

Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC)

COMMISSION DECISION

of 15 July 2004

implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States

(notified under document number C(2004) 2104)

(Text with EEA relevance)

(2004/558/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine⁽¹⁾, and in particular Articles 9(2) and 10(2) thereof,

Whereas:

- (1) Infectious bovine rhinotracheitis is the description of the most prominent clinical signs of the infection with the bovine herpesvirus type 1 (BHV1). As many infections with that virus run a subclinical course, control measures should be directed to the eradication of the infection rather than to the suppression of symptoms.
- (2) Annex E (II) to Directive 64/432/EEC lists ‘infectious bovine rhinotracheitis’ among the diseases for which national control programmes may be approved and additional guarantees requested.
- (3) Germany had submitted a programme conducted with the aim of eradicating the BHV1 infection in all parts of its territory, which complies with the criteria set out in Article 9(1) of Directive 64/432/EEC and provides for rules for the national movement of bovine animals which are equivalent to those previously implemented in Austria, the Province of Bolzano in Italy and Sweden which were successful in eradicating the disease from those countries.
- (4) The programme presented by Germany and, as requested by that Member State, the additional guarantees in relation to trade in bovine animals in order to secure the success of that programme were approved by Decision 2004/215/EC of 1 March 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-

Status: Point in time view as at 21/03/2017.

Changes to legislation: *There are currently no known outstanding effects for the Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC). (See end of Document for details)*

Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States⁽²⁾.

- (5) Additional guarantees exist as regards Denmark, Austria, Finland and Sweden as well as Italy, concerning the province of Bolzano. Those Member States consider that their territory is free from infectious bovine rhinotracheitis and Italy takes the same view for the Province of Bolzano. In accordance with Article 10(1) of Directive 64/432/EEC, they submitted supporting documentation to the Commission, in particular substantiating that monitoring of the situation is continued.
- (6) To Member States or regions thereof that are recognised as being free of that disease and which are currently listed in the Annex to Commission Decision 93/42/EEC⁽³⁾ only minimum requirements for the dispatch of bovine animals for breeding and production to other Member States should apply.
- (7) For the standardisation of BHV1 tests in laboratories the World Organisation for Animal Health (OIE) has adopted a strong positive, a weak positive and negative serum as OIE international standards for BHV1 tests which are available at the OIE Reference Laboratories for infectious bovine rhinotracheitis mentioned in the Manual of Standards for Diagnostic Tests and Vaccines⁽⁴⁾.
- (8) Problems have been encountered in relation to intra-Community trade in bovine animals originating in Member States of different status with regard to infectious bovine rhinotracheitis.
- (9) For reasons of clarity and in order to ensure the linguistic consistency of the measures, it is appropriate to combine in a single Decision the approval of the German programme and the additional guarantees for infectious bovine rhinotracheitis and to repeal Decision 2004/215/EC.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

The programmes presented by the Member States listed in the first column of the table in Annex I for the control and eradication of the infection with the bovine herpesvirus type 1 (BHV1), hereinafter referred to as 'infectious bovine rhinotracheitis' or 'IBR', in regions of these Member States specified in the second column of the table in Annex I are approved.

Article 2

1 Bovine animals for breeding and production coming from Member States or regions thereof other than those listed in Annex II and destined for Member States or regions thereof listed in Annex I, shall meet at least the following additional guarantees:

- a they must come from a holding on which, according to official information, no clinical or pathological evidence of infectious bovine rhinotracheitis has been recorded for the past 12 months;
- b they must have been isolated in a facility approved by the competent authority for 30 days immediately prior to movement and all bovine animals in the same isolation

Changes to legislation: There are currently no known outstanding effects for the Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC). (See end of Document for details)

facility must have remained free of clinical signs of infectious bovine rhinotracheitis during that period;

- c they and all other bovine animals in the same isolation facility must have been subjected with negative results to a serological test carried out on blood samples, taken not earlier than 21 days after their arrival at the isolation facility, for the detection of the following antibodies:
 - (i) in the case of vaccinated bovine animals, antibodies against the gE-glycoprotein of the BHV1; or
 - (ii) in the case of unvaccinated bovine animals, antibodies against the entire BHV1.

