Official Journal of the European Union

English edition

Legislation

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(1) Text with EEA relevance.

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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L18



ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

 II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Information concerning the entry into force of the Agreement on Air Transport between Canada and the European Community and its Member States

The Agreement on Air Transport between Canada and the European Community and its Member States, signed in Brussels on 17 December 2009, entered into force on 16 May 2019, in accordance with Article 23(1) of the Agreement, as the last notification was deposited on 16 April 2019.

Information concerning the entry into force of the Protocol amending the Agreement on Air Transport between Canada and the European Community and its Member States, to take account of the accession to the European Union of the Republic of Croatia

The Protocol amending the Agreement on Air Transport between Canada and the European Community and its Member States, to take account of the accession to the European Union of the Republic of Croatia, signed in Brussels on 27 January 2017 entered into force on 16 May 2019, in accordance with Article 3 of the Protocol, as the last notification was deposited on 16 April 2019.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1137

of 3 July 2019

renewing the approval of the active substance dimethenamid-P in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (¹), and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2003/84/EC (²) included dimethenamid-P as an active substance in Annex I to Council Directive 91/414/EEC (³).
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 (⁴).
- (3) The approval of the active substance dimethenamid-P, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 October 2019.
- (4) An application for the renewal of the approval of the active substance dimethenamid-P was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 (⁵) within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 11 August 2016.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

 ^{(&}lt;sup>2</sup>) Commission Directive 2003/84/EC of 25 September 2003 amending Council Directive 91/414/EEC to include flurtamone, flufenacet, iodosulfuron, dimethenamid-p, picoxystrobin, fosthiazate and silthiofam as active substances (OJ L 247, 30.9.2003, p. 20).
 (³) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991,

 ⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

^(*) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

^{(&}lt;sup>5</sup>) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (7) The Authority communicated the renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.
- (8) On 12 April 2018, the Authority communicated to the Commission its conclusion (⁶) on whether dimethenamid-P can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented the draft renewal report and the Regulation proposal regarding dimethenamid-P to the Standing Committee on Plants, Animals, Food and Feed on 24 January 2019.
- (9) As regards the criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 (7), the conclusion of the Authority indicates that, based on the scientific evidence, it is highly unlikely that dimethenamid-P is an endocrine disrupter and that no additional studies are considered necessary to be carried out. Thus, the Commission concludes that dimethenamid-P is not to be considered as having endocrine disrupting properties.
- (10) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the draft renewal report. The applicant submitted its comments, and the Commission has carefully examined them.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance dimethenamid-P that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of dimethenamid-P.
- (12) The risk assessment for the renewal of the approval of the active substance dimethenamid-P is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing dimethenamid-P may be authorised.
- (13) In accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 of that Regulation and in the light of current scientific and technical knowledge, it is, however, necessary to provide for certain conditions. It is, in particular, appropriate to require further confirmatory information as regards the effects of water treatment processes on the nature of residues present in drinking water and to recommend Member States to pay attention to the protection of operators and workers, of groundwater, of aquatic organisms and small herbivorous mammals in the framework of any authorisations to be granted, as appropriate.
- (14) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, the Annex to Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (15) Commission Implementing Regulation (EU) 2018/1262 (⁸) extended the approval period of dimethenamid-P to 31 October 2019 in order to allow the renewal process to be completed before the expiry of the approval of that active substance. Given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should apply from 1 September 2019.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

^(*) EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance dimethenamid-P, EFSA Journal 2018;16(4):5211.

 ⁽⁷⁾ Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).
 (8) Commission Implementing Regulation (EU) 2018/1262 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011

^(%) Commission Implementing Regulation (EU) 2018/1262 of 20 September 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 1-methylcyclopropene, beta-cyfluthrin, chlorothalonil, chlorotoluron, clomazone, cypermethrin, daminozide, deltamethrin, dimethenamid-p, diuron, fludioxonil, flufenacet, flurtamone, fosthiazate, indoxacarb, MCPA, MCPB, prosulfocarb, thiophanate-methyl and tribenuron (OJ L 238, 21.9.2018, p. 62).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of active substance

The approval of the active substance dimethenamid-P, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 1 September 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 July 2019.

For the Commission The President Jean-Claude JUNCKER

L 180/6

EN

Official Journal of the European Union

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Dimethenamid-P CAS No 163515-14-8 CIPAC No 638	(S)-2-chloro-N-(2,4- dimethyl-3-thienyl)-N- (2-methoxy1- methylethyl)acetamide	≥ 930 g/kg The following impurity is of toxicological concern and must not exceed the following level in the technical material: 1,1,1,2-Tetrachloroethane (TCE): 1,0 g/kg 	1 September 2019	31 August 2034	 For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on dimethenamid-P, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment; the protection of groundwater, in particular regarding the metabolites of dimethenamid-P; the protection of aquatic organisms and small herbivorous mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water.

 $(^1)$ Further details on identity and specification of active substance are provided in the renewal report.

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 67 on dimethenamid-P is deleted;

(2) in Part B, the following entry is added:

	Common Name, ntification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
CAS	ethenamid-P No 163515-14-8 C No 638	(S)-2-chloro-N-(2,4- dimethyl-3-thienyl)-N- (2-methoxy1- methylethyl)acetamide	≥ 930 g/kg The following impurity is of toxicological con- cern and must not ex- ceed the following level in the technical mate- rial: 1,1,1,2-Tetrachloroetha- ne (TCE): ≤ 1,0 g/kg	1 September 2019	31 August 2034	 For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on dimethenamid-P, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment; the protection of groundwater, in particular regarding the metabolites of dimethenamid-P; the protection of aquatic organisms and small herbivorous mammals. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water.

(1) Further details on identity and specification of active substance are provided in the renewal report.'

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1138

of 3 July 2019

approving the active substance florpyrauxifen-benzyl in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (1), and in particular Article 13(2) thereof,

Whereas:

- In accordance with Article 7(1) of Regulation (EC) No 1107/2009 Italy received on 24 March 2016 an (1)application from Dow AgroSciences for the approval of the active substance florpyrauxifen-benzyl.
- (2)In accordance with Article 9(3) of that Regulation, Italy, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority ('the Authority') on 17 June 2016 of the admissibility of the application.
- (3) On 28 April 2017 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether the active substance florpyrauxifen-benzyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) (4) of Regulation (EC) No 1107/2009, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report in May 2018.
- (5) On 5 July 2018, the Authority communicated to the applicant, the Member States and the Commission its conclusion (2) on whether the active substance florpyrauxifen-benzyl can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.
- On 22 March 2019 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the (6) review report for florpyrauxifen-benzyl and the draft of this Regulation providing that florpyrauxifen-benzyl is approved.
- The applicant was given the possibility to submit comments on the review report. (7)
- (8) As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605 (3), the Commission considers that florpyrauxifen-benzyl does not have endocrine disrupting properties based on the available scientific information summarised in the conclusion of the Authority. However, in order to increase the confidence in this conclusion, the applicant should provide an updated assessment, in accordance with point 2(2)(b) of Annex II to Regulation (EC) No 1107/2009, of the criteria laid down in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Regulation (EU) 2018/605 and in accordance with the guidance for the identification of endocrine disruptors (4).

