

Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC (Text with EEA relevance)

COUNCIL DIRECTIVE 2008/73/EC

of 15 July 2008

simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 37 thereof,

Having regard to the proposal from the Commission,

Having regard to the Opinion of the European Parliament,

Having regard to the Opinion of the European Economic and Social Committee,

Whereas:

- (1) Community legislation in the veterinary field provides that assembly centres for bovine, porcine, caprine and ovine animals, equine marshalling centres, dealers of those animals, poultry establishments, semen collection or storage centres and embryo collection or production teams and certain bodies, institutes and centres ('animal health establishments') are to comply with certain conditions and must be officially approved by Member States for intra-Community trade in certain live animals and their products, and in particular animal genetic materials, such as semen, ova and embryos.
- (2) Community legislation provides for different procedures with regard to the registration, listing, updating, transmission and publication of those animal health establishments. However, differences in the procedures make the listing and the updating complicated and the practical use of those lists for the competent control services and the concerned operators very difficult.

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- (3) Therefore those procedures should be harmonised and provide for more systematic, coherent and uniform rules with regard to the five key elements of such procedures, namely registration, listing, updating, transmission and publication of the lists.
- (4) In addition, since it is for the Member States to control the conditions that must be fulfilled by the different animal health establishments in order to be listed, the responsibility for the drawing up of the lists should lie with the Member States and not the Commission.
- (5) Member States should therefore draw up and keep up-to-date lists of the animal health establishments concerned and make them available to the other Member States and to the public. In order to harmonise the model forms of those lists and the way to achieve simple access to up-to-date lists for the Community, common criteria need to be established under a comitology procedure.
- (6) In the interests of clarity and consistency of Community rules, this new procedure should also apply in the zootechnical field, in particular to breeding associations approved for maintaining or establishing herd books in Member States and to information to be provided by Member States regarding equine competitions in accordance with Council Directive 90/428/EEC of 26 June 1990 on trade in equidae intended for competitions and laying down the conditions for participation therein<sup>(1)</sup>.
- (7) Similarly to the rules applied to intra-Community trade, imports of semen, ova and embryos are regulated in such a way that the animal health establishments of origin in third countries are to fulfil certain conditions in order to minimise animal health risks. Accordingly, imports into the Community of such genetic materials should only be authorised from semen collection or storage centres and embryo collection or production teams officially approved for export to the Community by the competent authorities of the third country concerned in accordance with Community requirements and following Community veterinary inspections, where appropriate.
- (8) Depending on the type of genetic materials and on the species concerned, the current procedures for listing animal health establishments and updating the relevant lists are different, ranging from decisions adopted under a comitology procedure in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(2)</sup> to a simple consultation with Member States.
- (9) The co-existence of different procedures can lead to confusion and uncertainty amongst administrative officials in third countries, the farming industry and trade operators. Since it is for the third countries to check on the conditions that must be fulfilled by the different animal health establishments in order to be listed as approved for export to the Community in accordance with Community requirements, the current legal framework for the authorisation of those establishments should be harmonised and simplified, so that the responsibility for drawing up and updating the lists lies with the third countries and not the Commission. It is important to ensure that the level of animal health guarantees given by the third country concerned is not affected. The

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simplification measures are without prejudice to the right of the Commission to take safeguard measures if necessary.

