House of Lords
House of Commons

Joint Committee on Statutory Instruments

Twelfth Report of Session 2012-13

Drawing special attention to:

Homelessness (Suitability of Accommodation) (England) Order 2012 **(S.I. 2012/2601)**

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Joint Committee on Statutory Instruments

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The full constitution and powers of the Committee are set out in House of Commons Standing Order No. 151 and House of Lords Standing Order No. 74, available on the Internet via www.parliament.uk/jcsi.

Remit

The Joint Committee on Statutory Instruments (JCSI) is appointed to consider statutory instruments made in exercise of powers granted by Act of Parliament. Instruments not laid before Parliament are included within the Committee's remit; but local instruments and instruments made by devolved administrations are not considered by JCSI unless they are required to be laid before Parliament.

The role of the JCSI, whose membership is drawn from both Houses of Parliament, is to assess the technical qualities of each instrument that falls within its remit and to decide whether to draw the special attention of each House to any instrument on one or more of the following grounds:

i. that it imposes, or sets the amount of, a charge on public revenue or that it requires payment for a licence, consent or service to be made to the Exchequer, a government department or a public or local authority, or sets the amount of the payment;
ii. that its parent legislation says that it cannot be challenged in the courts;
iii. that it appears to have retrospective effect without the express authority of the parent legislation;
iv. that there appears to have been unjustifiable delay in publishing it or laying it before Parliament;
v. that there appears to have been unjustifiable delay in sending a notification under the proviso to section 4(1) of the Statutory Instruments Act 1946, where the instrument has come into force before it has been laid;
vi. that there appears to be doubt about whether there is power to make it or that it appears to make an unusual or unexpected use of the power to make;
vii. that its form or meaning needs to be explained;
viii. that its drafting appears to be defective;
ix. any other ground which does not go to its merits or the policy behind it.

The Committee usually meets weekly when Parliament is sitting.

Publications

The reports of the Committee are published by The Stationery Office by Order of both Houses. All publications of the Committee are on the Internet at www.parliament.uk/jcsi.

Committee staff

The current staff of the Committee are Charlotte Littleboy (*Commons Clerk*), Jane White (*Lords Clerk*) and Liz Booth (*Committee Assistant*). Advisory Counsel: Peter Davis, Peter Brooksbank, Philip Davies and Daniel Greenberg (*Commons)*; Allan Roberts, Nicholas Beach and Peter Milledge *(Lords)*.

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Instruments reported

At its meeting on 28 November 2012 the Committee scrutinised a number of Instruments in accordance with Standing Orders. It was agreed that the special attention of both Houses should be drawn to one of those considered. The Instrument and its grounds for reporting it are given below. The relevant Departmental memorandum is published as an appendix to this report.

1 S.I. 2012/2601: Reported for requiring elucidation

Homelessness (Suitability of Accommodation) (England) Order 2012 (S.I. 2012/2601)

1.1 **The Committee draws the special attention of both Houses to this Order on the ground that in one respect it calls for elucidation.**

1.2 This Order is made under section 210(2) of the Housing Act 1996, which permits the Secretary of State by order to specify circumstances in which accommodation is or is not to be regarded as suitable for a [homeless] person, and matters to be taken into account or disregarded in determining whether accommodation is suitable for a [homeless] person. The range of accommodation to which the Order applies includes accommodation provided privately (see section 206 of that Act).

1.3 Article 2 of the Order requires the local housing authority to take various matters (related to location) into account in determining whether accommodation is suitable for the person concerned.

1.4 Article 3 specifies various circumstances in which accommodation is not to be regarded as suitable. These include:

(a) the local housing authority are of the view that the accommodation is not in a reasonable physical condition;

(b) the local housing authority are of the view that any electrical equipment supplied with the accommodation does not meet [specified statutory requirements];

(c) the local housing authority are of the view that the landlord has not taken reasonable fire safety precautions with the accommodation and any furnishings supplied with it;

(d) the local housing authority are of the view that the landlord has not taken reasonable precautions to prevent the possibility of carbon monoxide poisoning in the accommodation;

(e) the local housing authority are of the view that the landlord is not a fit and proper person to act in the capacity of landlord, having considered if the person has [behaved in any of five specified ways].