^{(&}lt;sup>1</sup>) OJ L 309, 24.11.2009, p. 1. (²) Conclusion of the EFSA (2018) on the peer review of the pesticide risk assessment of the active substance florpyrauxifen (variant assessed florpyrauxifen-benzyl). EFSA Journal 2018;16(8):5378. doi: 10.2903/j.efsa.2018.5378.

Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33). Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009.

https://efsa.onlinelibrarv.wilev.eom/doi/epdt710.2903/i.efsa.2018.5311

- (9) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (10) It is therefore appropriate to approve florpyrauxifen-benzyl.
- (11) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to include certain conditions. It is, in particular, appropriate to require further confirmatory information.
- (12) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁵⁾ should be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of active substance

The active substance florpyrauxifen-benzyl, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 July 2019.

For the Commission The President Jean-Claude JUNCKER

⁽⁵⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

L 180/10

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Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Florpyrauxifen-benzyl CAS No: 1390661-72-9 CIPAC No: 990.227	benzyl 4-amino-3- chloro-6-(4-chloro-2- fluoro-3- methoxyphenyl)-5- fluoropyridine-2- carboxylate	≥ 920 g/kg The impurity toluene shall not exceed 3 g/kg in the technical material.	24 July 2019	24 July 2029	 For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 22 March 2019, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: the protection of aquatic and terrestrial non-target plants. Conditions of use shall include risk mitigation measures such as buffer zones and/or drift reduction nozzles, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority an updated assessment of the information submitted and, where relevant, further information to confirm the absence of endocrine activity in accordance with points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 by 24 July 2021.

 $(^{1})$ Further details on identity and specification of active substance are provided in the review report.

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No	Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
'139	Florpyrauxifen-benzyl CAS No: 1390661-72-9 CIPAC No: 990.227	benzyl 4-amino-3- chloro-6-(4-chloro-2- fluoro-3- methoxyphenyl)-5- fluoropyridine-2- carboxylate	≥ 920 g/kg The impurity toluene shall not exceed 3 g/kg in the technical material.	24 July 2019	24 July 2029	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on 22 March 2019, and in particular Appendices I and II thereto, shall be taken into account.
						In this overall assessment Member States shall pay particular attention to:
						 the protection of aquatic and terrestrial non- target plants.
						Conditions of use shall include risk mitigation measures such as buffer zones and/or drift reduction nozzles, where appropriate.
						The applicant shall submit to the Commission, the Member States and the Authority an updated assessment of the information submitted and, where relevant, further information to confirm the absence of endocrine activity in accordance with points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 by 24 July 2021.

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

(1) Further details on identity and specification of active substance are provided in the review report.'

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1139

of 3 July 2019

amending Regulation (EC) No 2074/2005 as regards official controls on food of animal origin in relation to requirements concerning food chain information and fishery products and to the reference to recognised testing methods for marine biotoxins and to testing methods for raw milk and heat-treated cow's milk

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (¹), and in particular point (f) of the first subparagraph of Article 18(8) thereof,

After consulting the Committee on Plants, Animals, Food and Feed,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for the official controls and other official activities performed by the competent authorities of the Member States to verify compliance with Union legislation, inter alia, in the area of food safety at all stages of production, processing and distribution. In particular, it provides for official controls in relation to products of animal origin intended for human consumption.
- (2) Commission Regulation (EC) No 2074/2005 (²) lays down implementing measures for certain products under, inter alia, Regulation (EC) No 853/2004 of the European Parliament and of the Council (³). These include live bivalve molluscs, raw milk and heat-treated cow's milk.
- (3) Commission Implementing Regulation (EU) 2019/627 (⁴) amends Regulation (EC) No 2074/2005 as regards official controls. That Regulation sets out, that as regards requirements concerning food chain information, Section II and the Appendix in Annex I to Regulation (EC) No 2074/2005 are deleted and that as regards requirements concerning fishery products, Section II in Annex II to Regulation (EC) No 2074/2005 is deleted.
- (4) Regulation (EC) No 853/2004 requires the slaughterhouse operator to request, receive, check and act upon food chain information for all animals, other than wild game, sent or intended to be sent to the slaughterhouse. In addition, he should make sure the food chain information provides all the details required under Regulation (EC) No 853/2004.

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

 ⁽²⁾ Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council and Regulations (EC) No 853/2004 and (EC) No 854/2004 (OJ L 338, 22.12.2005, p. 27).
 (7) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for

 ^{(&}lt;sup>3</sup>) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55)
 (⁴) Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the

^(*) Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

- (5) Regulation (EC) No 853/2004 sets out the requirements governing parasite checks during handling of fishery products on shore and on board vessels. It is up to food business operators to carry out their own checks at all stages in the production of fishery products in accordance with the rules in Chapter V(D) of Section VIII of Annex III to Regulation (EC) No 853/2004 so that fish which are obviously infested with parasites are not released for human consumption. The adoption of detailed rules relating to visual inspections calls for the concepts of visible parasites and visual inspection to be defined and the type and frequency of the observations to be determined.
- (6) Implementing Regulation (EU) 2019/627 lays down rules on uniform practical arrangements for the performance of official controls on food of animal origin. That Regulation sets out, in its Annex V, the recognised testing methods for the detection of marine biotoxins in live bivalve molluscs to be used by the competent authorities for the purpose of official controls. Furthermore, it sets out, in its Annex III, the testing methods for raw milk and heat-treated cow's milk to be used by the competent authorities for the purpose of official controls. Furthermore, it sets out, in its Annex III, the testing methods for raw milk and heat-treated cow's milk to be used by the competent authorities for the purpose of official controls. Regulation (EC) No 853/2004 requires food business operators to carry out their own checks at all stages in the production to ensure that live bivalve molluscs, raw milk and heat-treated cow's milk comply with the hygiene rules for food of animal origin laid down in that Regulation. To ensure a high level of consumer protection with regard to food safety, Regulation (EC) No 2074/2005 should therefore include an obligation for food business operators to use the same recognised testing methods for marine biotoxins and testing methods for raw milk and heat-treated cow's milk as the competent authorities are to use in accordance with Implementing Regulation (EU) 2019/627.
- (7) Regulation (EC) No 2074/2005 should therefore be amended accordingly.
- (8) As Regulation (EU) 2017/625 applies with effect from 14 December 2019, this Regulation should apply from the same date.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 2074/2005 is amended as follows:

(1) Article 1 is replaced by the following:

'Article 1

Requirements concerning food chain information for the purpose of Regulation (EC) No 853/2004

Requirements concerning food chain information as referred to in Section III of Annex II to Regulation (EC) No 853/2004 are set out in Annex I to this Regulation.'

(2) Article 2 is replaced by the following:

'Article 2

Requirements concerning fishery products for the purpose of Regulation (EC) No 853/2004

Requirements concerning fishery products as referred to in Article 11(9) of Regulation (EC) No 853/2004 are set out in Annex II to this Regulation.'

(3) Article 3 is replaced by the following:

'Article 3

Recognised testing methods for marine biotoxins for the purpose of Regulation (EC) No 853/2004

The recognised testing methods for detecting marine biotoxins as referred to in Article 11(4) of Regulation (EC) No 853/2004 are as set out in Annex V to Implementing Regulation (EU) 2019/627.'

