation and gives Member States a possibility under certain conditions to keep measures ensuring more extensive protection of animals falling within the scope of this Directive. Article 2 specifies further the conditions which must be fulfilled in order for Member States to keep their stricter measures. Next to general obligations to observe the rules contained in the Treaty:

		- the respective provisions must be in force on 9 November 2010; - they shall be notified to the COM before 1 January 2013. Paragraph 1 of Article 2 is to be read as a whole and therefore the notification has not only an informative function but constitutes a pre-condition for keeping the stricter measure. **<u>Question</u>:** **Assuming matters covered in primary legislation are classed as '*provisions in force*'. What is the status of provisions contained in secondary legislation, such as statutory guidance and codes of practice which have been laid before parliament? Can also those be maintained?** **<u>Answer</u>**: We believe that Article 2(1) of the Directive addresses only the national provisions that have legally binding effect. If a stricter measure is stated in a Code of Practice in force before 9 November 2010 but which is not legally binding, such a measure does not fall within the scope of application of Article 2(1) of the Directive. Equally, the Directive does not prohibit the use of such codes of practices, provided it is made clear that these are not legally binding and that Article 2(2) is fully respected. It should be noted that according to case law non-binding measures can also constitute a breach of Article 34 TFEU (see Case 249/81, *Commission v Ireland*). **<u>Question</u>:** **A Member State has a more stringent measure concerning cage sizes than those prescribed in the Directive. The measure was in place before 9 November 2010 and notified to the Commission pursuant to Article 2(1) of the Directive. Can this national measure be amended to reduce the cage sizes so that they are still**

		bigger (that is, it is still a more stringent measure, but less stringent than the notified one) than prescribed in the Directive? **<u>Answer</u>**: Article 2(1) of the Directive concerns maintaining national provisions not introducing new ones. However, as the objective of the Directive is to achieve a high level of protection of laboratory animals, we believe it would be within the spirit of the law to allow the amendment of an existing more stringent national rule, in place before 9 November 2010 and notified to the Commission, to make it less stringent, whilst remaining overall more stringent than the provisions set out in the Directive. **<u>Question:</u>** **How is the word "*maintain*" in Article 2 paragraph 1 to be understood? Does "*maintain*" require to maintain the provisions in question with their <u>exact wording</u> (i.e. strictly as they were in force on 9 Nov 2010) or would it be possible to adapt for example terminology to be in line with the new Directive?** **<u>Answer:</u>** The interpretation of "*maintaining a stricter measure*" allows for the alignment of terminology used in the new Directive as this seems not to alter the substance of the current stricter measure in place. See also the previous question & answer. **<u>Question</u>:** **The Directive does not contain any provision on fees. Should a Member State**

		wish to introduce fees for the authorisation of users, breeders or suppliers; or for the authorisation of projects, would this constitute a measure to distort the internal market and thus be considered as a stricter national measure as defined in Article 2 (and thus not allowed)? **Answer**: In the absence of provisions on fees in the Directive, this area is to be considered as non-harmonised. Consequently, Articles 34-36 TFEU apply when examining if a fee/authorisation system introduced by national legislation forms an obstacle to cross-border trade. National systems subjecting the marketing of goods to prior authorisation can restrict access to the market of the importing Member State and may therefore be regarded as a measure having equivalent effect to a quantitative restriction on imports within the meaning of Article 34 TFEU. The Court of Justice has set a number of conditions under which such prior authorisation might be justified (see Case C-390/99, *Canal Satélite Digital*). • It must be based on objective, non-discriminatory criteria which are known in advance to the undertakings concerned, in such a way as to circumscribe the exercise of the national authorities' discretion, so that it is not used arbitrarily. • It should not essentially duplicate controls which have already been carried out in the context of other procedures, either in the same Member State or in another Member State. • A prior authorisation procedure will be necessary only where subsequent control must be regarded as being too late to be genuinely effective and to enable it to achieve the aim pursued. • The procedure should not, on account of its duration and the disproportionate costs

		to which it gives rise, <u>be such as to deter the operators concerned from pursuing their business plan</u>. **<u>Question</u>:** **Does the Directive specifically prohibit the adoption of new stricter measures or maintenance of those stricter measures which are not related to animal welfare?** **<u>Answer</u>**: The scope of the Directive is defined in Article 1. According to that provision the Directive aims at protecting animals used for scientific or educational purposes. Article 2 on stricter national measures acknowledges the scope of the Directive when it refers to "*the protection of animals falling within the scope of this Directive*". Hence, Article 2 should not affect stricter national measures which are not related to animal welfare. However, potential overlaps between the Directive and new or existing more stringent national measures have to be assessed on a case-by-case basis. Moreover, the general rules laid down in the TFEU have to be observed.
3(5)	***Article 3*** ***Definitions*** *For the purposes of this Directive the following definitions shall apply:* *… 4. 'breeder' means any natural or legal person breeding animals referred to in Annex I with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, or breeding other animals primarily for those purposes, whether for profit or not;*	**<u>Question</u>:** **Does the definition of "*breeder*" also cover breeders of farm animals (e.g. pigs) when these animals are also used for scientific purposes?** **<u>Answer:</u>** According to Article 3(4) a "*breeder*" is a natural or legal person which breeds the animals with view to their use in procedures or for the use of their tissue or organs for specific purposes, whether for profit or not. Article 3(4) distinguishes between animals listed in Annex I of the Directive (e.g. mouse, rat, guinea pig) and other animals. In order to be a breeder, the natural or

	… 5. 'supplier' means any natural or legal person, other than a breeder, supplying animals with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, whether for profit or not;	legal person has to therefore either breed the Annex I animals with the purpose of using them in the procedures or breed any other animals primarily with such a view. Farm animals appear not to be covered by the animals listed in Annex I and thus would fall under "*other animals*". In case of farm animals the breeders do not breed these animals (e.g. pigs) with the primary view of using them in the procedures or use of their tissue or organs for scientific purposes but for consumption and commercial purposes. The breeders of farm animals do not fulfil the definition of a breeder within the meaning of article 3(4) of the Directive. **Question:** **What operations are covered by the term "*supplying*"/ "*supplier*"? Could transporters of animals be considered suppliers or agents who trade but do not keep animals themselves?** **Answer:** A supplier is someone supplying animals with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, whether for profit or not. Generally, supply means the making available to a third party. A supplier is someone who does not breed, neither uses the animals himself. As an example, an actor who buys a number of non-human primates or dogs from a third country, has them transported in the EU and then supplies them either directly or indirectly to different users in the EU. Most likely the supplier would house these animals temporarily (e.g. during the quarantine period when applicable) before being sold or transported to their final destination, however, that is not a prerequisite. Someone who is only transporting animals, i.e. performing the necessary transport for

		a third party, cannot be considered a supplier. In other words, it cannot be considered to be supplying in his own capacity. **<u>Question</u>:** **Should pet owners allowing their pets to be used in a project be considered as a "*supplier*"? An example case of a pet owner giving a permission to use his dog in a study to investigate an improved treatment for a specific disease the dog is already suffering from. In practice, the dog would stay with the owner and would only come for check-ups to the institute.** **<u>Answer:</u>** The pet owner, when going to the vet would not be going there with the intention of participating in a study (i.e. not <u>with a view</u> for his pet <u>to be used in scientific procedures)</u>. In this case, the intentional element of the definition ("*with a view to their use*") seems to be lacking. Also, there is no supply, in the meaning of making available to a third party: the animal remains in the custody of the pet owner who also remains responsible for the holding and care of the animal. **<u>Question</u>:** **Does "*a supplier*" need to be in a possession of a permanent facility in order to qualify as "*a supplier*"?** **<u>Answer</u>**: A supplier is someone supplying animals with a view to their use in procedures or for the use of their tissue or organs for scientific purposes, whether for profit or not. The definition does not provide for any further additional requirements, therefore a facility ("*an establishment*" within the meaning of Article 3(3) of the Directive) is not