2 By way of derogation to paragraph 1, the competent authorities of the Member State of origin may authorise the dispatch to holdings situated in regions listed in Annex I of bovine animals complying with at least one of the following alternative conditions:

- a the animals originate in a Member State listed in Annex I and come from BHV1-free holdings meeting at least the requirements set down in Annex III;
- b the animals are intended for meat production and comply with the following conditions:
 - (i) the animals either
 - originate in BHV1-free holdings as defined in Annex III, or
 - descend from vaccinated and regularly re-vaccinated dams, or
 - have been regularly vaccinated and re-vaccinated according to the instructions of the manufacturer with a gE-deleted vaccine, or
 - have been subjected in the Member State of origin with negative result to a serological test for antibodies as referred to in paragraph 1(c) carried out on a sample of blood taken within 14 days of dispatch, and
 - (ii) [F¹they are transported without coming into contact with animals of lesser health status to a holding of unknown BHV1 status in the Member State of destination listed in Annex I, where according to the approved national eradication programme all animals are fattened indoors, and from which they can only be transported to the slaughterhouse;]
- c the animals originate from holdings on which all bovine animals on the holding older than 15 months of age have been vaccinated and regularly revaccinated and all animals on the holding older than nine months have been subjected with negative result to a serological test for antibodies against the gE-glycoprotein of the BHV1 at intervals of not more than 12 months and the animals have been tested with negative results for antibodies as referred to in paragraph 1(c)(i) on blood samples taken during the past 14 days prior to dispatch;
- d the animals originate from BHV1-free holdings as defined in Annex III which are situated in a Member State in which infectious bovine rhinotracheitis is a compulsorily notifiable disease and in which within an area of 5 km radius around the holdings there was no clinical or pathological evidence of BHV1-infection during the past 30 days and the animals have been tested with negative results for antibodies as referred to in paragraph 1(c) on a sample of blood taken during the past 14 days prior to dispatch.

3 Bovine animals for slaughter coming from Member States or regions thereof other than those listed in Annex II and destined for Member States or regions thereof listed in Annex I shall be transported directly to the slaughterhouse of destination or to an approved assembly centre

Status: Point in time view as at 21/03/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC). (See end of Document for details)

from where they shall be removed in accordance with Article 7, second indent, of Directive 64/432/EEC to the slaughterhouse to be slaughtered.

[^{F24} In point II.3.3 of Section C of the health certificate set out in model 1 of Annex F to Directive 64/432/EEC accompanying bovine animals as referred to in paragraph 1 of this Article, the appropriate Article, paragraph and point numbers of this Decision shall be indicated in the corresponding spaces to be filled in in that point.]

Textual Amendments

- F1** Substituted by Commission Decision of 5 August 2010 amending Decision 2004/558/EC implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Union trade in bovine animals relating to infectious bovine rhinotracheitis (notified under document C(2010) 5352) (Text with EEA relevance) (2010/433/EU).
- F2** Substituted by Commission Implementing Decision (EU) 2015/2278 of 4 December 2015 amending Annexes I and II to Decision 2004/558/EC as regards the infectious bovine rhinotracheitis-free status of the Federal States of Bremen, Hesse and Lower Saxony of Germany (notified under document C(2015) 8462) (Text with EEA relevance).

Article 3

1 Bovine animals for breeding and production coming from Member States or regions thereof other than those listed in Annex II and destined for Member States or regions thereof free of infectious bovine rhinotracheitis and listed in Annex II, shall meet the following additional guarantees:

- a they shall comply with the additional guarantees provided for in Article 2(1)(a) and (b);
- b they and all other bovine animals in the same isolation facility referred to in Article 2(1)(b) must have been subjected with negative results to a serological test carried out on blood samples taken not earlier than 21 days after their arrival at the isolation facility, for the detection of antibodies against the entire BHV1;
- c they must not have been vaccinated against infectious bovine rhinotracheitis.

2 Bovine animals for slaughter coming from Member States or regions thereof other than those listed in Annex II and destined for Member States or regions thereof listed in Annex II shall be transported directly to the slaughterhouse of destination to be slaughtered in accordance with Article 7, first indent, of Directive 64/432/EEC.