(4) Article 6a is replaced by the following:

'Article 6a

Testing methods for raw milk and heat-treated cow's milk

The analytical methods set out in Annex III to Implementing Regulation (EU) 2019/627 shall be used by food business operators to check compliance with the limits set out in Part III of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 and to ensure appropriate application of a pasteurisation process to dairy products as referred to in Part II of Chapter II of Section IX of Annex III to that Regulation.'

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 14 December 2019.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 July 2019.

For the Commission The President Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1140

of 3 July 2019

establishing models for the control reports and annual audit reports concerning financial instruments implemented by the EIB and other international financial institutions in which a Member State is a shareholder in accordance with Regulation (EU) No 1303/2013 of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006 (¹), as amended by Regulation (EU, Euratom) 2018/1046 (²), and in particular the fourth subparagraph of Article 40(1), thereof,

After consulting the Coordination Committee for the European Structural and Investment Funds,

Whereas:

- (1) The third subparagraph of Article 40(1) of Regulation (EU) No 1303/2013, as amended by Regulation (EU, Euratom) 2018/1046, sets out the requirement that the EIB and other international financial institutions in which a Member State is a shareholder are to provide to the authorities designated in accordance with Article 124 of that Regulation and with Article 65 of Regulation (EU) No 1305/2013 of the European Parliament and of the Council (³) a control report with each application for payment, on the one hand, and to the Commission and to the designated authorities an annual audit report drawn up by their external auditors, on the other hand.
- (2) In order to ensure consistency, quality and timely submission of the information to be provided by the EIB or other international financial institutions in which a Member State is a shareholder to the designated authorities and to the Commission, especially in view of the deadline for the submission of the report referred to in Article 127(5) of Regulation (EU) No 1303/2013 and in Article 9(2) of Regulation (EU) No 1306/2013 of the European Parliament and of the Council (⁴), a standard format laying down uniform requirements for the structure, the timing and the content of the information should be established for both the control report and the annual audit report.
- (3) In order to enable the designated authorities to carry out their obligations with regard to verifications, checks and audits, it is appropriate that the EIB or other international financial institutions in which a Member State is a shareholder provide necessary documents to the designated authorities.
- (4) In order to ensure that the designated authorities can effectively make use of the new provisions which apply from 2 August 2018 in accordance with Article 282 of Regulation (EU, Euratom) 2018/1046, this Regulation should enter into force on the day following that of its publication in the Official Journal of the European Union,

^{(&}lt;sup>1</sup>) OJ L 347, 20.12.2013, p. 320.

⁽²⁾ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

 ^{(&}lt;sup>3</sup>) Regulation (EU) No 1305/2013 of the European Parliament and of the Council of 17 December 2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005 (OJ L 347, 20.12.2013, p. 487).
 (⁴) Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management

^(*) Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (OJ L 347, 20.12.2013, p. 549).

HAS ADOPTED THIS REGULATION:

Article 1

Model for the control report

The control report referred to in the third subparagraph of Article 40(1) of Regulation (EU) No 1303/2013 shall be drawn up in accordance with the model set out in Annex I to this Regulation.

Article 2

Model for the annual audit report

The annual audit report referred to in the third subparagraph of Article 40(1) of Regulation (EU) No 1303/2013 shall be drawn up in accordance with the model set out in Annex II to this Regulation and submitted to the designated authorities and the Commission by 31 December following the end of the reference accounting year.

Article 3

Documents necessary for verifications and audits

The EIB or other international financial institutions in which a Member State is a shareholder shall provide all available documents to the designated authorities that are necessary for these authorities to carry out the obligations set out in Article 125(5) and Article 127 of Regulation (EU) No 1303/2013 and in Articles 9 and 59(1) of Regulation (EU) No 1306/2013.

Article 4

Entry in force

This Regulation shall enter into force on the day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 July 2019.

For the Commission The President Jean-Claude JUNCKER

ANNEX I

Model for the control report

- A. Control report related to application for payment to the Commission: [reference] [planned date]
- B. Date of the Member State's request for control report (at least two months before the planned date in point A. above): [date]
- C. Reference period:
 - 1. Total amount of payments to final recipients and, in the cases referred to in Article 37(7) of Regulation (EU) No 1303/2013, of payments to the benefit of final recipients, indicating separately ESI Funds, national public and private contributions.
 - 2. Total amount of resources committed for guarantee contracts, whether outstanding or already come to maturity, in order to honour possible guarantee calls for losses, calculated on the basis of a prudent *ex ante* risk assessment, covering a multiple amount of underlying new loans or other risk-bearing instruments for new investments in final recipients, indicating separately ESI Funds, national public and private contributions.
 - 3. Total amount of management costs incurred and/or management fees paid by the financial instrument, indicating separately ESI Funds, national public and private contributions.
 - 4. State of implementation of the investment strategy or equivalent documents as defined in the funding agreement.
 - 5. Progress analysis: volume of committed amounts from the operational programme and disbursements to financial intermediaries.
 - 6. Monitoring activities and resulting follow-up.
 - 7. Level of interest and other gains attributable to support from the ESI Funds paid to financial instruments as referred to in Article 43 of Regulation (EU) No 1303/2013.
 - 8. Level of resources paid back to financial instruments from investments or from the release of resources committed for guarantee contracts including capital repayments and gains and other earnings or yields, such as interest, guarantee fees, dividends, capital gains or any other income generated by investments, which are attributable to the support from the ESI Funds, as referred to in Article 44 of Regulation (EU) No 1303/2013.

Attachment: list of transactions to final recipients who received support by the financial instrument, the sum of which should correspond to the amounts referred to in points 1 and 2 above, and detailed breakdown by financial instrument of the amounts referred to in point 3 above.

ANNEX II

Model for the annual audit report

1. INTRODUCTION

- 1.1. Identification of the external audit firm that has been involved in preparing the report.
- 1.2. Reference period (e.g. 01 July N-1 to 30 June N).
- 1.3. Identification of the financial instrument(s)/mandate(s) and operational programme(s) or rural development programme(s) covered by the audit report. Identification of the funding agreement to which the report relates to (the 'Funding agreement').
- 2. AUDIT OF INTERNAL CONTROL SYSTEMS APPLIED BY THE EIB/EIF OR OTHER INTERNATIONAL FINANCIAL INSTITUTIONS

Results of the external audit of the internal control system of the EIB or other international financial institutions (IFIs), in which a Member State is a shareholder, assessing the set-up and effectiveness of this internal control system and covering the following elements:

- 2.1. Mandate acceptance process.
- 2.2. Process for the appraisal and selection of financial intermediaries: formal and quality assessment.
- 2.3. Process for the approval of transactions with financial intermediaries and signature of relevant funding agreements.
- 2.4. In case of financial contribution to financial instruments set up at Union level, including SME Initiative instruments and in case of ESI Funds/EFSI combination under Article 39a of Regulation (EU) No 1303/2013, process for the set-up of the instrument in line with the rules defined in the relevant Articles (e.g. Article 39, Article 39a of Regulation (EU) No 1303/2013).
- 2.5. Processes for the monitoring of financial intermediaries relating to:
- 2.5.1. reporting by financial intermediaries;
- 2.5.2. maintenance of records;
- 2.5.3. disbursements to final recipients;
- 2.5.4. eligibility of support to final recipients;
- 2.5.5. management fees and costs charged by the financial intermediaries;
- 2.5.6. visibility requirements;
- 2.5.7. implementation of State aid requirements by the financial intermediaries, and in the case of EAFRD (partly exempted from State aid rules) the implementation of Fund-specific requirements, including rules on cumulation of aid, when applicable;
- 2.5.8. differentiated treatment of investors, where relevant;
- 2.5.9. compliance with tax-related requirements of Article 38 of Regulation (EU) No 1303/2013 as updated in Regulation (EU, Euratom) 2018/1046.
- 2.6. Systems for the processing of payments received from the managing authority.
- 2.7. Systems for the calculation and payment of amounts related to management costs and fees.
- 2.8. Systems for the processing of payments to financial intermediaries.