	…6. 'user' means any natural or legal person using animals in procedures, whether for profit or not; ***Article 20*** ***Authorisation of breeders, suppliers and users*** *1. Member States shall ensure that all breeders, suppliers and users are authorised by, and registered with, the competent authority. Such authorisation may be granted for a limited period.*	a prerequisite for the definition of a supplier. Consequently a supplier can but does not need to be in a possession of an establishment. Article 3(3) defines establishment in a broad sense, covering both permanent and non-permanent installations and buildings. It may also include a place that is not wholly enclosed or covered and mobile facilities. Therefore, if a supplier has an establishment, it does not need to be a permanent one. **<u>Question</u>:** **In most places in the Directive the terms "*user*", "*breeder*" and "*supplier*" are used in relation to corporate entities or institutions. It is, however, also possible to interpret them as referring to individuals using, breeding and supplying animals or responsible for projects. How should the terms be interpreted in Article 20 – only as corporate users, breeders and suppliers?** **<u>Answer</u>**: Article 3 clearly defines the user, breeder and supplier as any <u>natural</u> or <u>legal</u> person. Therefore, wherever these terms are mentioned in the Directive both, individuals as well as corporate entities or institutions are meant. Article 20 is not an exemption in this regard and it refers to both, individuals as well as corporate entities or institutions.
4 and 13 **and** **24(2) and 40(2)**	***Article 4*** ***Principle of replacement, reduction and refinement*** *1. Member States shall ensure that, wherever possible, a scientifically satisfactory method or testing strategy, not entailing the use of live*	**<u>Question</u>**: **There is an unresolved tension inherent in Articles 4 and 13 between reducing numbers and reducing ("*refining*") the suffering of individual animals. Is there a hierarchy between reducing individual suffering versus reducing numbers of animals?**

	animals, shall be used instead of a procedure. *2. Member States shall ensure that the number of animals used in projects is reduced to a minimum without compromising the objectives of the project.* *3. Member States shall ensure refinement of breeding, accommodation and care, and of methods used in procedures, eliminating or reducing to the minimum any possible pain, suffering, distress or lasting harm to the animals.* *4. This Article shall, in the choice of methods, be implemented in accordance with Article 13.* ***Article 13*** ***Choice of methods*** *1. Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union.* *2. In choosing between procedures, those which to the greatest extent meet the following requirements shall be selected:* *(a) use the minimum number of animals;* *(b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;*	**<u>Answer</u>**: No, after all means to replace are exhausted, the Directive does not make a hierarchy between reduction and refinement. This is part of the tasks of the case-by-case project evaluation that needs to take in to account the principle of the "Three Rs" as well as "*ethical considerations*" (Article 38(2)(d)). **<u>Question</u>**: **Does the inclusion of the words "*or testing strategy*" in Article 4(1) require that when the desired information can be obtained through other means than a direct non-animal replacement method (even if it involves a variety of steps) this approach should be used? Other means being e.g. a combination of read-across from other data (animal or otherwise), QSARs and *in vitro* assays?** **<u>Answer</u>**: Yes, provided that the testing strategy (i) delivers the results sought and that (ii) the results obtained are scientifically satisfactory. It should also be noted that in the case of testing for regulatory purposes, the methods used should be recognised in accordance with the relevant legislation of the Union. **<u>Question</u>**: **Should Member States take a proactive approach to the availability of non-animal methods? The words "*wherever possible*" in Article 4(1) seem to give the required flexibility. If, for example, a non-animal method could be developed by a company with reasonable ease, that should be a relevant consideration.**

	(c) cause the least pain, suffering, distress or lasting harm; *and are most likely to provide satisfactory results.* *3. Death as the end-point of a procedure shall be avoided as far as possible and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to:* *(a) result in the deaths of as few animals as possible; and* *(b) reduce the duration and intensity of suffering to the animal to the minimum possible and, as far as possible, ensure a painless death.*	**Answer**: No. A proactive approach can be *encouraged* but the legal text allows for the Member State to require the use of an alternative method only in cases when a scientifically satisfactory alternative method is already available or in the area of regulatory testing available and recognised by the legislation of the EU. **Question:** **What is the legal requirement to use alternative methods in the areas for which methods are not described in Union legislation, and in this sense what is the meaning of "*wherever possible*"?** **Answer:** We believe Article 4 of the Directive imposes a general requirement to use alternative methods including in the areas of basic and applied research. "*Wherever possible*" in Article 4 cannot be separated from the sentence where it belongs ("*Member States shall ensure that, wherever possible, a scientific satisfactory method or testing strategy […] shall be used instead of a procedure*"). Therefore "*wherever possible*" is linked to the scientific satisfaction with a method or testing strategy. "*Wherever possible*" is to mean "when capable of ensuring scientific satisfaction". The proposed approach is in line with the rest of the provisions as well as the spirit of the Directive. The use of justifications for any of the exemptions elsewhere in the Directive is systematically linked to a scientific reasoning. When looking at the exceptions provided by the Directive we can conclude that (apart from one or two when it is on an animal welfare basis) these are always based on a scientific justification.

		<u>Question</u>: **In the area of biologicals (such as vaccines) after the inclusion of an alternative method in the European Pharmacopoeia, the manufacturer is still required to carry out a product-specific validation to demonstrate the validity of the method vis-à-vis their product. Should the authorities demand the manufacturer of a biological for which an alternative method is incorporated in the European Pharmacopoeia to carry out a product-specific validation? If the validation is not carried out, is the manufacture allowed to use the animal-method?** **<u>Answer</u>:** The methods specified in the European Pharmacopoeia can be considered as "*recognised by EU legislation*" within the meaning of Article 13 of the Directive through a number of EU pieces of legislation such as Directives 2001/82/EC, 2001/83/EC, and 2003/63/EC, as amended, on medicines for human and veterinary use. If a product specific validation is a prerequisite for the use of such a method, the Directive does not foresee a waving from the requirement on the basis of time or cost. The Directive sets some limitations to this rule providing that the new method shall be applied: • without prejudice to national legislation prohibiting certain types of methods, or • are most likely to provide satisfactory results, Since a Directive gives generally the Member States some room for manoeuvre concerning its aims, the Competent Authority should apply the proportionality principle in their actions. The Competent Authority has to be satisfied that all efforts to complete the validation are made within a reasonable time to comply with the

		requirements of this Directive. Should the validation fail due to scientific reasons and thus the method proved not valid for the product in question, the use of the animal method could in those cases continue to be allowed. Once a successful validation is completed, or the manufacturer fails to undertake the validation in a reasonable time, the animal method could no longer be authorised. **<u>Question</u>:** **If a third country requires the use of an animal method, even when a non-animal method is recognised by the legislation of the Union, would it be allowed to be performed under this Directive?** **<u>Answer</u>:** The requirement to use a non-animal method is conditional on various factors, amongst others: • That the result sought by the procedure is achieved by the non-animal method or testing strategy • That the non-animal method or testing strategy is recognised under Union legislation All the above is overridden by any national legislation prohibiting certain types of methods. Therefore, if a non-animal method is recognised under Union legislation but a third country requires an animal method to be performed, the only situation where the animal method could be authorised would be that where the non-animal method does not provide "*the result sought*", provided national legislation of the Member State authorising the procedure does not prohibit it.

	Article 24 ***Specific requirements for personnel*** *… 2. Member States shall ensure that persons specified in Article 40(2)(b) shall:* ***…*** *(b) ensure that the projects are carried out in accordance with the project authorisation or, in the cases referred to in Article 42, in accordance with the application sent to the competent authority or any decision taken by the competent authority, and ensure that in the event of non-compliance, the appropriate measures to rectify it are taken and recorded.* ***Article 40*** ***Granting of project authorisation*** *…2. The project authorisation shall specify the following:* *(a) the user who undertakes the project;* *(b) the persons responsible for the overall implementation of the project and its compliance with the project*	In this context, we believe that the concept of "*result sought*" should be interpreted as meaning "*end-point*": <u>obtaining information from the animal test</u> could not be argued to be a result in itself. As an example, a replacement alternative, recognised by the EU legislation that identifies a toxic hazard but is not able to differentiate between different levels of that toxicity (for example as required under a legislation for Classification and Labelling depending on the endpoint); If the third country regulatory requirement is to be able to identify only the existence of that toxicity, the respective animal method could no longer be used. However, if the third country requirement is to identify between different levels of that toxicity, the animal method could still be used. **<u>Question</u>**: **Should the availability of alternatives be assessed on an individual substance or product basis in cases where Member States would use the possibility to allow the authorisation of multiple generic projects (as per Article 40(4))?** **How can Member State ensure compliance with Articles 4 and 13 for those Three R methods that become available after the initial project evaluation but still during the course of the project?** **<u>Answer</u>**: No, the individual substances may not necessarily be known at the time of the project evaluation of a multiple generic project. Similarly, new alternative methods may become available during the course of any authorised project, as these can be authorised up till 5 years. Therefore, it is important for Member States to ensure that the authorisation will specifically emphasise for the user the legal obligations under Articles 4 and 13