[^{F23} In point II.3.3 of Section C of the health certificate set out in model 1 of Annex F to Directive 64/432/EEC accompanying bovine animals as referred to in paragraph 1 of this Article, the appropriate Article, paragraph and point numbers of this Decision shall be indicated in the corresponding spaces to be filled in in that point.]

[^{F34} By way of derogation to paragraph 1(a) and (b), the competent authority in the Member State of destination may authorise the introduction of bovine animals intended for meat production onto a BHV1-free holding as defined in Annex III (BHV1-free holding) situated in a region of that Member State listed in Annex II under the following conditions:

- a the animals must not have been vaccinated against BHV1 and must originate in and have remained since birth on BHV1-free holdings;
- b the animals are transported without coming into contact with animals of lesser health status;
- c for at least 30 days immediately prior to dispatch, or since birth where the animals are less than 30 days old, the animals have remained on the holding of origin, or in an isolation facility approved by the competent authority, which is situated in a Member

Status: Point in time view as at 21/03/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC). (See end of Document for details)

State in which infectious bovine rhinotracheitis is a compulsorily notifiable disease and in which within an area of 5 km radius around the holding or isolation facility there was no clinical or pathological evidence of BHV1 infection during the past 30 days;

- d the animals have been subjected with negative result either to a serological test for antibodies against the gE-glycoprotein of the BHV1 in the case the animals originate from a BHV1 vaccinated herd, or in all other cases to a serological test for antibodies against the entire BHV1 carried out on a sample of blood taken within 7 days prior to dispatch from the holding referred to in point (c);
- e on the BHV1-free holding of destination all animals are fattened indoors and are only removed to be transported to the slaughterhouse;
- f the animals referred to in point (d) are subjected to a serological test for antibodies against the gE-glycoprotein of the BHV1 or the entire BHV1 carried out on a sample of blood taken within 21 to 28 days after arrival in the holding referred to in point (e):
 - (i) either with negative result in each case; or
 - (ii) the BHV1-free status of the holding remains suspended until the infected animals have been slaughtered within less than 45 days after arrival on the holding, and
 - either the animals in direct contact with the infected animals have reacted with negative results to a test for antibodies against the gE-glycoprotein of the BHV1 or the entire BHV1 carried out on a sample of blood collected not earlier than 28 days following the removal of the infected animals, or
 - the animals which shared a common airspace with the infected animals have reacted with negative results to a test for antibodies against the entire BHV1 carried out on a sample of blood collected not earlier than 28 days following the removal of the infected animals, or
 - the remaining animals on the holding have reacted with negative results to a test for antibodies against the entire BHV1 carried out on a sample of blood collected not earlier than 28 days following the removal of the infected animals, or
 - the BHV1-free status is restored in accordance with point 4 of Annex III.

5 The Member State of destination referred to in paragraph 4 shall notify to the Commission and to the other Member States the regions listed in Annex II in which the provisions of paragraph 4 are going to be implemented and the date of intended application.]

Textual Amendments

- F2** Substituted by Commission Implementing Decision (EU) 2015/2278 of 4 December 2015 amending Annexes I and II to Decision 2004/558/EC as regards the infectious bovine rhinotracheitis-free status of the Federal States of Bremen, Hesse and Lower Saxony of Germany (notified under document C(2015) 8462) (Text with EEA relevance).
- F3** Inserted by Commission Decision of 5 August 2010 amending Decision 2004/558/EC implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Union trade in bovine animals relating to infectious bovine rhinotracheitis (notified under document C(2010) 5352) (Text with EEA relevance) (2010/433/EU).

Status: Point in time view as at 21/03/2017.

Changes to legislation: *There are currently no known outstanding effects for the Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC). (See end of Document for details)*

Article 4

Bovine animals for breeding and production originating in a Member State or region thereof listed in Annex II and destined for a Member State or region thereof listed in Annexes I or II shall comply with the conditions provided for in Article 2(1)(a).

Article 5

Member States shall ensure that the serological test referred to in Article 2(1)(c) (ii) and in Article 3(1)(b) for the detection of antibodies against the entire BHV1 is standardised against the strong positive, weak positive and negative serum adopted as OIE international standards for BHV1 tests.