2.9. Systems for the processing of interest and other gains generated by support from the ESI Funds to financial instruments.

In relation to points 2.1 to 2.4 above following the submission of the first annual audit report: information only on the updates or changes to the procedures or arrangements in place and their assessment for subsequent annual reports.

In relation to points 2.5 to 2.9 above: results of the audit testing covering the relevant internal applicable systems and processes.

- 2.10. At closure, the following elements shall be covered in the last annual audit report in addition to the elements mentioned in points 2.1 to 2.9 above:
- 2.10.1. Use of differentiated treatment of investors.
- 2.10.2. Achieved multiplier ratio compared to the agreed multiplier ratio in the guarantee agreements for financial instruments delivering guarantees.
- 2.10.3. Amount of capitalised interest rate subsidies or guarantee fee subsidies in line with Article 42(1)(c) of Regulation (EU) No 1303/2013.
- 2.10.4. Amount of capitalised management costs and fees in line with Article 42(2) of Regulation (EU) No 1303/2013.
- 2.10.5. Amount of programme contribution paid into an escrow account in line with Article 42(3) of Regulation (EU) No 1303/2013.
- 2.10.6. Use of interest and other gains attributable to the support from the ESI Funds paid to financial instruments in line with Article 43 of Regulation (EU) No 1303/2013.
- 2.10.7. Use of resources paid back to financial instruments, which are attributable to the support from the ESI Funds, until the end of the eligibility period and arrangements put in place for the use of those resources after the end of the eligibility period in line with Articles 44 and 45 of Regulation (EU) No 1303/2013.
- 3. AUDIT CONCLUSIONS
- 3.1. Conclusion as to whether the external audit firm can provide reasonable assurance on the set-up and effectiveness of the internal control system put in place by the EIB or other IFIs, in which a Member State is a shareholder, in accordance with the applicable rules, as per the elements referred to in section 2.
- 3.2. Findings and recommendations resulting from the audit work carried out

Points 3.1 and 3.2 shall be based on the results of the audit work referred to in section 2 and where relevant, take account of the results of other national or Union audit work carried out in relation to the same body implementing financial instruments and/or to the same mandate for financial instruments.

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1141

of 3 July 2019

amending Council Regulation (EC) No 1210/2003 concerning certain specific restrictions on economic and financial relations with Iraq

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 1210/2003 of 7 July 2003 concerning certain specific restrictions on economic and financial relations with Iraq and repealing Regulation (EC) No 2465/96 (¹), and in particular Article 11(b) thereof,

Whereas:

- (1) Annex III to Regulation (EC) No 1210/2003 lists public bodies, corporations and agencies and natural and legal persons, bodies and entities of the previous government of Iraq covered by the freezing of funds and economic resources that were located outside Iraq on 22 May 2003 under that Regulation.
- (2) On 28 June 2019, the Sanctions Committee of the United Nations Security Council decided to remove thirteen entries from the list of persons or entities to whom the freezing of funds and economic resources should apply.
- (3) Annex III to Regulation (EC) No 1210/2003 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 1210/2003 is amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 3 July 2019.

For the Commission, On behalf of the President, Head of the Service for Foreign Policy Instruments

^{(&}lt;sup>1</sup>) OJ L 169, 8.7.2003, p. 6.

ANNEX

In Annex III to Council Regulation (EC) No 1210/2003, the following entries are deleted:

- AGRICULTURAL NATIONAL ESTABLISHMENT IN ABU-GREIB. Address: Baghdad International Airport, General Street, Baghdad, Iraq.'
- '14. ANIMAL HEALTH DEPARTMENT. Address: P.O. Box 22055, Al-Shaikh Omar Street, Baghdad, Iraq.'
- '15. ARAB IRAQI COMPANY FOR LIVESTOCK DEVELOPMENT. Address: P.O. Box 29041, Baghdad, Iraq.'
- '38. GENERAL AGRICULTURAL ESTABLISHMENT IN DALMAG. Address: Ahrar, Kut, Iraq.'
- '39. GENERAL AGRICULTURAL ORGANISATION IN KHALIS. Address: P.O. Box 564, Al-Khalis, Diala Muhafadha, Al-Khalis, Iraq.'
- '40. GENERAL ESTABLISHMENT FOR AGRICULTURAL ORGANISATIONS. Address: P.O. Box 21015, Battawin, Baghdad, Iraq.'
- '47. GENERAL ESTABLISHMENT FOR STATE FARMS. Address: P.O. Box 21035, General Ramadi Street, entrance of Agaruf Street, Baghdad, Iraq.'
- '88. NAHRAWAN AGRICULTURAL ESTABLISHMENT. Address: P.O. Box 20195, New Baghdad, Nahrawan, Baghdad, Iraq.'
- '112. STATE AGRICULTURAL ESTABLISHMENT IN ISHAQI. Address: Dujail Salah Eldin, Iraq.'
- '113. STATE AGRICULTURAL ESTABLISHMENT IN MUSSAYIB. Address: Mussayib Establishment, Babylon, Iraq.'
- '155. STATE ESTABLISHMENT OF AGRICULTURE IN DUJAILA / DUJAILA AGROINDUSTRIAL COMPLEX. Address: P.O. Box Aioroba, K 29 Oroba, Kut, Iraq.'
- '174. STATE ORGANISATION FOR ANIMAL PRODUCTION. Address: Zafaraniya Area, near Post Office, Baghdad, Iraq; P.O. Box 3073, Karadde Charkieya/Erkhaita, Baghdad, Iraq.'
- '180. STATE ORGANISATION FOR FISHERIES (alias (a) STATE FISHERIES ORGANISATION, (b) STATE ENTERPRISE FOR SEA FISHERIES, (c) STATE ENTERPRISE FOR INLAND FISHERIES). Addresses: (a) P.O. Box 3296, near Aqaba Bin Nafa Square, Baghdad, Iraq; (b) P.O. Box 260, Basrah, Iraq.'