1.5 The Committee asked the Department for Communities and Local Government to explain the extent to which local housing authorities are intended to be obliged to form a

view on the matters referred to in article 3(a) to (e) and, to the extent that such an obligation is intended, to explain how that intention is achieved.

1.6 In a memorandum printed at Appendix 1, the Department suggests that it is implicit in article 3(a) to (e) that a local housing authority is obliged to make reasonable enquiries in order to be able to form a view on whether any of the matters referred to render a property unsuitable. The Committee agrees that such an interpretation is possible and indeed reasonable, but observes that it is not the only possible interpretation: it could be argued that those matters are irrelevant if the local housing authority does not take the trouble to form a view on them.

1.7 The Department also refers to guidance which it has issued in respect of this Order. The guidance is issued by the Secretary of State under powers conferred by section 182 of the Housing Act 1996, and that section requires local housing authorities to have regard to it in carrying out their functions under the relevant legislation. The guidance makes it clear that authorities should consider each of the matters in question, and the Committee is satisfied that a satisfactory answer has been given to its question.

1.8 **The Committee accordingly reports this Order for requiring the elucidation provided by the Department's memorandum and the guidance to which it refers.**

Instruments not reported

At its meeting on 28 November 2012 the Committee considered the Instruments set out in the Annex to this Report, none of which were required to be reported to both Houses.

A memorandum from the Home Office in connection with the Draft S.I. Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012 is printed at Appendix 2.

Annex

Instruments to which the Committee does not draw the special attention of both Houses

- *denotes that the written evidence submitted in connection with the instrument is printed with this Report*

Instruments requiring affirmative approval

S.I. 2012/2904 Financial Restrictions (Iran) Order 2012

Draft Instruments requiring affirmative approval

• **Draft S.I.** Animals (Scientific Procedures) Act 1986 Amendment Regulations 2012

Instruments subject to annulment

S.I. 2012/2659 Bus Lane Contraventions (Approved Local Authorities) (England) (Amendment) and Civil Enforcement of Parking Contraventions Designation (No. 2) Order 2012

S.I. 2012/2707 Plant Health (Forestry) (Amendment) Order 2012

S.I. 2012/2711 Veterinary Medicines (Amendment) Regulations 2012

S.I. 2012/2723 Energy Act 2004 (Amendment) Regulations 2012

S.I. 2012/2732 Local Policing Bodies (Consequential Amendments No. 2) Regulations 2012

S.I. 2012/2733 Local Policing Bodies (Consequential Amendments and Transitional Provision) Order 2012

S.I. 2012/2734 Police and Crime Panels (Application of Local Authority Enactments) Regulations 2012

S.I. 2012/2743 Industrial Injuries Benefit (Injuries arising before 5th July 1948) Regulations 2012

S.I. 2012/2745 Nursing and Midwifery Council (Constitution) (Amendment) Order 2012

S.I. 2012/2754 Nursing and Midwifery Council (Education, Registration and Registration Appeals) (Amendment) Rules Order of Council 2012

S.I. 2012/2756 Employment and Support Allowance (Sanctions) (Amendment) Regulations 2012

S.I. 2012/2782 Feed-in Tariffs Order 2012

S.I. 2012/2791 Health Service Branded Medicines (Control of Prices and Supply of Information) Amendment Regulations 2012

S.I. 2012/2798 Consumer Credit (Green Deal) Regulations 2012

S.I. 2012/2806 Family Procedure (Amendment No. 4) Rules 2012

S.I. 2012/2812 Industrial Injuries Benefit (Injuries arising before 5th July 1948) (Amendment) Regulations 2012

Instruments not subject to Parliamentary proceedings not laid before Parliament

S.I. 2012/2770 Legal Aid, Sentencing and Punishment of Offenders Act 2012 (Commencement No. 3 and Saving Provision) Order 2012

Appendix 1

S.I. 2012/: memorandum from the Department for Communities and Local Government

Homelessness (Suitability of Accommodation) (England) Order 2012 (S.I. 2012/2601)

1. The Committee has requested a memorandum on the following points:

(1) Explain the extent to which local housing authorities are intended to be obliged to form a view on the matters referred to in article 3(1)(a) to (e), for example: the physical condition of the accommodation and the electrical equipment supplied with it, the precautions as to fire safety and prevention of carbon monoxide poisoning taken by the landlord, and whether the landlord is a fit and proper person.