	authorisation; *(c) the establishments in which the project will be undertaken, where applicable; and …*	which remain in force until the end of the project authorisation. To facilitate the enforcement, each project authorisation will have to detail the persons responsible for the overall implementation of the project and its compliance with the project authorisation as per Article 40. In addition, Article 24 concerning the requirements for the personnel in an establishments cross references to the same requirement.
5 (f)	***Article 5*** ***Purposes of procedures*** *Procedures may be carried out for the following purposes only:* *(a) basic research;* *(b) translational or applied research with any of the following aims:* *(i) the avoidance, prevention, diagnosis or treatment of disease, ill-health or other abnormality or their effects in human beings, animals or plants;* *(ii) the assessment, detection, regulation or modification of physiological conditions in human beings, animals or plants; or* *(iii) the welfare of animals and the improvement of the production conditions for animals reared for agricultural purposes;* *(c) for any of the aims in point (b) in the development, manufacture or testing of the quality, effectiveness and safety of drugs, foodstuffs and feed-stuffs and other substances or products;* *(d) protection of the natural environment in the interests of the health or welfare of human*	**<u>Question</u>:** **Is the use of live animals for experiments in primary and secondary schools no longer allowed? Does the Directive in fact prohibit all other uses of an animal that can be seen as procedures performed in the field of education or training other than those mentioned in Article 5(f)?** **<u>Answer</u>:** Correct, with the wording of Article 5 providing that "*procedures may be carried out for the following purposes <u>only</u>*". Therefore, the use of animals for <u>other</u> education <u>than higher education</u> or <u>training</u> for the acquisition, maintenance or improvement <u>of vocational skills,</u> is prohibited. **<u>Question</u>:** **Are "*forensic inquiries*" in Article 5(g) inquiries ordered only by a court?** **<u>Answer</u>:** We believe forensic inquiries are those inquiries performed for the interest of the legal system. Therefore, depending on the legal system of the Member State, they could be ordered by a court, but also undertaken by the police or other authorities.

	beings or animals; *(e) research aimed at preservation of the species;* *(f) higher education, or training for the acquisition, maintenance or improvement of vocational skills;* *(g) forensic inquiries.*	
6 and **Annex IV**	***Article 6*** ***Methods of killing*** *1. Member States shall ensure that animals are killed with minimum pain, suffering and distress.* *2. Member States shall ensure that animals are killed in the establishment of a breeder, supplier or user, by a competent person.* *However, in the case of a field study an animal may be killed by a competent person outside of an establishment.* *3. In relation to the animals covered by Annex IV, the appropriate method of killing as set out in that Annex shall be used.* *4. Competent authorities may grant exemptions from the requirement in paragraph 3:* *(a) to allow the use of another method provided that, on the basis of scientific evidence, the method is considered to be at least as humane; or* *(b) when, on the basis of scientific justification, the purpose of the procedure cannot be achieved by the use of a method of killing set out in Annex IV.*	**<u>Question</u>**: **To what extent can Member States develop guidance and regulation on killing methods in Annex IV i.e. to specify instructions for the use of different methods (e.g. method A may not be the best choice for new born animals or that method B might be difficult for some large mammals)?** **<u>Answer</u>:** Annex IV of the Directive provides for the list methods which can be used in the process of killing animals. It does not forbid Member State to develop guidance and other <u>non binding measures</u> concerning the killing methods listed in Annex IV. The national authority could also specify instructions for different methods. However, it should always be ensured that the national measures are fully respecting the list of methods allowed in Annex IV. **<u>Question</u>**: **In case a Member State considers some of the methods in Annex IV either less humane than methods currently required in the Member State in question, or unacceptable to the general public, and Article 6(4) allows Member States to grant exemptions for methods that are "*considered to be at least as humane*", and**

	5. Paragraphs 2 and 3 shall not apply where an animal has to be killed in emergency circumstances for animal-welfare, public-health, public-security, animal-health or environmental reasons. ***ANNEX IV*** ***METHODS OF KILLING ANIMALS*** *1. In the process of killing animals, methods listed in the table below shall be used.* *Methods other than those listed in the table may be used:* *(a) on unconscious animals, providing the animal does not regain consciousness before death;* *(b) on animals used in agricultural research, when the aim of the project requires that the animals are kept under similar conditions to those under which commercial farm animals are kept; these animals may be killed in accordance with the requirements laid down in Annex I to Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of killing (1).* *2. The killing of animals shall be completed by one of the following methods:* *(a) confirmation of permanent cessation of the circulation;* *(b) destruction of the brain;* *(c) dislocation of the neck;* *(d) exsanguination; or*	**Article 2 allows Member States to maintain provisions aimed at ensuring more extensive protection of animals than the provisions contained in the Directive, could these provisions be used to substitute methods of killing in Annex IV with ones used today?** **What level of proof is required for a method to be "*considered to be at least as humane"*?** **<u>Answer</u>:** Yes, provided that the competent authority is satisfied that the conditions under Article 6(4) are fulfilled. It is worth noting that if a Member State introduces a measure in line with Article 6(4)(a), pursuant to Article 54(3) the Member State must annually report detailed information on such exemption to the Commission , in addition to the notification requirement under Article 2. The Member State will need to explain its decision and conviction that a specific method is at least as humane as those in Annex IV of the Directive. A sound scientific justification would be necessary. **<u>Question</u>**: **Can maceration, which is currently the only practical method of confirming death of large numbers of small fish, be accepted as 'destruction of the brain' which is a method permitted in Annex IV?** **<u>Answer</u>:** It is important to note that Annex IV paragraph 2 does not list <u>methods of killing</u> but for <u>completion of death.</u> We believe it is important that the Member State justifies why they consider that maceration (by which we understand mechanical maceration

	(e) confirmation of the onset of rigor mortis. *3. Table ...*	via use of a specially designed mechanical apparatus having rotating blades or projections that causes immediate fragmentation and death of animals) is the only practical way of performing the "*destruction of the brain*" in certain species with small specimens, e.g. some types of fish.
12(1) **23** **40(2) (b)**	***Article 12*** ***Procedures*** *1. Member States shall ensure that procedures are carried out in a user's establishment.* *The competent authority may grant an exemption from the first subparagraph on the basis of scientific justification.* *Article 23* ***Competence of personnel*** *1. Member States shall ensure that each breeder, supplier and user has sufficient staff on site.* *2. The staff shall be adequately educated and trained before they perform any of the following functions:* *(a) carrying out procedures on animals;* *(b) designing procedures and projects;* *(c) taking care of animals; or* *(d) killing animals.* *Persons carrying out the functions referred to in point (b) shall have received instruction in a scientific discipline relevant to the work being undertaken and shall have species-specific knowledge.* *Staff carrying out functions referred to in points (a), (c) or (d) shall be supervised in the*	**<u>Question</u>**: **Besides wildlife, what other cases are envisaged by this article since the definition of an establishment includes also outdoor facilities?** **<u>Answer</u>**: A number of examples could be foreseen; procedures carried out in the wild (wild life studies) as well as those carried out e.g. in a farm or a zoo could benefit from this exemption. Equally, it covers procedures carried out exceptionally at either breeding or supplying establishments. It is important to note that the above applies in cases when it is a working farm with the primary purposes of producing animals for food consumption. In case the farm uses animals for scientific procedures on a regular basis or breeds and supplies animals <u>with a view to their use in scientific procedures,</u> these should be authorised and registered as such i.e. breeding/supplying/user establishments as per Article 20 of this Directive. **<u>Question:</u>** **Who is allowed to carry out procedures at the user's establishment under Article 12(1) and outside of it, if the exemption under paragraph 1 was granted? Should these persons be workers of the authorised user named under Article 23? Or is it possible that persons who are not staff of the user carry out certain projects?** **Is it possible to authorise projects which were carried out at the user's**