Article 6

Decision 2004/215/EC is repealed.

Article 7

This Decision shall apply from 26 July 2004.

Article 8

This Decision is addressed to the Member States.

Status: Point in time view as at 21/03/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC). (See end of Document for details)

[^{F4}]^{F5} ANNEX I

Textual Amendments

- F4** Substituted by Commission Decision of 21 August 2007 amending Decision 2004/558/EC implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2007) 3905) (Text with EEA relevance) (2007/584/EC).
- F5** Substituted by Commission Implementing Decision (EU) 2017/486 of 17 March 2017 amending Annexes I and II to Decision 2004/558/EC as regards the infectious bovine rhinotracheitis-free status of Luxembourg, of the Federal States Hamburg and Schleswig-Holstein of Germany and of Jersey, and amending Annex II to Decision 2008/185/EC as regards the Aujeszky's disease-free status of the Friuli Venezia Giulia region of Italy (notified under document C(2017) 1689) (Text with EEA relevance).

Member States	Regions of Member States to which the additional guarantees for infectious bovine rhinotracheitis apply in accordance with Article 9 of Directive 64/432/EEC
Belgium	All regions
Czech Republic	All regions
Germany	The following Regierungsbezirke in North Rhine-Westphalia: Düsseldorf Köln
Italy	Region Friuli-Venezia Giulia Autonomous Province of Trento
Luxembourg	All regions

ANNEX II

Member States	Regions of Member States to which the additional guarantees for infectious bovine rhinotracheitis apply in accordance with Article 10 of Directive 64/432/EEC
Denmark	All regions
Germany	The Federal States of: Baden-Württemberg Bavaria Berlin Brandenburg Bremen Hamburg Hesse

Status: Point in time view as at 21/03/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC). (See end of Document for details)

	Lower Saxony Mecklenburg-Western Pomerania Rhineland-Palatinate Saarland Saxony Saxony-Anhalt Schleswig-Holstein Thuringia The following Regierungsbezirke in North Rhine-Westphalia: Arnsberg Detmold Münster
Italy	Region Valle d'Aosta Autonomous Province of Bolzano
Austria	All regions
Finland	All regions
Sweden	All regions
United Kingdom	Jersey]

ANNEX III

BHV1-free holding

1. A holding keeping bovine animals shall be considered free of BHV1 infection if it complies with the conditions set out in this Annex.
 - 1.1. No suspicion of BHV1 infection has been recorded for the holding during the previous six months and all bovine animals on the holding are free from clinical symptoms indicative of BHV1 infection.

The holding and any non-adjacent pastures or premises, independently of ownership, that form part of the holding as an epidemiological entity, must be effectively separated from any pasture or premises of lesser BHV1-status, either by natural or physical barriers that effectively prevent direct contact between animals of different health status.

- 1.2. Only bovine animals from holdings situated in Member States or regions thereof listed in Annex II or from BHV1-free holdings have been introduced and none of the bovine animals on the holding have been in contact with bovine animals other than those coming from holdings situated in Member States or regions thereof listed in Annex II or from BHV1-free holdings.
- 1.3. Female bovine animals are only inseminated with bovine semen produced in accordance with Directive 88/407/EEC, or have been serviced by bulls from holdings situated in Member States or regions thereof listed in Annex II to this Decision or from BHV1-free holdings.
- 1.4. At least one of the following control regimes is applied on the holding:

Status: Point in time view as at 21/03/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC). (See end of Document for details)