(2) To the extent that such an obligation is intended, explain how that intention is achieved.

2. Section 206(1) of the Housing Act 1996 ("the 1996 Act") provides that accommodation secured by a local housing authority, or secured from another person on the advice and assistance of the local housing authority, in discharge of their housing functions under Part VII of the 1996 Act, must be suitable. Section 210 of the 1996 Act gives the Secretary of State the power by order to specify circumstances in which accommodation is or is not to be regarded as suitable for a person. This power has been exercised in SI 2012/2601 and a local housing authority may not regard accommodation as suitable where one or more of article 3(1)(a) to (j) applies.

3. Articles 3(1)(a) to (e) incorporate a subjective test, in that the local housing authority is required to reach a view on the matters in each provision. Our view is that it is implicit in article 3(1)(a) to (e) that a local housing authority is obliged to make reasonable enquiries in order to be able to form a view on whether any of the matters in article 3(1)(a) to (e) render a property unsuitable. We do not think that an objective test is required in these provisions. Not making such enquiries as would be sufficient to establish a view, or deciding not to reach a view at all, would carry a significant risk for the authority, in that it could be found not to have made a lawful decision as to the suitability of the accommodation for a person. We would therefore submit that it is not necessary to incorporate an obligation on the local housing authority view to reach a view on the matters referred to in article 3(1)(a) to (e).

4. This department has also published supplementary guidance[a] on the homelessness changes in the Localism Act 2011 and on the Homelessness (Suitability of Accommodation) (England) Order 2012 on 8th November. Under section 182 (1) of the 1996 Act, local housing authorities must have regard to this guidance. This guidance sets out in detail at paragraphs 59 – 71 the steps which local housing authorities are advised to take in order to form a view of the suitability of private rented sector accommodation secured under s193(7F).

Department for Communities and Local Government
12 November 2012

Appendix 2

TRANSPOSITION OF DIRECTIVE 2010/63/EU ON THE PROTECTION OF ANIMAL USED FOR SCIENTIFIC PURPOSES

Memorandum from the Home Office

The Home Office is providing the Joint Committee on Statutory Instruments with a Voluntary Memorandum in respect of the implementation of Directive 2010/63 ("the Directive"). We wish to clarify certain aspects of our transposition of the Directive.

Article 3.1 (GM Animals)

1. We have decided to clarify the position in case there is a view that article 3.1 should mean 'any' genetic modification of an animal must be counted a procedure to reflect that genetic modification in and of itself has the potential to cause pain, suffering, distress and lasting harm.

2. Under Article 3(1) 'procedure' means any use, invasive or non-invasive, of an animal for experimental or other scientific purposes, with known or unknown outcome, or educational purposes, which may cause the animal a level of 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. This includes any course of action intended, or liable, to result in the creation and maintenance of a genetically modified animal line in any such condition. In this context "any such condition" refers to being caused "a level of pain, suffering, distress or lasting harm". Genetic modification procedures that will *not* result in such a condition are, therefore, sub-threshold. It should not be assumed that genetic modification always results in adverse welfare effects. Often genetically altered animals exhibit no such effects.

[a] http://www.communities.gov.uk/publications/housing/homelessnessguidance

Articles 4 and 13 (Application of the 3Rs)

3. We do not accept that our implementation of articles 4 & 13 will result in a reduction of the requirement on the Secretary of State to ensure that, wherever possible, an alternative is used.