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2019 OF THE COMMUNITY/SWITZERLAND INLAND TRANSPORT COMMITTEE

of 7 June 2019

amending Annex 1 to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road [2019/1142]

THE COMMITTEE,

Having regard to the Agreement between the European Community and the Swiss Confederation on the carriage of goods and passengers by rail and road (hereinafter 'the Agreement'), and in particular Article 52(4) thereof,

Whereas:

- The first indent of Article 52(4) of the Agreement provides for the Joint Committee to adopt decisions revising Annex 1. This Annex was last amended by Decision 1/2018/EC of the Joint Committee of 12 June 2018 (¹).
- (2) New legal acts of the European Union have been adopted in areas covered by the Agreement since it was last amended. Consequently, Annex 1 should be amended to include these relevant new legislative acts. For the sake of legal clarity and simplification, it is preferable to replace Annex 1 to the Agreement by the Annex to this Decision,

HAS DECIDED AS FOLLOWS:

Article 1

Annex 1 to the Agreement is replaced by the text of the Annex to this Decision.

Article 2

This Decision shall enter into force on 15 June 2019.

Done at Brussels, 7 June 2019.

For the European Union The President Elisabeth WERNER For the Swiss Confederation The Head of the Swiss Delegation Peter FÜGLISTALER

⁽¹⁾ OJ L 166, 3.7.2018, p. 20.

ANNEX

'ANNEX 1

APPLICABLE PROVISIONS

In accordance with Article 52(6) of this Agreement, Switzerland shall apply legal provisions equivalent to the following:

RELEVANT PROVISIONS OF UNION LAW

SECTION 1 — ADMISSION TO THE OCCUPATION

- Directive 2006/1/EC of the European Parliament and of the Council of 18 January 2006 on the use of vehicles hired without drivers for the carriage of goods by road (OJ L 33, 4.2.2006, p. 82).
- Regulation (EC) No 1071/2009 of the European Parliament and of the Council of 21 October 2009 establishing common rules concerning the conditions to be complied with to pursue the occupation of road transport operator and repealing Council Directive 96/26/EC (OJ L 300, 14.11.2009, p. 51), as last amended by Council Regulation (EU) No 517/2013 of 13 May 2013 (OJ L 158, 10.6.2013, p. 1).
- Regulation (EC) No 1072/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international road haulage market (OJ L 300, 14.11.2009, p. 72), as last amended by Council Regulation (EU) No 517/2013 of 13 May 2013 (OJ L 158, 10.6.2013, p. 1).

For the purposes of this Agreement,

- (a) the European Union and the Swiss Confederation shall exempt from the obligation to hold a driver attestation all citizens of the Swiss Confederation, of an EU Member State and of a Member State of the European Economic Area;
- (b) the Swiss Confederation may not exempt citizens of States other than those mentioned in point (a) from the obligation to hold a driver attestation without prior consultation with and approval by the European Union;
- (c) the provisions of Chapter III of Regulation (EC) No 1072/2009 (on cabotage) shall not apply.
- Regulation (EC) No 1073/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international market for coach and bus services, and amending Regulation (EC) No 561/2006 (OJ L 300, 14.11.2009, p. 88), as last amended by Council Regulation (EU) No 517/2013 of 13 May 2013 (OJ L 158, 10.6.2013, p. 1).

For the purposes of this Agreement, the provisions of Chapter V of Regulation (EC) No 1073/2009 (on cabotage) shall not apply.

- Commission Decision 2009/992/EU of 17 December 2009 on minimum requirements for the data to be entered in the national electronic register of road transport undertakings (OJ L 339, 22.12.2009, p. 36).
- Commission Regulation (EU) No 1213/2010 of 16 December 2010 establishing common rules concerning the interconnection of national electronic registers on road transport undertakings (OJ L 335, 18.12.2010, p. 21).
- Commission Regulation (EU) No 361/2014 of 9 April 2014 laying down detailed rules for the application of Regulation (EC) No 1073/2009 as regards documents for the international carriage of passengers by coach and bus and repealing Commission Regulation (EC) No 2121/98 (OJ L 107, 10.4.2014, p. 39).
- Commission Regulation (EU) 2016/403 of 18 March 2016 supplementing Regulation (EC) No 1071/2009 of the European Parliament and of the Council with regard to the classification of serious infringements of the Union rules, which may lead to the loss of good repute by the road transport operator, and amending Annex III to Directive 2006/22/EC of the European Parliament and of the Council (OJ L 74, 19.3.2016, p. 8).

SECTION 2 — SOCIAL STANDARDS

 Directive 2002/15/EC of the European Parliament and of the Council of 11 March 2002 on the organisation of the working time of persons performing mobile road transport activities (OJ L 80, 23.3.2002, p. 35).

- Directive 2003/59/EC of the European Parliament and of the Council of 15 July 2003 on the initial qualification and periodic training of drivers of certain road vehicles for the carriage of goods or passengers, amending Council Regulation (EEC) No 3820/85 and Council Directive 91/439/EEC and repealing Council Directive 76/914/EEC (OJ L 226, 10.9.2003, p. 4).
- Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport and amending Council Regulations (EEC) No 3821/85 and (EC) No 2135/98 and repealing Council Regulation (EEC) No 3820/85 (OJ L 102, 11.4.2006, p. 1), as last amended by Regulation (EU) No 165/2014 of the European Parliament and of the Council of 4 February 2014 (OJ L 60, 28.2.2014, p. 1).
- Directive 2006/22/EC of the European Parliament and of the Council of 15 March 2006 on minimum conditions for the implementation of Council Regulations (EEC) No 3820/85 and (EEC) No 3821/85 concerning social legislation relating to road transport activities and repealing Council Directive 88/599/EEC (OJ L 102, 11.4.2006, p. 35), as last amended by Regulation (EU) 2016/403 of 18 March 2016 (OJ L 74, 19.3.2016, p. 8).
- Commission Regulation (EU) No 581/2010 of 1 July 2010 on the maximum periods for the downloading of relevant data from vehicle units and from driver cards (OJ L 168, 2.7.2010, p. 16).
- Regulation (EU) No 165/2014 of the European Parliament and of the Council of 4 February 2014 on tachographs in road transport, repealing Council Regulation (EEC) No 3821/85 on recording equipment in road transport and amending Regulation (EC) No 561/2006 of the European Parliament and of the Council on the harmonisation of certain social legislation relating to road transport (OJ L 60, 28.2.2014, p. 1).
- Commission Implementing Regulation (EU) 2016/68 of 21 January 2016 on common procedures and specifications necessary for the interconnection of electronic registers of driver cards (OJ L 15, 22.1.2016, p. 51), as amended by Commission Implementing Regulation (EU) 2017/1503 of 25 August 2017 (OJ L 221, 26.8.2017, p. 10).
- Commission Implementing Regulation (EU) 2016/799 of 18 March 2016 implementing Regulation (EU) No 165/2014 of the European Parliament and of the Council laying down the requirements for the construction, testing, installation, operation and repair of tachographs and their components (OJ L 139, 26.5.2016, p. 1), as amended by Commission Implementing Regulation (EU) 2018/502 of 28 February 2018 (OJ L 85, 28.3.2018, p. 1).
- Commission Implementing Regulation (EU) 2017/548 of 23 March 2017 laying down a standard form for the written statement on the removal or breakage of a tachograph seal (OJ L 79, 24.3.2017, p. 1).
- Commission Implementing Decision (EU) 2017/1013 of 30 March 2017 drawing up the standard reporting form referred to in Article 17 of Regulation (EC) No 561/2006 of the European Parliament and of the Council (OJ L 153, 16.6.2017, p. 28).