	performance of their tasks until they have demonstrated the requisite competence. *Member States shall ensure, through authorisation or by other means, that the requirements laid down in this paragraph are fulfilled.* *3. Member States shall publish, on the basis of the elements set out in Annex V, minimum requirements with regard to education and training and the requiremen* *ts for obtaining, maintaining and demonstrating requisite competence for the functions set out in paragraph 2.* *4. Non-binding guidelines at the level of the Union on the requirements laid down in paragraph 2 may be adopted in accordance with the advisory procedure referred to in Article 56(2).* *Article 40* ***Granting of project authorisation*** *2. The project authorisation shall specify the following:* *(a) the user who undertakes the project;* *(b) the persons responsible for the overall implementation of the project and its compliance with the project authorisation;* *(c) the establishments in which the project will be undertaken, where applicable; and* *(d) any specific conditions following the project evaluation, including whether and when the project shall be assessed retrospectively.*	**establishment by scientists who were not staff of the user? And can it also be accepted that the person named under Article 40(2) b) is not a worker of the user's establishment, although the project is carried out at the authorised user's establishment?** **<u>Answer:</u>** Article 23 concerns the competence of the personnel working on the site of the breeder, supplier and user. The provision specifies that the Member State have to ensure that "*each breeder, supplier and user has sufficient staff on site*". However, the article does not define who would fall under the term 'staff' and does not link the staff explicitly to the breeder, supplier or user. In order to be allowed to carry out procedures the staff should be "*adequately educated and trained…*" as well as *"demonstrated the requisite competence*". Thus, it allows external staff such as scientists to carry out procedures as long as they fulfil the requirements provided under the Article. Moreover, Annex VI point 12 of the Directive ensures that only persons with the relevant competences are involved in projects. Article 40(2) (b) refers to the "*person responsible for the overall implementation of the project and its compliance with the project authorisation*". That person does not have to be a member of the staff of the user's establishment. It is a named person, responsible to oversee a project in general and its compliance with the project authorisation. Hence, this person, e.g. a visiting scientist, is held answerable to any problems arising with the compliance.

13(1)	***Article 13*** ***Choice of methods*** *1. Without prejudice to national legislation prohibiting certain types of methods, Member States shall ensure that a procedure is not carried out if another method or testing strategy for obtaining the result sought, not entailing the use of a live animal, is recognised under the legislation of the Union.* *2. In choosing between procedures, those which to the greatest extent meet the following requirements shall be selected:* *(a) use the minimum number of animals;* *(b) involve animals with the lowest capacity to experience pain, suffering, distress or lasting harm;* *(c) cause the least pain, suffering, distress or lasting harm;* *and are most likely to provide satisfactory results.* *3. Death as the end-point of a procedure shall be avoided as far as possible and replaced by early and humane end-points. Where death as the end-point is unavoidable, the procedure shall be designed so as to:* *(a) result in the deaths of as few animals as possible; and* *(b) reduce the duration and intensity of suffering to the animal to the minimum*	**<u>Question</u>**: **Does Article 13(1) refer only to regulatory testing or what is meant with "*methods or testing strategies that are recognised under the legislation of the Union*"?** **<u>Answer</u>**: Yes, it refers to areas of animal testing for which EU either describes in its own legislation or in its legislation recognises specific methods from other sources (such as OECD, European Pharmacopoeia). This also covers any production method using animals and for which the method would be recognised the same way by EU legislation.

	possible and, as far as possible, ensure a painless death.	
15	***Article 15*** ***Classification of severity of procedures*** *1. Member States shall ensure that all procedures are classified as 'non-recovery', 'mild', 'moderate', or 'severe' on a case- by-case basis using the assignment criteria set out in Annex VIII.* *2. Subject to the use of the safeguard clause in Article 55(3), Member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated.*	**Question**: **Does it follow from Article 15 that procedures classified as "*moderate*" or "*severe*", which are likely to cause more than transitory or short-term suffering, be prohibited unless the pain or distress can be substantially relieved and indeed, these procedures would need to abide by the safeguard clause under Article 55(3)?** **Answer**: The text of Article 15(2) states that *"Subject to the use of the safeguard clause in Article 55(3), Member States shall ensure that a procedure is not performed if it involves severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated."* Annex VIII provides that a 'moderate' pain, suffering or distress which is prolonged, should be classified as 'severe'. Therefore the duration of the pain already plays a role in the classification of the procedure. Thus, it does not follow from that that Article 15(2) would prohibit procedures which involve 'moderate' (not severe) pain, suffering or distress that is likely to be long lasting and cannot be ameliorated.
16	***Article 16*** ***Reuse*** *1. Member States shall ensure that an animal already used in one or more procedures, when a different animal on which no procedure has previously been carried out could also be used, may only be reused in a new procedure provided that the following conditions are met:*	**Question**: **Article 16 places the obligation of ensuring that re-use only takes place in certain circumstances. Does it follow from this that Member States have to specifically authorise re-use?** **Answer**: Competent Authorities authorise "*projects*", not "*procedure*s", or "*re-use*". Re-use is examined during a project evaluation in accordance with Article 38 to ensure that it

	(a) the actual severity of the previous procedures was 'mild' or 'moderate'; *(b) it is demonstrated that the animal's general state of health and well-being has been fully restored;* *(c) the further procedure is classified as 'mild', 'moderate' or 'non-recovery'; and* *(d) it is in accordance with veterinary advice, taking into account the lifetime experience of the animal.* *2. In exceptional circumstances, by way of derogation from point (a) of paragraph 1 and after a veterinary examination of the animal, the competent authority may allow reuse of an animal, provided the animal has not been used more than once in a procedure entailing severe pain, distress or equivalent suffering.*	complies with the provisions of the Directive. **<u>Question</u>**: **Paragraph (1)(b) requires demonstration that an animal's general state of health and well-being has been fully restored. Does it follow from this that the animal can no longer suffer from adverse effects as a result of the previous procedure(s) and that it would not suffer greater adverse effects as a result of being re-used than a naive animal would experience?** **<u>Answer</u>**: Animal should no longer suffer from adverse effects as a result of the previous procedure(s). However, to require that the animal "*would not suffer <u>greater adverse effect than a naïve animal</u>*" is not explicit from the legal text. **<u>Question</u>**: **Does paragraph (1)(d) require that a veterinary surgeon examines the individual animals before authorising their re-use?** **<u>Answer</u>**: No, (1)(d) requires <u>veterinary advice</u> to be the basis of the decision on whether re-use should be allowed. The advice can be e.g. in a form of written instructions as to when re-use can take place. Cross reference to paragraph 16(2) that requires <u>veterinary examination</u> of the animal in question.

		<u>Question</u>: **The derogation in paragraph 2 - allowing the re-use of an animal even though it has already experienced severe pain, distress or equivalent suffering – is only a derogation from paragraph (1)(a). Do all the other preconditions, including in particular paragraph (1)(b), still need to be met?** **<u>Answer</u>**: Correct. All conditions of paragraph 16(1)(b),(c) and (d) have to be met. **<u>Question</u>**: **In the overall context of the Directive, the "*exceptional circumstances*" contemplated by the derogation must truly be exceptional – i.e. that there is real urgency arising, for example, from a health emergency, such that there would be insufficient time to acquire or prepare a naive animal. Apart from this kind of situation, it is difficult to see when the derogation could lawfully be invoked?** **<u>Answer</u>**: The "*exceptional circumstances*" need to be justified on a case-by-case basis. The legal text does not specify the conditions to satisfy being "*exceptional circumstances*" and thus these are not necessarily limited to urgency or health emergencies. **<u>Question</u>**: **Can re-use be allowed simply because it would be cheaper or easier?**