4. Articles 4 and 13 set out the way in which the Directive seeks to facilitate and promote the advancement of alternative approaches and to ensure a high level of protection for animals that need to be used in procedures Article 13 considers the choice of methods authorised to ensure the 3Rs are being effectively implemented. Article 4 addresses the principle of replacement, reduction and refinement.

5. The draft Regulations implement Article 4 by inserting sections 2A and 5B(3)(b) of the Animals (Scientific Procedures) Act 1986 (ASPA) and by inserting paragraphs 1 and 13 of Schedule 2C to that Act. These provisions require both the Secretary of State and all personal and establishment licence holders to uphold the principles of replacement, reduction and refinement.

6. There are many factors beyond the control of the Secretary of State who can never guarantee a particular outcome. All she can do is direct her resources most effectively to produce the desired outcome. Under section 2A that is what she is required to do. If she fails to do this she will be breaching this provision.

7. With regard to Article 13, we believe it is wrong to suggest that new section 5B(3)(b) fails to place on the Secretary of State an obligation to "consider alternatives at <u>a procedural level</u>". New section 5B(3)(b) places on the Secretary of State an obligation to assess compliance of the proposed programme of work with the "principle of replacement". The principle of replacement is defined in new section 2A(2)(a) as "the principal that, wherever possible, a scientifically satisfactory method or testing strategy not entailing the use of protected animals must be used instead of <u>a regulated procedure".</u> So, in order to decide if a proposed programme of work complies with the principle of replacement it will be necessary for the Secretary of State to look at <u>each type of regulated procedure</u> that would be applied as part of the programme and satisfy herself that there is no scientifically satisfactory method or testing strategy which does not entail the use of protected animals that could be used as an alternative <u>to that type of procedure</u>. In other words, the Secretary of State will have to "consider alternatives at a procedural level". In any event, the Home Office need not rely on new section 5B(3)(b) to show that Article 13 has been transposed. This is because Article 13 is, in any event, sufficiently transposed by paragraphs 14(e), 17, 18 and 22(a) of new Schedule 2C.

8. Likewise, it is wrong to say that it is inappropriate to transpose Article 13 with provisions which require conditions to be included in licences. There is nothing in Article 13 that indicates <u>*how*</u> Member States should ensure the outcomes referred to in the Article. It is reasonable for the Home Office to ensure the outcomes referred to by

requiring certain conditions to be included in project/personal licences. The Home Office takes the view that the provisions in the Act about inspections and about sanctions for failing to comply with conditions will be sufficient to ensure that the conditions included in licences by virtue of paragraphs 14(e), 17, 18 and 22(a) of new Schedule 2C will be complied with.

9. Our view is that it is appropriate for Article 4 to be transposed via an express requirement on the Secretary of State but for Article 13 to be transposed via a requirement placed on licence holders. The Directive allows Member States a discretion regarding implementation; it does not require implementation to be achieved in a particular way.

Article 8 (Non-human primates)

10. Article 8(1) stipulates that non-human primates are not to be used in procedures except where (a) the procedure has one of the purposes referred to in (i) points (b)(i) or (c) of Article 5 of the Directive and is undertaken with a view to the avoidance, prevention, diagnosis or treatment of debilitating or potentially life-threatening clinical conditions in human beings; or (ii) points (a) or (e) of Article 5.

11. In the Government response to the public consultation on the options for transposing the Directive 2010/63/EU, we explained that we believe that it would be unwise for the United Kingdom to further define '*debilitating or potentially life-threatening clinical condition*' unilaterally. The government response also recognised that a Europe-wide definition could provide useful clarity and we have subsequently asked the Commission to bring forward a draft definition for consideration by all Member States.

12. In paragraph 5 of Schedule 2B to the new ASPA, we have included a definition of 'debilitating clinical condition' using wording drawn from Article 8(1)(b) - '*a condition which causes a reduction in a person's normal physical or psychological ability to function*'. We do not think the Home Office can be criticised for using this definition, since it follows the wording used in Article 8. It is unfortunate the recital 17 uses different language to that used in Article 8 when referring to the (slightly different) term "debilitating conditions". But faced with the inconsistency between recital 17 and Article 8, it must be right for the Home Office to adopt the language used in the Article that is being transposed.