SECTION 3 — TECHNICAL STANDARDS

Motorised vehicles

- Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles (OJ L 42, 23.2.1970, p. 16), as last amended by Commission Directive 2007/34/EC of 14 June 2007 (OJ L 155, 15.6.2007, p. 49).
- Council Directive 88/77/EEC of 3 December 1987 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from compression ignition engines for use in vehicles, and the emission of gaseous pollutants from positive ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles (OJ L 36, 9.2.1988, p. 33), as last amended by Commission Directive 2001/27/EC of 10 April 2001 (OJ L 107, 18.4.2001, p. 10).
- Council Directive 91/671/EEC of 16 December 1991 on the approximation of the laws of the Member States relating to compulsory use of safety belts in vehicles of less than 3,5 tonnes (OJ L 373, 31.12.1991, p. 26), as last amended by Commission Implementing Directive 2014/37/EU of 27 February 2014 (OJ L 59, 28.2.2014, p. 32).
- Council Directive 92/6/EEC of 10 February 1992 on the installation and use of speed limitation devices for certain categories of motor vehicles in the Community (OJ L 57, 2.3.1992, p. 27), as amended by Directive 2002/85/EC of the European Parliament and of the Council of 5 November 2002 (OJ L 327, 4.12.2002, p. 8).

- Council Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic (OJ L 235, 17.9.1996, p. 59), as amended by Directive 2002/7/EC of the European Parliament and of the Council of 18 February 2002 (OJ L 67, 9.3.2002, p. 47).
- Council Regulation (EC) No 2411/98 of 3 November 1998 on the recognition in intra-Community traffic of the distinguishing sign of the Member State in which motor vehicles and their trailers are registered (OJ L 299, 10.11.1998, p. 1).
- Directive 2000/30/EC of the European Parliament and of the Council of 6 June 2000 on the technical roadside inspection of the roadworthiness of commercial vehicles circulating in the Community (OJ L 203, 10.8.2000, p. 1), as last amended by Commission Directive 2010/47/EU of 5 July 2010 (OJ L 173, 8.7.2010, p. 33).
- Directive 2005/55/EC of the European Parliament and of the Council of 28 September 2005 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from compression-ignition engines for use in vehicles, and the emission of gaseous pollutants from positive-ignition engines fuelled with natural gas or liquefied petroleum gas for use in vehicles (OJ L 275, 20.10.2005, p. 1), as last amended by Commission Directive 2008/74/EC of 18 July 2008 (OJ L 192, 19.7.2008, p. 51).
- Regulation (EC) No 595/2009 of the European Parliament and of the Council of 18 June 2009 on type-approval of motor vehicles and engines with respect to emissions from heavy duty vehicles (Euro VI) and on access to vehicle repair and maintenance information and amending Regulation (EC) No 715/2007 and Directive 2007/46/EC and repealing Directives 80/1269/EEC, 2005/55/EC and 2005/78/EC (OJ L 188, 18.7.2009, p. 1), as last amended by Commission Regulation (EU) No 133/2014 of 31 January 2014 (OJ L 47, 18.2.2014, p. 1).
- Regulation (EC) No 661/2009 of the European Parliament and of the Council of 13 July 2009 concerning typeapproval requirements for the general safety of motor vehicles, their trailers and systems, components and separate technical units intended therefor (OJ L 200, 31.7.2009, p. 1), as last amended by Commission Regulation (EU) 2016/1004 of 22 June 2016 (OJ L 165, 23.6.2016, p. 1).
- Commission Regulation (EU) No 582/2011 of 25 May 2011 implementing and amending Regulation (EC) No 595/2009 of the European Parliament and of the Council with respect to emissions from heavy duty vehicles (Euro VI) and amending Annexes I and III to Directive 2007/46/EC of the European Parliament and of the Council (OJ L 167, 25.6.2011, p. 1), as last amended by Commission Regulation (EU) No 627/2014 of 12 June 2014 (OJ L 174, 13.6.2014, p. 28).
- Directive 2014/45/EU of the European Parliament and of the Council of 3 April 2014 on periodic roadworthiness tests for motor vehicles and their trailers and repealing Directive 2009/40/EC (OJ L 127, 29.4.2014, p. 51).
- Regulation (EU) No 540/2014 of the European Parliament and of the Council of 16 April 2014 on the sound level of motor vehicles and of replacement silencing systems, and amending Directive 2007/46/EC and repealing Directive 70/157/EEC (OJ L 158, 27.5.2014, p. 131), as amended by Commission Delegated Regulation (EU) 2017/1576 of 26 June 2017 (OJ L 239, 19.9.2017, p. 3).

Transportation of dangerous goods

- Council Directive 95/50/EC of 6 October 1995 on uniform procedures for checks on the transport of dangerous goods by road (OJ L 249, 17.10.1995, p. 35), as last amended by Council Directive 2008/54/EC of the European Parliament and of the Council of 17 June 2008 (OJ L 162, 21.6.2008, p. 11).
- Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13), as last amended by Commission Directive (EU) 2018/1846 of 23 November 2018 (OJ L 299, 26.11.2018, p. 58).

For the purposes of this Agreement the following derogations to Directive 2008/68/EC shall apply in Switzerland:

1. Road transport

Derogations for Switzerland under Article 6(2)(a) of Directive 2008/68/EC of 24 September 2008 on the inland transport of dangerous goods

RO - a - CH - 1

Subject: Transport of diesel fuel and heating oil with UN number 1202 in tank containers.

Reference to Annex I, Section I.1, to this Directive: points 1.1.3.6 and 6.8.

Content of the Annex to the Directive: Exemptions related to the quantities transported per transport unit; regulations concerning the construction of tanks.

Content of the national legislation: Tank containers which are not constructed according to point 6.8 but according to national legislation, which have a capacity of less than or equal to 1 210 l and which are used to transport heating oil or diesel fuel with UN number 1202 may benefit from the exemptions in point 1.1.3.6 ADR.

Initial reference to the national legislation: Appendix 1, points 1.1.3.6.3(b) and 6.14 of the Ordinance on the carriage of dangerous goods by road (SDR; RS 741.621).

Date of expiry: 1 January 2023.

RO — a — CH — 2

Subject: Exemption from the requirement to carry a transport document for certain quantities of dangerous goods as defined in point 1.1.3.6.

Reference to Annex I, Section I.1, to this Directive: points 1.1.3.6 and 5.4.1.

Content of the Annex to the Directive: Requirements for transport documentation.

Content of the national legislation: The transport of uncleaned empty containers belonging to Transport Category 4 and filled or empty gas cylinders for breathing apparatuses for use by emergency services or as diving equipment, in quantities not exceeding the limits set in point 1.1.3.6, is not subject to the obligation to carry the transport document provided for in point 5.4.1.

Initial reference to the national legislation: Appendix 1, point 1.1.3.6.3(c) of the Ordinance on the carriage of dangerous goods by road (SDR; RS 741.621).

Date of expiry: 1 January 2023.

RO — a — CH — 3

Subject: Transport of uncleaned empty tanks by companies servicing storage facilities for liquids hazardous to water.

Reference to Annex I, Section I.1, to this Directive: points 6.5, 6.8, 8.2 and 9.

Content of the Annex to the Directive: Construction, equipping and inspection of tanks and vehicles; driver training.