		<u>Answer</u>: No, in line with recital 25, reuse is part of the implementation of the principle of the Three R's, in particular of Reduction. Additionally, it is worth remembering that "*cheaper*" or "*easier*" are not criteria for resorting to reuse pursuant to Article 16.
19 **[Recital 26]**	***Article 19*** ***Setting free of animals and rehoming*** *Member States may allow animals used or intended to be used in procedures to be rehomed, or returned to a suitable habitat or husbandry system appropriate to the species, provided that the following conditions are met:* *(a) the state of health of the animal allows it;* *(b) there is no danger to public health, animal health or the environment; and* *(c) appropriate measures have been taken to safeguard the well- being of the animal.* ***[Recital 26*** *At the end of the procedure, the most appropriate decision should be taken as regards the future of the animal on the basis of animal welfare and potential risks to the environment. The animals whose welfare would be compromised should be killed. In some cases, animals should be returned to a suitable habitat or husbandry system* ***<u>or animals such as dogs and cats should be allowed to be rehomed in families…]</u>***	**<u>Question</u>**: **Does re-homing mean any permanent housing outside a breeder's, supplier's or user's establishment?** **<u>Answer</u>**: Rehoming is used as the term to indicate that an animal can be placed in a private home. For example, returning farm animals to a farm, or zoo animals to a zoo is covered under "*suitable husbandry system', and wild animals under 'suitable habitat*". **<u>Question:</u>** **Do the provisions on 'rehoming' only apply to cats and dogs?** **<u>Answer:</u>** "R*e-homing*" is a possibility provided by the Directive. The Article does not specify which animals could be re-homed. The recital mentions cats and dogs but looking from the context only as an example of the type of species that could be considered for re-homing. As this is a possibility, not a requirement, Member States are free to decide whether they want to use it and for which species (also others than dogs and cats if they so

		wish). However, the conditions in Articles 19 and 29 have to be met.
20(1) **22(3)**	***Article 20*** ***Authorisation of breeders, suppliers and users*** *1. Member States shall ensure that all breeders, suppliers and users are authorised by, and registered with, the competent authority. Such authorisation may be granted for a limited period.* *Authorisation shall be granted only if the breeder, supplier or user and its establishment is in compliance with the requirements of this Directive.* ***Article 22*** ***Requirements for installations and equipment*** *3. For the purposes of implementation of paragraphs 1 and 2, Member States shall ensure that the relevant requirements as set out in Annex III are complied with.*	**<u>Question:</u>** **If a University has more than one department using animals, can these departments be authorised separately or does the legal body need to be authorised, in this case the University as such? Is it possible to grant one authorisation for the University and name in the authorisation decision all the different places where animals are bred, supplied and used in procedures?** **<u>Answer:</u>** Article 20(1) provides for the authorisation of breeders, suppliers and users. Member States have to ensure that breeders, suppliers and users are authorised by, and registered with, the Competent Authority of the respective Member State. In accordance with Article 3, a breeder, supplier or user is defined as "*any natural or legal person*". Thus, provided that a department in question has a legal personality under the national law of the Member State, it is possible under Article 20 to authorise the departments in question separately. Alternatively an authorisation could be issued for the University as a legal person, specifying that it acts as breeder, supplier as well as user (if this is the case). In case of a single authorisation as described above, the Member State has to ensure (as per Articles 20(1)(2nd sub-paragraph and 22(3)) that any locations where animals are bred, supplied and used comply with the requirements of this Directive such as Annex III.
22(2)	***Article 22*** ***Requirements for installations and equipment*** *1. Member States shall ensure that all establishments of a breeder, supplier or user have installations and equipment suited to the*	**<u>Question</u>**: **What is meant by *"as effectively as possible"* in paragraph 22(2)?** **<u>Answer</u>**: "*As effectively as possible*" refers to the equipment and installations. It means that the

	species of animals housed and, where procedures are carried out, to the performance of the procedures. *2. The design, construction and method of functioning of the installations and equipment referred to in paragraph 1 shall ensure that the procedures are carried out as effectively as possible, and aim at obtaining reliable results using the minimum number of animals and causing the minimum degree of pain, suffering, distress or lasting harm.*	choice of infrastructure and equipment should not result in increasing the number of animals, or pain, suffering, distress and lasting harm caused to the animals to obtain the same results.
23(2)	***Article 23*** ***Competence of personnel*** *… 2. The staff shall be adequately educated and trained before they perform any of the following functions:* *(a) carrying out procedures on animals;* *(b) designing procedures and projects;* *(c) taking care of animals; or* *(d) killing animals.* *Persons carrying out the functions referred to in point (b) shall have received instruction in a scientific discipline relevant to the work being undertaken and shall have species-specific knowledge.* *Staff carrying out functions referred to in points (a), (c) or (d) shall be supervised in the performance of their tasks until they have demonstrated the requisite competence.* *Member States shall ensure, through authorisation or by other means, that the requirements laid down in this paragraph are fulfilled.*	**<u>Question</u>**: **Can an existing personal licensing system be considered as "*authorisation*"? It is not clear what would be covered by the term "*by other means*".** **<u>Answer</u>**: An existing licensing system can be considered as "*authorisation*" provided it fulfils the requirements of Article 23(2). "*By other means*" covers others means than authorisation, for example it could be required by law or decree that certain education or training is achieved. **See also a Q&A under Article 12 making reference to Article 23**

24 **20(2)** **21(2)** **60**	***Article 24*** ***Specific requirements for personnel*** *1. Member States shall ensure that each breeder, supplier and user has one or several persons on site who shall:* *(a) be responsible for overseeing the welfare and care of the animals in the establishment;* *(b) ensure that the staff dealing with animals have access to information specific to the species housed in the establishment;* *(c) be responsible for ensuring that the staff are adequately educated, competent and continuously trained and that they are supervised until they have demonstrated the requisite competence.* *2. Member States shall ensure that persons specified in Article 40(2)(b) shall:* *(a) ensure that any unnecessary pain, suffering, distress or lasting harm that is being inflicted on an animal in the course of a procedure is stopped; and* *(b) ensure that the projects are carried out in accordance with the project authorisation or, in the cases referred to in Article 42, in accordance with the application sent to the competent authority or any decision taken by the competent authority, and ensure that in the event of non-compliance, the appropriate measures to rectify it are taken and recorded.* ***Article 20*** ***Authorisation of breeders, suppliers and users*** *2. The authorisation shall specify the person*	**<u>Question:</u>** **Who is ultimately responsible for ensuring that the staff is adequately and continuously trained?** **Article 24 specifies that there can be one or several persons on site responsible for this task. Is it acceptable and up to the institution to e.g. allow the project applicant having technicians working for him/her, the animal-welfare body or someone from that structure and/or the designated veterinarian to fulfil this role?** **What if there are infringements? What would be the impact for the establishment?** **<u>Answer:</u>** Article 20(2) provides that the authorisation shall specify the person/persons referred to in Article 24(1). Hence, every breeder, supplier and user has to have at least one person on site who is specified in the authorisation and who is responsible for the education, competency and continuous training as well as ensuring the supervision of the staff. It is this person, named in the authorisation, who is responsible for the compliance with the provisions of Article 24(1)(c). It is up to the institution, i.e. the breeder, supplier or user to determine the person(s) responsible under Article 24(1) and to include this(these) person(s) in the authorisation. It is important to note that persons under Article 24(1) need to be **on site** in the establishment, which is not necessarily required for e.g. a designated veterinarian. Furthermore, the animal-welfare body as described in Article 26 is not a 'person' and thus cannot be made responsible for the activities under 24(1)(c).

	responsible for ensuring compliance with the provisions of this Directive and the person or persons referred to in Article 24(1) and in Article 25. ***Article 21*** ***Suspension and withdrawal of authorisation*** *2. Member States shall ensure that, where the authorisation is suspended or withdrawn, the welfare of the animals housed in the establishment is not adversely affected.* ***Article 60*** ***Penalties*** *Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. The Member States shall notify those provisions to the Commission by 10 February 2013, and shall notify the Commission without delay of any subsequent amendment affecting them.*	With regard to infringements, it is up to the Member State to lay down rules on penalties applicable to infringements of the national provisions implementing the Directive as well as to how these are carried out. In accordance with Article 60, the penalties must be "*effective, proportionate and dissuasive*". Where a breeder, supplier or user does not comply with the obligations under the Directive anymore, the Competent Authority has to take "*appropriate remedial action*" which may include the suspension or withdrawal of the authorisation (Article 21(1)). In this case, Article 21(2) requires that the welfare of the animals housed in the establishment is not adversely affected.
24(1)(a) **25** **(26)**	***Article 24*** ***Specific requirements for personnel*** *1. Member States shall ensure that each breeder, supplier and user has one or several persons on site who shall:* *(a) be responsible for overseeing the welfare and care of the animals in the establishment; …*	**<u>Question</u>**: **Could the person responsible for the welfare and care of the animals in an establishment be the same person as the designated veterinarian or expert?** **<u>Answer</u>**: Yes. However, it is important to note in this context that the requirement for the person responsible for the welfare and care of animals in establishment requires the