13. In addition it is clear, that when Article 8 comes to be applied in project authorisation it is not going to be applied in such a way that any reduction in person's ability to function, however trivial, would be acceptable justification for the use of non-human primates. The definition in the draft regulations will necessarily fall to be construed in accordance with the underlying principles of the Directive. This will ensure that it is not given a meaning that is wider than is justified under the Directive.

Article 14(3) (Neuromuscular Blocking Agents (NBA))

14. We do not accept that the draft Regulations have failed fully to transpose the requirements of Article 14.3 with respect to the application of anaesthesia or analgesia when NBAs are used. The requirement in Article 14.3 to provide details of the anaesthetic or analgesic regimen is implemented by section 5A(1)(c) when read together with Point 3 of Annex 6 to the Directive. The requirement to provide a scientific justification is dealt with by section 17(2). We take the view that, in the light of section 17(2), an applicant would be required to provide the Secretary of State with the necessary information. The clear implication of section 17(1)(b) is that the Secretary of State will include, in a project licence which authorises the use of NBAs, provisions for determining the level of anaesthesia or analgesia to be used. In the light of the requirement in Article 14.3, it must also be the case that the Secretary of State would be acting unlawfully if the provisions in the licence did not have the effect of ensuring that the level of anaesthesia or analgesia used is adequate.

Article 16 (Re-use)

15. The basic position under Article 16.1 is that procedures should not be applied to an animal if it has previously been subject to a severe procedure. This is subject to the "exceptional circumstances" derogation in Article 16.2 which is only capable of applying where an animal has been used no more than once in a procedure involving severe pain or suffering. We understand there may be a concern that section 14(2)(b) of ASPA (as inserted by the draft Regulations) is incompatible with Article 16 because it appears generally to allow the re-use of an animal which has previously been subject to a single severe procedure.

16. We consider that section 14(2)(b) is consistent with Article 16. Although section 14(2)(b) generally allows re-use of an animal to which no more than one severe procedure has been applied, this is subject to section 14(6) which ensures that this is only done in the exceptional circumstances allowed for by Article 16.2 of the Directive.

17. The Home Office would like to clarify subsections (2) and (6) of section 14 of ASPA which refer to retrospective classification of severity under paragraph 23 in Part 3 of Schedule 2C to ASPA. That requires the Secretary of State to impose a condition on project licence-holders to ensure that classification, in accordance with Annex VIII of the Directive, is carried out by a 'suitably qualified person'. Since re-use is only permissible where the previous procedure or procedures were less than 'severe' (save with the specific consent of the Secretary of State to be given only in exceptional circumstances), it is essential that the classification is done properly. We consider that this will be achieved by the condition imposed under paragraph 23 of Part 3 of Schedule 2C. Requiring the classification to be carried out "by a suitably qualified person" and "using the criteria in Annex 8 of the Animals Directive" in our view will ensure that the classification is done "properly". Failure to follow the requirement would be a breach of

the relevant licence condition with potential for licence variation, suspension or revocation.

18. We understand there may also be a concern that subsection (5) of section 14 is incompatible with Article 16 in allowing the necessary consent of the Secretary of State to relate to more than one animal (except in the case of an animal who has previously undergone a procedure classified as severe), whereas the requirements of Article 16 have to be complied with in relation to individual animals.

19. Subsection (5) is not implementing any of the provisions of the Directive; it has been included in the new section 14 as it follows the wording of existing subsection (4), with some minor cosmetic alterations. The consent of the competent authority is only required under Article 16 in the context of allowing the re-use of an animal which has previously undergone a severe procedure. In such a case, section 14(6) also requires the consent to relate to the individual animal.