- (10) The different existing procedures should therefore be replaced by a procedure under which imports into the Community should only be permitted from third countries in which competent authorities draw up and keep up to date the lists and communicate them to the Commission. The Commission should inform the Member States about those lists and make them available to the public for information purposes. In the case of concerns with regard to the lists communicated by the third countries, safeguard measures are to be adopted in accordance with Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries<sup>(3)</sup>.
- (11) For reasons of clarity and consistency of Community legislation, that procedure should also apply to authorities in third countries approved for the purpose of keeping herd books, flock books or stud books in accordance with Community zootechnical legislation.
- (12) Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries<sup>(4)</sup> provides that in the case where animals imported from third countries are placed in a quarantine centre within Community territory, this quarantine centre must be approved and the list of quarantine centres published in the *Official Journal of the European Union*. In the interests of clarity and consistency of Community rules, a simplified procedure should also apply to the updating of the list of quarantine centres in the Member States.
- (13) In the veterinary field, the Commission is responsible for setting up and updating the lists of approved national reference laboratories and other approved laboratories on the basis of information provided by the Member States.
- (14) In accordance with Community legislation, amendments to those lists are made, following a request from a Member State and a decision adopted under a comitology procedure in accordance with Decision 1999/468/EC, or by the Council on a proposal from the Commission.
- (15) However, amendments to such lists are often of a purely formal nature, such as changes in the contact details of the national reference laboratories or the other approved laboratories in question.
- (16) The current practice has been to make only periodic updates of the lists of those laboratories to reduce the number of Commission decisions to be taken. However, that practice does not guarantee a rapid update of those lists. This could compromise the legal status of national reference laboratories and other approved laboratories.
- (17) Since the Member States designate the national reference laboratories and provide all the necessary details and updates, the responsibility for the drawing up of the lists of such laboratories should lie with the Member States and not the Commission. Similarly, the responsibility for drawing up lists of other approved laboratories should lie with the Member States.

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- (18) Member States should therefore draw up and keep up to date the lists of the national reference laboratories and other approved laboratories concerned and make them available to the other Member States and the public. In order to harmonise the model of those lists and the way to achieve simple access to up-to-date lists for the Community, common criteria should be established under the comitology procedure.
- (19) However, where the lists concern approved laboratories situated in third countries, the Commission should continue to be responsible for drawing up and publishing the lists of such laboratories.
- (20) In order to avoid any disruption concerning applications for approval of laboratories submitted by Member States pursuant to Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines<sup>(5)</sup>, transitional measures should be provided for in this Directive.
- (21) Article 6(2)(a) of Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine<sup>(6)</sup> provides that bovine animals for breeding and production intended for intra-Community trade must come from an officially tuberculosis-free herd and, if more than six weeks old, have reacted negatively to an intradermal tuberculin test carried out during the 30 days prior to leaving the herd of origin. Due to traditional farming and trade practices, some Member States have encountered difficulties to comply with this pre-movement testing. It is therefore necessary to provide for the possibility of carrying out the intradermal tuberculin test at a place other than the holding of origin to be established under the comitology procedure.
- (22) Moreover, certain Annexes to Directive 64/432/EEC, which are of purely technical nature such as those relating to animal health tests, the list of compulsory notifiable diseases or the animal health certificates, should be amended by means of the comitology procedure to be able to rapidly take account of new scientific developments. However, the amendment of Annexes laying down detailed conditions with regard to the disease-free status, which may have an impact on intra-Community trade, should be reserved for the Council.
- (23) Technological and scientific developments have taken place since the beginning of the 1990s in the collection and the production of genetic materials. Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A(I) to Directive 90/425/EEC<sup>(7)</sup> has not been updated to take account of this evolution and of the new OIE standards. It is therefore appropriate to amend the said Directive and to bring into its scope, provisions in respect of trade in and imports of genetic material derived from animals other than those of the ovine, caprine, equine and porcine species. Further, pending the establishment of detailed harmonised rules in this field, Member States should be allowed to apply national rules. Similarly, pending the establishment of detailed harmonised rules in respect of imports of animals covered by that Directive, Member States should be allowed to apply national rules.