	Article 25 ***Designated veterinarian*** *Member States shall ensure that each breeder, supplier and user has a designated veterinarian with expertise in laboratory animal medicine, or a suitably qualified expert where more appropriate, charged with advisory duties in relation to the well-being and treatment of the animals.* ***Article 26*** ***Animal-welfare body*** *1. Member States shall ensure that each breeder, supplier and user sets up an animal-welfare body.* *2. The animal-welfare body shall include at least the person or persons responsible for the welfare and care of the animals and, in the case of a user, a scientific member. The animal-welfare body shall also receive input from the designated veterinarian or the expert referred to in Article 25. …*	person to be on-site *in the establishment* whereas the veterinarian or other qualified expert can be designated and thus not need to be present on-site. **Question:** **What is meant by "*or a suitably qualified expert where more appropriate*" in Article 25. Can an establishment choose freely whether to designate a veterinarian or another expert?** **Answer:** The decision has to be made on a case-by-case basis and with the agreement of the authorities when the establishment is authorised as per Article 21. It requires the designated veterinarian or a suitably qualified expert to be named in the authorisation. The provision lays out two conditions, the expert has to be 1) 'suitably qualified' and 2) 'more appropriate' than the use of a designated veterinarian. The provision was drafted with the intention to allow in some specific cases to use experts when e.g. the user/breeder/supplier is dealing with more rare species such as cephalopods or amphibians and veterinarians specialised in these specific species are not available, making such specialised expert **more** appropriate. The proposed approach is in line with the rest of the provisions as well as the spirit of the Directive. The justifications used elsewhere in the Directive are systematically linked to a scientific reasoning.
33(4)	***Article 33*** ***Care and accommodation*** *1. Member States shall, as far as the care and*	**Question**: **It is unclear why exemptions to housing and care requirements of paragraph**

	accommodation of animals is concerned, ensure that: *(a) all animals are provided with accommodation, an environment, food, water and care which are appropriate to their health and well-being;* *(b) any restrictions on the extent to which an animal can satisfy its physiological and ethological needs are kept to a minimum;* *(c) the environmental conditions in which animals are bred, kept or used are checked daily;* *(d) arrangements are made to ensure that any defect or avoidable pain, suffering, distress or lasting harm discovered is eliminated as quickly as possible; and* *(e) animals are transported under appropriate conditions.* *2. For the purposes of paragraph 1, Member States shall ensure that the care and accommodation standards set out in Annex III are applied from the dates provided for therein.* *3. Member States may allow exemptions from the requirements of paragraph 1(a) or paragraph 2 for scientific, animal-welfare or animal-health reasons.*	**1(a) or paragraph 2 should be allowed for animal-welfare reasons, because these requirements were laid down specifically for animal welfare reasons in the first place. What is "*for animal-welfare reasons*" to be taken to mean?** **<u>Answer</u>**: There are a number of cases where exemptions could be granted on animal welfare grounds. For example, a situation where an animal has developed self-injurious behaviour can sometimes be improved by temporarily decreasing space allowance. Another example could be in reference to maternal bonding between the mother and the new-borns which can be increased with reduced space allowances.
34	***Article 34*** ***Inspections by the Member States*** *1. Member States shall ensure that the competent authorities carry out regular inspections of all breeders, suppliers and users,*	**<u>Question</u>**: **Seeing the importance of correct transposition of the requirements for inspections, should they be transposed textually in national legislation?**

	including their establishments, to verify compliance with the requirements of this Directive. *2. The competent authority shall adapt the frequency of inspections on the basis of a risk analysis for each establishment, taking account of:* *(a) the number and species of animals housed;* *(b) the record of the breeder, supplier or user in complying with the requirements of this Directive;* *(c) the number and types of projects carried out by the user in question; and* *(d) any information that might indicate non-compliance.* *3. Inspections shall be carried out on at least one third of the users each year in accordance with the risk analysis referred to in paragraph 2. However, breeders, suppliers and users of non-human primates shall be inspected at least once a year.* *4. An appropriate proportion of the inspections shall be carried out without prior warning.* *5. Records of all inspections shall be kept for at least 5 years.*	**<u>Answer</u>**: National legislation should set the means to achieve the objectives set in the Directive. Transposition does not require textual transposition but many Member States use that technique.
37 **40(2)(b)**	***Article 37*** ***Application for project authorisation*** *1. Member States shall ensure that an application for project authorisation is submitted by the user or the person responsible for the project. The application shall include at least*	**<u>Question:</u>** **Article 37 names the person who can submit an application. Is there any link between that person and any other persons named in other articles such as Article 40(2)(b)?**

	the following: *(a) the project proposal;* *(b) a non-technical project summary; and* *(c) information on the elements set out in Annex VI.* *2. Member States may waive the requirement in paragraph 1(b) for projects referred to in Article 42(1).* ***Article 40*** ***Granting of project authorisation*** *2. The project authorisation shall specify the following:* *(a) the user who undertakes the project;* *(b) the persons responsible for the overall implementation of the project and its compliance with the project authorisation;* *…*	**Answer:** Article 37 establishes that the application for a project authorisation has to be submitted by 1) "*the user"* or *2) "the person responsible for the project*". The 'user' under point 1 can be any "*natural or legal person using animals in procedures*" as defined in Article 3(6). The person under point 2 who is *'responsible for the project'* is not further defined in the Directive. In the project application, it should be specified who will be the person responsible for the *overall implementation of the project* as required by Article 40(2)(b). This may not necessarily be the same person. In this context, it is important to note that none of the requirement above refers to the designer of the project. The person designing the project has to fully comply with the requirements of Article 23(2) but can also be the person referred to either in Article 37(1) or 40(2)(b)) in addition to his role under Article 23(2).
38 **59** **49**	***Article 38*** ***Project evaluation*** *…3. The competent authority carrying out the project evaluation shall consider expertise in particular in the following areas:* *(a) the areas of scientific use for which animals will be used including replacement, reduction and refinement in the respective areas;* *(b) experimental design, including statistics where appropriate;* *(c) veterinary practice in laboratory*	**Question:** **What is meant by transparent in this context?** **Answer:** The project evaluation is carried out by the Member States' Competent Authorities. Article 38(4) provides that the "*project evaluation* ***process*** *has to be transparent"*. It implies that the information as to - how the process of the project evaluation is carried out and - how the requirements in Article 38 are met

	animal science or wildlife veterinary practice where appropriate; *(d) animal husbandry and care, in relation to the species that are intended to be used.* *4. The project evaluation process shall be transparent.* *Subject to safeguarding intellectual property and confidential information, the project evaluation shall be performed in an impartial manner and may integrate the opinion of independent parties.* ***Article 59*** ***Competent authorities*** *1. Each Member State shall designate one or more competent authorities responsible for the implementation of this Directive.* *Member States may designate bodies other than public authorities for the implementation of specific tasks laid down in this Directive only if there is proof that the body:* *(a) has the expertise and infrastructure required to carry out the tasks; and* *(b) is free of any conflict of interests as regards the performance of the tasks.* *Bodies thus designated shall be considered competent authorities for the purposes of this Directive. …* ***Article 49*** ***National committees for the protection of animals used for scientific purposes***	is made available by the Member States. **<u>Question</u>**: **Could the project evaluation be carried out by an internal ethical committee, or the animal welfare body (as per Article 26), of the establishment in question (as the "*competent authority*" as described by Article 59) of the laboratory which will implement the very project? Would the requirements for impartiality, independence and freedom of any conflict of interests as required under Article 59 be guaranteed with such an internal committee without any other external and impartial advice?** **<u>Answer</u>**: The national authorities need to be satisfied that the requirements under Article 38(3) (on the expertise to be considered), under Article 38(4) (on the transparency of the process and impartiality) as well as those under Article 59(1)(a) and (b) (on the body to have the required expertise and infrastructure and to be free of conflict of interest with regards the performance of the tasks) are met. Depending on the situation, there may be cases where these conditions could be fulfilled; equally there would be cases where some of them would not be able to be fulfilled by an internal committee. This needs to be judged by the national authority on a case-by-case basis. If contested, the decision should be defensible in the court of law demonstrating how the different requirements are being met. **<u>Question</u>**: **In cases of smaller Member States where the number of experts in the field of animals used for scientific purposes is limited, could the National Committee for**