- 1.4.1. a serological investigation for antibodies against BHV1 has been carried out with negative results in each case on at least two samples of blood, taken with an interval of five to seven months from all female bovine animals older than nine months of age, and from all male bovine animals older than nine months of age which are used or intended for breeding purposes;
 - 1.4.2. a serological investigation for antibodies against BHV1 has been carried out with negative results in each case on at least:
 - two samples of milk taken with an interval of five to seven months from all lactating female bovine animals, either individually or in a pool of milk samples taken from not more than five animals; and
 - two samples of blood, taken with an interval of five to seven months from all non-lactating female bovine animals older than nine months of age, and from all male bovine animals older than nine months of age which are used or intended for breeding purposes;
 - 1.4.3. in the case of dairy farms on which at least 30 % of the bovine animals are lactating female bovine animals, a serological investigation for antibodies against BHV1 has been carried out with negative results in each case on at least:
 - three milk samples collected with an interval of at least three months from a bulk of milk of not more than 50 lactating female bovine animals, depending on the specification of the test employed; and
 - one individual sample of blood, taken from all non-lactating female bovine animals older than nine months of age, and from all male bovine animals older than nine months of age which are used or intended for breeding purposes;
 - 1.4.4. all bovine animals on the holding originate either from holdings situated in Member States or regions thereof listed in Annex II or from BHV1- free holdings.
2. The BHV1-free status of a holding keeping bovine animals shall be retained if:
 - 2.1. the conditions in points 1.1 to 1.4 continue to apply, and
 - 2.2. at least one of the following control regimes is applied on the holding within a 12-month period:
 - 2.2.1. a serological investigation for antibodies against BHV1 has been carried out with negative results in each case on at least one individual sample of blood taken from all bovine animals older than 24 months of age;
 - 2.2.2. a serological investigation for antibodies against BHV1 has been carried out with negative results in each case on at least:
 - one individual sample of milk taken from all lactating female bovine animals, either individually or in a pool of milk samples taken from not more than five animals; and
 - one individual sample of blood taken from all non-lactating female bovine animals older than 24 months of age, and from all male bovine animals older than 24 months of age;
 - 2.2.3. in the case of dairy farms on which at least 30 % of the bovine animals are lactating female bovine animals, a serological investigation for antibodies against BHV1 has been carried out with negative results in each case on at least:

Status: Point in time view as at 21/03/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC). (See end of Document for details)

- two milk samples collected with an interval of three to 12 months from a bulk of milk of not more than 50 lactating female bovine animals, depending on the specification of the test employed; and
 - one individual sample of blood, taken from all non-lactating female bovine animals older than 24 months of age, and from all male bovine animals older than 24 months of age.
3. The BHV1-free status of a holding keeping bovine animals shall be suspended where during the investigations referred to in points 2.2.1 to 2.2.3. an animal has reacted with positive results in a test for antibodies against BHV1.
4. The BHV1-free status of a holding which was suspended in accordance with point 3, shall only be restored after a serological investigation for antibodies against BHV1, commencing not earlier than 30 days after the removal of the seropositive animals, has been carried out with negative result in each case on at least:
- two samples of milk taken with an interval of at least two months from all lactating female bovine animals, either individually or in a pool of milk samples taken from not more than five animals; and
 - two samples of blood, taken with an interval of at least three months from all non-lactating female bovine animals, and from all male bovine animals.
- Note:
- (a) Where reference is made in this Annex to a serological test for the detection of antibodies against BHV1, the principles laid down in Article 2(1)(c) relating to the vaccination status of the tested animals shall apply.
- (b) The size of the pool of milk samples referred to in this Annex, may be modulated based on documented evidence that the test is under all circumstances of day to day laboratory work sensitive enough to detect a single weak positive reaction in the pool of the modulated size.]

Status: Point in time view as at 21/03/2017.

Changes to legislation: There are currently no known outstanding effects for the Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC). (See end of Document for details)

- (1) [OJ 121, 29.7.1964, p. 1977/64](#). Directive as last amended by Commission Regulation (EC) No 21/2004 ([OJ L 5, 9.1.2004, p. 8](#)).
- (2) [OJ L 67, 5.3.2004, p. 24](#).
- (3) [OJ L 16, 25.1.1993, p. 50](#). Decision as last amended by Decision 2000/502/EC ([OJ L 200, 8.8.2000, p. 62](#)).
- (4) *Manual of Standards for Diagnostic Tests and Vaccines*, Fourth Edition, August 2000.

Status:

Point in time view as at 21/03/2017.

Changes to legislation:

There are currently no known outstanding effects for the Commission Decision of 15 July 2004 implementing Council Directive 64/432/EEC as regards additional guarantees for intra-Community trade in bovine animals relating to infectious bovine rhinotracheitis and the approval of the eradication programmes presented by certain Member States (notified under document number C(2004) 2104) (Text with EEA relevance) (2004/558/EC).