Content of the national legislation: Vehicles and uncleaned empty tanks/containers used by companies servicing storage facilities for liquids hazardous to water to contain liquids while stationary tanks are being serviced are not subject to the construction, equipping and inspection regulations or to the labelling and orange-plate identification regulations stipulated by the ADR. They are subject to specific labelling and identification regulations, and the driver of the vehicle is not required to have undergone the training described in point 8.2.

Initial reference to the national legislation: Appendix 1, point 1.1.3.6.3.10 of the Ordinance on the carriage of dangerous goods by road (SDR; RS 741.621).

Date of expiry: 1 January 2023.

Derogations for Switzerland under Article 6(2)(b)(i) of Directive 2008/68/EC of 24 September 2008 on the inland transport of dangerous goods

RO - bi - CH - 1

Subject: Transport of domestic waste containing dangerous goods to waste disposal installations.

Reference to Annex I, Section I.1, to this Directive: points 2, 4.1.10, 5.2 and 5.4.

Content of the Annex to the Directive: Classification, combined packaging, marking and labelling, documentation.

Content of the national legislation: The rules include provisions relating to the simplified classification of domestic waste containing (domestic) dangerous goods by an expert recognised by the competent authority, to the use of appropriate receptacles and to driver training. Domestic waste which cannot be classified by the expert may be transported to a treatment centre in small quantities identified by package and by transport unit.

Initial reference to the national legislation: Appendix 1, point 1.1.3.7 of the Ordinance on the carriage of dangerous goods by road (SDR; RS 741.621).

Comments: These rules may only be applied to the transport of domestic waste containing dangerous goods between public treatment sites and waste disposal installations.

Date of expiry: 1 January 2023.

RO - bi - CH - 2

Subject: Return transport of fireworks.

Reference to Annex I, Section I.1, to this Directive: points 2.1.2 and 5.4.

Content of the Annex to the Directive: Classification and documentation.

Content of the national legislation: With the aim of facilitating the return transport of fireworks with UN numbers 0335, 0336 and 0337 from retailers to suppliers, exemptions regarding the indication of the net mass and product classification in the transport document are provided for.

Initial reference to the national legislation: Appendix 1, point 1.1.3.8 of the Ordinance on the carriage of dangerous goods by road (SDR; RS 741.621).

Comments: Detailed checking of the exact contents of each item of unsold product in each package is impossible in practice for products intended for retail trade.

Date of expiry: 1 January 2023.

RO - bi - CH - 3

Subject: ADR training certificate for journeys undertaken with the purpose of transporting vehicles which have broken down, journeys related to repairs, journeys made to the examination of tank vehicles/tanks, and journeys with tank vehicles made by experts responsible for the examination of the vehicle in question.

Reference to Annex I, Section I.1, to this Directive: point 8.2.1.

Content of the Annex to the Directive: Drivers of vehicles must attend training courses.

Content of the national legislation: ADR training and certificates are not required for journeys undertaken with the purpose of transporting vehicles that have broken down or test drives related to repairs, journeys with tank vehicles made to the examination of the tank vehicle or its tank, and journeys made by experts responsible for the examination of tank vehicles.

Initial reference to the national legislation: Instructions of 30 September 2008 of the Federal Department of Environment, Transport, Energy and Communication (DETEC) on the carriage of dangerous goods by road.

Comments: In some cases, vehicles which have broken down or are undergoing repairs and tank vehicles being prepared for technical inspection or being checked at the time of the inspection still contain dangerous goods.

The requirements in points 1.3 and 8.2.3 are still applicable.

Date of expiry: 1 January 2023.

2. Railway transport

Derogations for Switzerland under Article 6(2)(a) of Directive 2008/68/EC of 24 September 2008 on the inland transport of dangerous goods

RA - a - CH - 1

Subject: Transport of diesel fuel and heating oil with UN number 1202 in tank containers.

Reference to Annex II, Section II.1, to this Directive: point 6.8.

Content of the Annex to the Directive: Regulations concerning the construction of tanks.

Content of the national legislation: Tank containers which are not constructed according to point 6.8 but according to national legislation, which have a capacity of less than or equal to 1 210 l and which are used to transport heating oil or diesel fuel with UN number 1202 are authorised.

Initial reference to the national legislation: Annex to the DETEC Ordinance of 3 December 1996 relating to the transport of dangerous goods by rail and cableway installation (RSD, RS 742.401.6) and Appendix 1, Chapter 6.14, of the Ordinance relating to the carriage of dangerous goods by road (SDR, RS 741.621).

Date of expiry: 1 January 2023.

RA — a — CH — 2

Subject: Transport document.

Reference to Annex II, Section II.1, to this Directive: point 5.4.1.1.1.

Content of the Annex to the Directive: General information required in the transport document.

Content of the national legislation: Use of a collective term in the transport document and an annexed list containing the information prescribed as stipulated above.

Initial reference to the national legislation: Annex to the DETEC Ordinance of 3 December 1996 relating to the transport of dangerous goods by rail and cableway installation (RSD, RS 742.401.6).

Date of expiry: 1 January 2023.

Directive 2010/35/EU of the European Parliament and of the Council of 16 June 2010 on transportable pressure equipment and repealing Council Directives 76/767/EEC, 84/525/EEC, 84/526/EEC, 84/527/EEC and 1999/36/EC (OJ L 165, 30.6.2010, p. 1).

SECTION 4 — ACCESS AND TRANSIT RIGHTS WITH REGARD TO RAILWAYS

- Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways (OJ L 237, 24.8.1991, p. 25).
- Council Directive 95/18/EC of 19 June 1995 on the licensing of railway undertakings (OJ L 143, 27.6.1995, p. 70).
- Council Directive 95/19/EC of 19 June 1995 on the allocation of railway infrastructure capacity and the charging of infrastructure fees (OJ L 143, 27.6.1995, p. 75).
- Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety on the Community's railways and amending Council Directive 95/18/EC on the licensing of railway undertakings and Directive 2001/14/EC on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (Railway Safety Directive) (OJ L 164, 30.4.2004, p. 44), as last amended by Commission Directive 2014/88/EU of 9 July 2014 (OJ L 201, 10.7.2014, p. 9).
- Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community (OJ L 315, 3.12.2007, p. 51), as last amended by Commission Directive (EU) 2016/882 of 1 June 2016 (OJ L 146, 3.6.2016, p. 22).
- Commission Regulation (EC) No 653/2007 of 13 June 2007 on the use of a common European format for safety certificates and application documents in accordance with Article 10 of Directive 2004/49/EC of the European Parliament and of the Council and on the validity of safety certificates delivered under Directive 2001/14/EC (OJ L 153, 14.6.2007, p. 9), as amended by Commission Regulation (EU) No 445/2011 of 10 May 2011 (OJ L 122, 11.5.2011, p. 22).