	1. Each Member State shall establish a national committee for the protection of animals used for scientific purposes. It shall advise the competent authorities and animal-welfare bodies on matters dealing with the acquisition, breeding, accommodation, care and use of animals in procedures and ensure sharing of best practice. …	**the protection of animals used for scientific purposes (Article 49) also be assigned as the competent authority to carry out project evaluations?** **<u>Answer</u>**: It seems acceptable when seeking for a pragmatic implementation, however, in their operation, the work of the two different functions including any documentation, reports etc would need to be clearly differentiated so that it can be identified in which capacity the committee is convening. The most important elements are in relation to impartiality and lack of conflict of interests, especially when performing project evaluation and this does not seem to be infringed in this particular set-up. Ideally, some additional members should be included when performing the task of the National Committee, which would then allow fulfilling the task of advising the CA for project evaluation.
39	*Article 39* ***Retrospective assessment*** *1. Member States shall ensure that when determined in accordance with Article 38(2)(f), the retrospective assessment shall be carried out by the competent authority which shall, on the basis of the necessary documentation submitted by the user, evaluate the following:* *(a) whether the objectives of the project were achieved;* *(b) the harm inflicted on animals, including the numbers and species of animals used, and the severity of the procedures; and* *(c) any elements that may contribute to the further implementation of the requirement of*	**<u>Question</u>:** **When does the retrospective assessment need to be carried out; at the end or during the project? What kind of documents have to be submitted for it?** **Answer**: Article 39 implies that the retrospective assessment is to be carried out at the end of the project. For instance, some of the elements which need to be assessed pursuant to Article 39(1) can only be assessed once the project is finished e.g. Article 39(1) (a): "*whether the objectives of the project were achieved*". Article 39 refers to Article 38(2) (f) which establishes that the project evaluation has to include "*a determination as to whether and **when** the project should be assessed retrospectively*". It would suggest that it is up to the Member State to decide when, after the completion of the project, an assessment should be carried out allowing

	replacement, reduction and refinement. *2. All projects using non-human primates and projects involving procedures classified as 'severe', including those referred to in Article 15(2), shall undergo a retrospective assessment.* *3. Without prejudice to paragraph 2 and by way of derogation from Article 38(2)(f), Member States may exempt projects involving only procedures classified as 'mild' or 'non-recovery' from the requirement for a retrospective assessment.*	some flexibility to take into account the type of project and how soon, after the completion of the project, the emerging benefits are feasible to be assessed. This is also in line with the ordinary meaning of the word '**retrospective'**, which implies that one is to look at the events belonging to the past. Furthermore, only at the end of a project it is possible to assess whether further work under a new project is justified.
40(4) **42**	***Article 40*** ***Granting of project authorisation*** *… 4. Member States may allow the authorisation of multiple generic projects carried out by the same user if such projects are to satisfy regulatory requirements or if such projects use animals for production or diagnostic purposes with established methods.* ***Article 42*** ***Simplified administrative procedure*** *1. Member States may decide to introduce a simplified administrative procedure for projects containing procedures classified as 'non-recovery', 'mild' or 'moderate' and not using non-human primates, that are necessary to satisfy regulatory requirements, or which use animals for production or diagnostic purposes with established methods.* *2. When introducing a simplified administrative procedure, Member States shall ensure that the*	**<u>Question</u>**: **What is meant by "*multiple generic projects*"? "*Generic*" is not defined nor is it clear what "*multiple*" adds to "*generic*"?** **<u>Answer</u>**: "*Multiple*" means several and refers to the number of projects. "[*G*]*eneric*" refers to the nature of the project. These are two separate elements. It could be argued that the provision does not allow Member States to have one authorisation for multiple specific projects. Therefore "*multiple*" adds to "*generic*". There are only two instances in which several projects could be authorised under one authorisation: in the case of projects being carried out to satisfy regulatory requirements, and in the case of projects that use animals for production or diagnostic purposes with established methods. There is coherence and similarity of the projects authorised together. Member States are free to establish the rules to carry out group authorisation as well as they are free not to implement this possibility ("*Member States <u>may</u> allow…"*). Please see also:

	following provisions are met: *(a) the application specifies elements referred to in Article 40(2)(a), (b) and (c);* *(b) a project evaluation is performed in accordance with Article 38; and* *(c) that the period referred to in Article 41(1) is not exceeded.*	*http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Consensus_document.pdf* **Question**: **Does the fact that a Member State may grant authorisation for multiple generic projects absolve them of the duty to carry out a project evaluation under Article 38 for each of the projects authorised under Article 40(4)? Is a project evaluation needed for projects falling under a simplified administrative procedure in Article 42?** **Answer**: No, the requirements of Article 38 on the project evaluation cover all projects, including those authorised under a multiple generic project authorisation as well as those carried out under the rules on simplified administrative procedure in Article 42. The Directive does not foresee any exceptions to the requirement to carry out project evaluation for each project.
41(1)	***Article 41*** ***Authorisation decisions*** *1. Member States shall ensure that the decision regarding authorisation is taken and communicated to the applicant 40 working days at the latest from the receipt of the complete and correct application. This period shall include the project evaluation.* *2. When justified by the complexity or the multi-disciplinary nature of the project, the competent authority may extend the period referred to in paragraph 1 once, by an additional period not exceeding 15 working days. The extension and its duration shall be duly motivated and shall be*	**Question**: **Is a researcher entitled to begin a project using animals before a favourable project evaluation has been received; what about in cases when the project is examined under a simplified administrative procedure and no specific authorisation is issued?** **Answer**: No, Article 36 states clearly that Member States will have to ensure that no project is started unless a favourable project evaluation by the competent authority has been received. The requirements of Article 38 on the project evaluation cover all projects, including those carried out under the rules on simplified administrative procedure in

	notified to the applicant before the expiry of the period referred to in paragraph 1. ….	Article 42. **<u>Question</u>**: **Can an authorisation be considered as "*granted*" / "*refused*" when the competent authority fails to make and communicate the authorisation decision in the given deadline?** **<u>Answer</u>**: The Directive in its Article 41 does not foresee a possibility for a "*tacit agreement*", neither for a "*tacit refusal*", when the competent authority fails to make and communicate the authorisation decision within the given deadline. In absence of a decision granting or refusing authorisation, the applicant cannot start the project and is obliged to wait for the authorisation decision. Other interpretation would go against the objectives of the Directives as it would allow carrying out a project without an authorisation. The wording of Article 41 clearly requires Member States to ensure that the decision regarding the authorisation is <u>taken and communicated to the applicant</u>. Furthermore Article 36 requires Member States to ensure that projects are not carried out without prior authorisation and the projects are carried out in accordance with the authorisation. Finally the authorisation shall include any specific conditions following the project evaluation. Equally information on the reasons for a refusal of authorisation is required to be communicated to the applicant. If in certain situations the national administrative law would foresee a tacit agreement or tacit refusal in case of an authority failing to respect deadlines, this can not hinder the applicability of EU law which shall prevail in such cases. Such positive or negative silence is incompatible with the implementation and transposition of this Directive, in particular with Article 41, which obliges the Member States <u>to</u>

		communicate the decision within the given deadline. If the decision of authorisation is late and the applicant has suffered damages because of that, he may seek a remedy from the national courts. **Question:** **Would Article 41(2) allow Member State to systematically add additional 15 days to the authorisation time or is this to be justified on a case-by-case basis?** **Answer:** The wording of Article 41(2) suggests that the extension of the deadline has to be justified on a case-by case basis. It starts by setting out on which basis an extension can be justified namely *"[w]hen justified by the complexity or the multi-disciplinary nature of the project"*. It then goes on to provide that an *"extension and its duration shall be duly motivated and shall be notified to the applicant"*. The fact that an extension needs to be duly motivated indicates that the justification has to be provided for each individual case and has to take into the account case-specific circumstances. Thus, the 40 working days deadline envisaged by Article 41(1) should not be systematically extended. Instead, it should be applied as an exception rather than the rule. Indeed, to this effect, Recital 44 explains that "*the extension of deadlines for project evaluation should remain the exception"*. Hence, Article 41(2) should be considered only for exceptional cases justified on a case-by-case basis.
42	***Article 42*** ***Simplified administrative procedure*** *1. Member States may decide to introduce a simplified administrative procedure for projects containing procedures classified as 'non-recovery', 'mild' or 'moderate' and not using*	**Question**: **Is a specific document required also for simplified administrative procedure for the project to be allowed to start?** **Answer**:

	non-human primates, that are necessary to satisfy regulatory requirements, or which use animals for production or diagnostic purposes with established methods. *2. When introducing a simplified administrative procedure, Member States shall ensure that the following provisions are met:* *(a) the application specifies elements referred to in Article 40(2)(a), (b) and (c);* *(b) a project evaluation is performed in accordance with Article 38; and* *(c) that the period referred to in Article 41(1) is not exceeded.* *3. If a project is changed in a way that may have a negative impact on animal welfare, Member States shall require an additional project evaluation with a favourable outcome.* *4. Article 40(3) and (4), Article 41(3) and Article 44(3), (4) and (5) shall apply mutatis mutandis to projects that are allowed to be carried out in accordance with this Article.*	No, however, the requirement is for the Member State to ensure that the competent authority has carried out a favourable project evaluation before the project can start.
45 **41(1)**	***Article 45*** ***Documentation*** *1. Member States shall ensure that all relevant documentation, including project authorisations and the result of the project evaluation is kept for at least 3 years from the expiry date of the authorisation of the project or from the expiry of the period referred to in Article 41(1) and shall be available to the competent authority.* *2. Without prejudice to paragraph 1, the documentation for projects which have to*	**<u>Question</u>**: **It is unclear in which cases the expiry of the *"period referred to in Article 41(1)"* is to be the deciding factor instead of the expiry date of the authorisation of the project?** **<u>Answer</u>**: The reference to the period referred to in Article 41(1) foresees situations in which the authorisation was not granted (negative decision). In such cases the 3-year period will start 40 days from the complete and correct application. Therefore the "*period*

	undergo retrospective assessment shall be kept until the retrospective assessment has been completed. ***Article 41*** ***Authorisation decisions*** *1. Member States shall ensure that the decision regarding authorisation is taken and communicated to the applicant 40 working days at the latest from the receipt of the complete and correct application. This period shall include the project evaluation. …*	*referred to in Article 41(1)*" is to be the deciding factor in cases in which the authorisation was not granted.
46	***Article 46*** ***Avoidance of duplication of procedures*** *Each Member State shall accept data from other Member States that are generated by procedures recognised by the legislation of the Union, unless further procedures need to be carried out regarding that data for the protection of public health, safety or the environment.*	**<u>Question</u>**: **What are the legal implications of Article 46 and how will it be enforced?** **<u>Answer</u>**: In general Member States must ensure in their national transposition the objective of Article 46. The provisions in the national legislation have to foresee that data from other Member States, that are generated by procedures recognised by the legislation of the Union, are accepted by the authorities in their territory. Duplication of procedures is possible only when Member State can demonstrate that further procedures need to be carried out for the protection of public health, safety or the environment. The measures of enforcement remain the responsibility of Member States.
47(1)	***Article 47*** ***Alternative approaches*** *1. The Commission and the Member States shall contribute to the development and*	**<u>Question:</u>** **What kind of obligation does Article 47(1) impose on the Member States?** **<u>Answer:</u>**

	validation of alternative approaches which could provide the same or higher levels of information as those obtained in procedures using animals, but which do not involve the use of animals or use fewer animals or which entail less painful procedures, and they shall take such other steps as they consider appropriate to encourage research in this field.	Article 47 imposes an obligation on Member States "*to contribute to the development and validation of alternative approaches which could provide the same or higher levels of information as those obtained in procedures using animals…"*. However, the provision does not define the nature or the level of the contribution, leaving a margin of discretion to the Member States. Hence, three elements can be drawn from the text: • the legislator imposes an obligation <u>on the Member States</u> • <u>to contribute</u> but • leaves it to Member States to <u>decide on the specific nature and level</u> of these contributions.
55 **44(4)**	***Article 55*** ***Safeguard clauses*** *1. Where a Member State has scientifically justifiable grounds for believing it is essential to use non-human primates for the purposes referred to in Article 8(1)(a)(i) with regard to human beings, but where the use is not undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions, it may adopt a provisional measure allowing such use, provided the purpose cannot be achieved by the use of species other than non-human primates.* *2. Where a Member State has justifiable grounds for believing that action is essential for the preservation of the species or in relation to an unexpected outbreak of a life- threatening or debilitating clinical condition in human beings, it*	**<u>Question</u>**: **Is a Member State obliged to transpose all of Article 55 even if the Member State in question does not intend to make use of all of it?** **<u>Answer</u>**: A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods. Therefore, each Member State has to find the means to achieve the prescribed result. The safeguard clause is addressed to Member States and it provides them with the possibility of introducing provisional measures in specified situations. As the provision is addressed only to Member States and does not provide any additional rights to 3rd parties, it is up to the Member State to decide whether it will or will not use its prerogative. Therefore if a Member State is not intending to make use at all

	may adopt a provisional measure allowing the use of great apes in procedures having one of the purposes referred to in points (b)(i), (c) or (e) of Article 5; provided that the purpose of the procedure cannot be achieved by the use of species other than great apes or by the use of alternative methods. However, the reference to Article 5(b)(i) shall not be taken to include the reference to animals and plants. *3. Where, for exceptional and scientifically justifiable reasons, a Member State deems it necessary to allow the use of a procedure involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, as referred to in Article 15(2), it may adopt a provisional measure to allow such procedure. Member States may decide not to allow the use of non-human primates in such procedures.* *4. A Member State which has adopted a provisional measure in accordance with paragraph 1, 2 or 3 shall immediately inform the Commission and the other Member States thereof, giving reasons for its decision and submitting evidence of the situation as described in paragraphs 1, 2 and 3 on which the provisional measure is based.* *The Commission shall put the matter before the Committee referred to in Article 56(1) within 30 days of receipt of the information from the Member State and shall, in accordance with the regulatory procedure referred to in Article 56(3), either:* *(a) authorise the provisional measure for a time period defined in the decision; or*	from the provisions of Article 55, they are not obliged to transpose it. **<u>Question</u>**: **What information does the Commission require under Article 55(4)? What information must be submitted to the other Member States? Should the information provided to the Commission and the other Member States be the same and how would operational or business secrets be protected?** **<u>Answer</u>**: Under Article 55(4) a Member State, which has adopted provisional measures, is required to submit to the Commission all information that it considers relevant to justify the action and which should not disclose any operational or business secrets. The information submitted to the Commission and Member States should be the same as the following Commission Decision is the result of the vote by the Member State Committee as described in Art 55(4). **<u>Question</u>**: **May a project based on a provisional measure, adopted by a Member State under Article 55, be started before the Commission has given its approval?** **<u>Answer</u>**: Yes, the project can be started on the basis of the national provisional measure. The provisional measure will then be either confirmed or revoked on the basis of the decision through the regulatory procedure. If the measure is revoked, the project has to be stopped, however, ensuring that the requirements for the welfare of animals

	(b) require the Member State to revoke the provisional measure. ***Article 44*** ***Amendment, renewal and withdrawal of a project authorisation*** *… 4. Where a project authorisation is withdrawn, the welfare of the animals used or intended to be used in the project must not be adversely affected.*	under Article 44(4) are complied with.
55	***Article 55*** ***Safeguard clauses*** *1. Where a Member State has scientifically justifiable grounds for believing it is essential to use non-human primates for the purposes referred to in Article 8(1)(a)(i) with regard to human beings, but where the use is not undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions, it may adopt a provisional measure allowing such use, provided the purpose cannot be achieved by the use of species other than non-human primates.* *2. Where a Member State has justifiable grounds for believing that action is essential for the preservation of the species or in relation to an unexpected outbreak of a life- threatening or debilitating clinical condition in human beings, it may adopt a provisional measure allowing the use of great apes in procedures having one of the purposes referred to in points (b)(i), (c) or (e) of Article 5; provided that the purpose of the procedure cannot be achieved by the use of species other than great apes or by the use of*	**<u>Question</u>**: **Why are scientifically justifiable grounds considered necessary in paragraphs 1 and 3 for adopting a provisional measure allowing such use or authorisation, but "*only*" justifiable grounds in paragraph 2?** **<u>Answer</u>**: Paragraph 2 of Article 55 concerns the use of great apes in procedures. Since great apes are non-human primates an authorisation to use them in procedures can only be granted after a full scrutiny of Article 8 on non-human primates, in which the "*scientific justification*" criteria is one of the requirements to be fulfilled. Therefore if ever great apes could be used in a procedure all the requirements for non-human primates and additionally special requirements for great apes must be fulfilled.

	alternative methods. However, the reference to Article 5(b)(i) shall not be taken to include the reference to animals and plants. *3. Where, for exceptional and scientifically justifiable reasons, a Member State deems it necessary to allow the use of a procedure involving severe pain, suffering or distress that is likely to be long-lasting and cannot be ameliorated, as referred to in Article 15(2), it may adopt a provisional measure to allow such procedure. Member States may decide not to allow the use of non-human primates in such procedures. ….*	