(Articles 15.1, 36.1, 38.2(c), 38.2(d) and 40.1(b))Severity classifications, mitigating suffering and harm-benefit analysis

20. In relation to severity classification, we would like to clarify that we do not consider that the Directive requires that the classifications of severity of procedures are adhered to. In this context the Home Office does not consider this requirement can be said to be imposed by Article 40.1(b) of the Directive. In our view that provision does no more than limit a project authorisation to those procedures which have had a severity classification assigned to them. Nor do we consider that Article 36.1 is capable of imposing such a requirement. Article 36.1 requires Member States to ensure that projects are carried out in accordance with the relevant authorisation, but it says nothing about the scope of that authorisation.

21. Nevertheless, despite the position under the Directive, the Home Office will in practice ensure that the severity classifications *are* adhered to. We will do this via the authorisation process and the application and interpretation of the licence conditions, backed up by the inspection regime, to ensure that the severity classifications will apply as limits. In particular, we are retaining existing project licence condition 8 which requires that severity limits are adhered to, and personal licence condition 13 which in conjunction with project licence condition 8 sets a clear line of responsibility for notifying the Secretary of State if the severity limits appears to have been or is likely to be breached.

Section 2C (7) & 8: Requirements to mitigate animal suffering

22. We did not link these sections to the severity limits because this provision is not transposed from the Directive. It is the existing wording retained from sections 6(6) and 7(6) as a higher welfare measure in force in accordance with Article 2.

23. We have given considerable thought to whether the term 'long lasting' should be defined in the context of severity (see Article 15.2 of the Directive). We take the view that it is more sensible to retain flexibility as what may be long lasting for one species will not be for another. It is also worth pointing out that paragraphs 14(a) and 20 of Schedule 2C to ASPA, which are the places where this expression is used, do not operate themselves to impose the relevant requirement but place an obligation on the Secretary of State to impose a condition doing so. This means it is possible for the Secretary of State to make provision in a particular case which is more specific in defining what is meant by "long lasting". Given that what is long lasting may vary on a case by case basis, it seems reasonable to leave any further clarification to the specific conditions imposed under those provisions.

Section 5B: Harm-Benefit Analysis

24. Article 38 requires that, as part of the evaluation of a project, a harm/benefit assessment is made. This is transposed in section 5B(3)(d). We do not agree that putting the requirement to carry out a harm-benefit analysis (HBA) in 5B(3) instead of 5B(2) fails to appropriately transpose the requirements of the Directive (as it potentially obviates the requirement for the HBA to justify authorisation (Article 38.2(d))). We have transposed Article 38 as closely as possible in new section 5B for it to make sense as UK legislation. The Directive requires a harm benefit analysis to be carried out (Article 38.2(d)) and the Home Office has transposed this almost word for word in section 5B(3)(d). This provision is in Article 38(2) and not in Article 38(1). We consider that our transposition is faithful to the Directive and implements it correctly.

25. We do not think that our transposition provides different thresholds for harm and benefit. Section 5B3(d) requires the harm to be justified against the benefit. The expression "expected outcome" is a copy out of the wording in the Directive. We have transposed this provision as closely as possible in plain English and taken some time to ensure that it mirrors as closely as possible the words and intent of the Directive. We believe that it does so.

Articles 38.4 and 43 (Transparency of project evaluation/Non-technical project summaries)

26. We do not think that the retention of Section 24 – a 'Confidentiality Clause' - is likely to conflict with the requirements for transparent project evaluation processes (Article 38.4) and the publication of project summaries (Article 43).

27. The effect of ASPA s24 is to prohibit the disclosure of information provided in confidence that relates to the use of animals in scientific procedures by Home Office Ministers and officials, and members of the Animal Procedures Committee, other than in the discharge of their functions under ASPA. We do not accept that the retention of s24 conflicts with the requirements for a transparent project evaluation process. The transparency of the project evaluation process is facilitated by the exemption in section

24(1) which allows information to be disclosed for the purposes of discharging functions under ASPA. Thus, to the extent that the Secretary of State considers it necessary to share information with third parties for the purposes of carrying out her functions in relation to the evaluation process, there would be no contravention of section 24 because it would be done for the purposes of discharging a function under ASPA. In addition article 38.4 is not dealing with individual applications but with the whole evaluation process, in that sense section 24 is not relevant to Article 38.4.