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- (24) The Council, in accordance with point 34 of the Interinstitutional Agreement on better law-making<sup>(8)</sup>, should encourage the Member States to draw up, for themselves and in the interest of the Community their own tables, which will, as far as possible, illustrate the correlation between the Directive and the transposition measures and to make them public.
- (25) Council Directives 64/432/EEC, 77/504/EEC<sup>(9)</sup>, 88/407/EEC<sup>(10)</sup>, 88/661/EEC<sup>(11)</sup>, 89/361/EEC<sup>(12)</sup>, 89/556/EEC<sup>(13)</sup>, 90/426/EEC<sup>(14)</sup>, 90/427/EEC<sup>(15)</sup>, 90/428/EEC, 90/429/EEC<sup>(16)</sup>, 90/539/EEC<sup>(17)</sup>, 91/68/EEC<sup>(18)</sup>, 91/496/EEC, 92/35/EEC<sup>(19)</sup>, 92/65/EEC, 92/66/EEC<sup>(20)</sup>, 92/119/EEC<sup>(21)</sup>, 94/28/EC<sup>(22)</sup>, 2000/75/EC<sup>(23)</sup>, Decision 2000/258/EC, Council Directives 2001/89/EC<sup>(24)</sup>, 2002/60/EC<sup>(25)</sup>, and 2005/94/EC<sup>(26)</sup> should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

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- (1) OJ L 224, 18.8.1990, p. 60.
- (2) OJ L 184, 17.7.1999, p. 23. Decision as last amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).
- (3) OJ L 24, 30.1.1998, p. 9. Directive as last amended by Directive 2006/104/EC (OJ L 363, 20.12.2006, p. 352).
- (4) OJ L 268, 24.9.1991, p. 56. Directive as last amended by Directive 2006/104/EC.
- (5) OJ L 79, 30.3.2000, p. 40. Decision as last amended by Commission Decision 2003/60/EC (OJ L 23, 28.1.2003, p. 30).
- (6) OJ L 121, 29.7.1964, p. 1977/64. Directive as last amended by Commission Decision 2007/729/EC (OJ L 294, 13.11.2007, p. 26).
- (7) OJ L 268, 14.9.1992, p. 54. Directive as last amended by Commission Decision 2007/265/EC (OJ L 114, 1.5.2007, p. 17).
- (8) OJ C 321, 31.12.2003, p. 1. Corrected by OJ C 4, 8.1.2004, p. 7.
- (9) OJ L 206, 12.8.1977, p. 8. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).
- (10) OJ L 194, 22.7.1988, p. 10. Directive as last amended by Commission Decision 2008/120/EC (OJ L 42, 16.2.2008, p. 63).
- (11) OJ L 382, 31.12.1988, p. 36. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
- (12) OJ L 153, 6.6.1989, p. 30.
- (13) OJ L 302, 19.10.1989, p. 1. Directive as last amended by Commission Decision 2006/60/EC (OJ L 31, 3.2.2006, p. 24).
- (14) OJ L 224, 18.8.1990, p. 42. Directive as last amended by Directive 2006/104/EC.
- (15) OJ L 224, 18.8.1990, p. 55.
- (16) OJ L 224, 18.8.1990, p. 62. Directive as last amended by Regulation (EC) No 806/2003.
- (17) OJ L 303, 31.10.1990, p. 6. Directive as last amended by Commission Decision 2007/729/EC (OJ L 294, 13.11.2007, p. 26).
- (18) OJ L 46, 19.2.1991, p. 19. Directive as last amended by Directive 2006/104/EC.
- (19) OJ L 157, 10.6.1992, p. 19. Directive as last amended by Commission Decision 2007/729/EC.
- (20) OJ L 260, 5.9.1992, p. 1. Directive as last amended by Directive 2006/104/EC.
- (21) OJ L 62, 15.3.1993, p. 69. Directive as last amended by Commission Directive 2007/10/EC (OJ L 63, 1.3.2007, p. 24).
- (22) OJ L 178, 12.7.1994, p. 66.
- (23) OJ L 327, 22.12.2000, p. 74. Directive as last amended by Commission Decision 2007/729/EC.
- (24) OJ L 316, 1.12.2001, p. 5. Directive as last amended by Commission Decision 2007/729/EC.
- (25) OJ L 192, 20.7.2002, p. 27. Directive as last amended by Commission Decision 2007/729/EC.
- (26) OJ L 10, 14.1.2006, p. 16.