- Commission Decision 2007/756/EC of 9 November 2007 adopting a common specification of the national vehicle register provided for under Articles 14(4) and (5) of Directives 96/48/EC and 2001/16/EC (OJ L 305, 23.11.2007, p. 30), as amended by Commission Decision 2011/107/EU of 10 February 2011 (OJ L 43, 17.2.2011, p. 33).
- Directive 2008/57/EC of the European Parliament and of the Council of 17 June 2008 on the interoperability of the rail system within the Community (Recast) (OJ L 191, 18.7.2008, p. 1), as last amended by Commission Directive 2014/38/EU of 10 March 2014 (OJ L 70, 11.3.2014, p. 20).
- Commission Decision 2009/965/EC of 30 November 2009 on the reference document referred to in Article 27(4) of Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community (OJ L 341, 22.12.2009, p. 1), as amended by Commission Implementing Decision (EU) 2015/2299 of 17 November 2015 (OJ L 324, 10.12.2015, p. 15).
- Commission Regulation (EU) No 36/2010 of 3 December 2009 on Community models for train driving licences, complementary certificates, certified copies of complementary certificates and application forms for train driving licences, under Directive 2007/59/EC of the European Parliament and of the Council (OJ L 13, 19.1.2010, p. 1).
- Commission Decision 2010/713/EU of 9 November 2010 on modules for the procedures for assessment of conformity, suitability for use and EC verification to be used in the technical specifications for interoperability adopted under Directive 2008/57/EC of the European Parliament and of the Council (OJ L 319, 4.12.2010, p. 1).
- Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates (OJ L 326, 10.12.2010, p. 11).
- Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation (OJ L 327, 11.12.2010, p. 13).
- Commission Regulation (EU) No 201/2011 of 1 March 2011 on the model of declaration of conformity to an authorised type of railway vehicle (OJ L 57, 2.3.2011, p. 8).
- Commission Decision 2011/275/EU of 26 April 2011 concerning a technical specification for interoperability relating to the "infrastructure" subsystem of the trans-European conventional rail system (OJ L 126, 14.5.2011, p. 53), as amended by Commission Decision 2012/464/EU of 23 July 2012 (OJ L 217, 14.8.2012, p. 20).
- Commission Regulation (EU) No 445/2011 of 10 May 2011 on a system of certification of entities in charge of maintenance for freight wagons and amending Regulation (EC) No 653/2007 (OJ L 122, 11.5.2011, p. 22).
- Commission Regulation (EU) No 454/2011 of 5 May 2011 on the technical specification for interoperability relating to the subsystem "telematics applications for passenger services" of the trans-European rail system (OJ L 123, 12.5.2011, p. 11), as last amended by Commission Regulation (EU) 2015/302 of 25 February 2015 (OJ L 55, 26.2.2015, p. 2).
- Commission Implementing Decision 2011/665/EU of 4 October 2011 on the European register of authorised types of railway vehicles (OJ L 264, 8.10.2011, p. 32).
- Commission Decision 2011/765/EU of 22 November 2011 on criteria for the recognition of training centres involved in the training of train drivers, on criteria for the recognition of examiners of train drivers and on criteria for the organisation of examinations in accordance with Directive 2007/59/EC of the European Parliament and of the Council (OJ L 314, 29.11.2011, p. 36).
- Commission Decision 2012/88/EU of 25 January 2012 on the technical specification for interoperability relating to the control-command and signalling subsystems of the trans-European rail system (OJ L 51, 23.2.2012, p. 1), as last amended by Commission Decision (EU) 2015/14 of 5 January 2015 (OJ L 3, 7.1.2015, p. 44).
- Commission Decision 2012/757/EU of 14 November 2012 concerning the technical specification for interoperability relating to the "operation and traffic management" subsystem of the rail system in the European Union and amending Decision 2007/756/EC (OJ L 345, 15.12.2012, p. 1), as amended by Commission Decision 2013/710/EU of 2 December 2013 (OJ L 323, 4.12.2013, p. 35).
- Commission Regulation (EU) No 1077/2012 of 16 November 2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation (OJ L 320, 17.11.2012, p. 3).
- Commission Regulation (EU) No 1078/2012 of 16 November 2012 on a common safety method for monitoring to be applied by railway undertakings, infrastructure managers after receiving a safety certificate or safety authorisation and by entities in charge of maintenance (OJ L 320, 17.11.2012, p. 8).

- Commission Regulation (EU) No 321/2013 of 13 March 2013 concerning the technical specification for interoperability relating to the subsystem "rolling stock — freight wagons" of the rail system in the European Union and repealing Decision 2006/861/EC (OJ L 104, 12.4.2013, p. 1), as amended by Commission Regulation (EU) No 1236/2013 of 2 December 2013 (OJ L 322, 3.12.2013, p. 23).
- Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 (OJ L 121, 3.5.2013, p. 8), as amended by Commission Implementing Regulation (EU) 2015/1136 of 13 July 2015 (OJ L 185, 14.7.2015, p. 6).
- Commission Implementing Decision 2014/880/EU of 26 November 2014 on the common specifications of the register of railway infrastructure and repealing Implementing Decision 2011/633/EU (OJ L 356, 12.12.2014, p. 489).
- Commission Regulation (EU) No 1300/2014 of 18 November 2014 on the technical specifications for interoperability relating to accessibility of the Union's rail system for persons with disabilities and persons with reduced mobility (OJ L 356, 12.12.2014, p. 110).
- Commission Regulation (EU) No 1301/2014 of 18 November 2014 on the technical specifications for interoperability relating to the "energy" subsystem of the rail system in the Union (OJ L 356, 12.12.2014, p. 179).
- Commission Regulation (EU) No 1302/2014 of 18 November 2014 concerning a technical specification for interoperability relating to the "rolling stock locomotives and passenger rolling stock" subsystem of the rail system in the European Union (OJ L 356, 12.12.2014, p. 228).
- Commission Regulation (EU) No 1303/2014 of 18 November 2014 concerning the technical specification for interoperability relating to "safety in railway tunnels" of the rail system of the European Union (OJ L 356, 12.12.2014, p. 394).
- Commission Regulation (EU) No 1304/2014 of 26 November 2014 on the technical specification for interoperability relating to the subsystem "rolling stock — noise" amending Decision 2008/232/EC and repealing Decision 2011/229/EU (OJ L 356, 12.12.2014, p. 421).
- Commission Regulation (EU) No 1305/2014 of 11 December 2014 on the technical specification for interoperability relating to the telematics applications for freight subsystem of the rail system in the European Union and repealing the Regulation (EC) No 62/2006 (OJ L 356, 12.12.2014, p. 438).
- Commission Implementing Regulation (EU) 2015/171 of 4 February 2015 on certain aspects of the procedure of licensing railway undertakings (OJ L 29, 5.2.2015, p. 3).
- Commission Implementing Regulation (EU) 2015/909 of 12 June 2015 on the modalities for the calculation of the cost that is directly incurred as a result of operating the train service (OJ L 148, 13.6.2015, p. 17).

SECTION 5 — OTHER FIELDS

- Council Directive 92/82/EEC of 19 October 1992 on the approximation of the rates of excise duties on mineral oils (OJ L 316, 31.10.1992, p. 19).
- Directive 2004/54/EC of the European Parliament and of the Council of 29 April 2004 on minimum safety requirements for tunnels in the Trans-European Road Network (OJ L 167, 30.4.2004, p. 39).
- Directive 2008/96/EC of the European Parliament and of the Council of 19 November 2008 on road infrastructure safety management (OJ L 319, 29.11.2008, p. 59).'

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