Article 43 (Non-technical project summaries)

28. Article 43.3 requires Member States to publish the non-technical project summaries of authorised projects and updates to such summaries. We consider that this requirement is adequately transposed by sections 5D(6) and 5F(3) of ASPA (which provisions are inserted by the draft Regulations), since they specifically require the publication of project summaries and their updates. There is no basis in our view on which section 24 can be said to impact on these obligations.

29. We do not agree that our implementation of Article 43 goes further than the Directive and will result in the retention of information which should be disclosed. The Directive requires the non-technical summary to be anonymous. There is a fine balance to be made between transparency and protecting confidential information. If the summaries contained information from which individuals or individual establishments could be identified then they would not be truly anonymous. In the area of science which still requires the use of animals, commercial confidentiality and the safety of staff are of paramount importance. We do not believe that our transposition in any way goes beyond the requirements of the Directive.

Article 34(Inspections)

30. We do not think that the use of the word ‘may’ in section 18(2A) in any way reduces the requirement on the Secretary of State to put in place a rigorous inspection regime which meets the requirements of Article 34.

31. Article 34.4 requires that an appropriate proportion of inspections must be carried out without warning. This is transposed through regulation 19 which inserts new subsection (2B) into section 18. The precise nature of the requirement imposed by Article 34.4 is unclear because of the use of the word “appropriate”. Therefore it is reasonable for section 18(2B) to leave the issue to the discretion of the Secretary of State. The effect will be that the Secretary of State will be able to give a direction under subsection (2A) which requires a proportion of the visits carried out in pursuance of the direction to be carried out without notice to the breeder, supplier or user. The Secretary of State will thus be able to ensure that an “appropriate” proportion of the visits carried out by inspectors are carried out without warning. Furthermore, the requirement in section 18(2D) requires the Secretary of State to seek to ensure that the level of

inspections defined in Article 34.3 takes place through a direction given under subsection (2A).

32. It is accepted that the Secretary of State is under a duty to ensure that the required minimum number of inspections are carried out and that an appropriate number are carried out without warning. It is not uncommon for a statute to frame something as a discretion but, when the statute is viewed as a whole, it is clear that a duty applies.

33. We understand that doubt may also have been expressed as to whether section 18(2D)(a) of ASPA is effective in implementing the requirement in Article 34.3. We understand the concern derives from the fact that, unlike Article 34.3, section 18(2D)(a) does not require inspections of at least one third of users in any year but instead frames the duty in terms that the Secretary of State "must seek to ensure" directions are given for the relevant number of inspections to be carried out. Whilst the precise wording of the requirement is different we consider that section 18(2D)(a) must be construed as requiring the Secretary of State to ensure that the required level of inspections takes place. Since the giving of directions under section 18(2A) is entirely at the discretion of the Secretary of State, there is no reason why the duty under section 18(2D)(a) should not have effect as a duty to ensure that the appropriate number of directions is given.

Article 40(4) (Multiple generic projects)

34. Article 40(4) of the Directive says that MSs may allow the authorisation of 'multiple generic projects' carried out by the same user if the projects are to satisfy regulatory requirements or use animals for production or diagnostic purposes with established methods. Section 5(4) of the new ASPA provides: "In the circumstances set out in Article 40.4 of the Animals Directive, a project licence may specify a programme of work which consists of multiple generic projects."

35. As far as the definition is concerned, we have in fact gone further than the Directive by saying that "a programme of work which consists of multiple generic projects". This makes clear that "project" in this sense is a subset of "programme of work", i.e. a type of experiment, study or production process; "multiple" clearly means that the programme of work may include more than one study of the same type and "generic" is best exemplified by reference to the breeding of genetically altered mice, the production of antibodies or the conduct of a safety evaluation test within each of which the particular experiment, study or production process is the same irrespective of the actual genotype, specific antibody or substance concerned. All of this will be reiterated in the Guidance.

Home Office
27 November 2012