Official Journal

L 355

of the European Union



English edition

Legislation

Volume 57

12 December 2014

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 1316/2014

of 11 December 2014

approving the active substance Bacillus amyloliquefaciens subsp. plantarum strain D747, 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 and allowing Member States to extend provisional authorisations granted for that active substance

(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) and Article 78(2) thereof,

Whereas:

- In accordance with Article 80(1)(a) of Regulation (EC) No 1107/2009, Council Directive 91/414/EEC (2) is to apply, with respect to the procedure and the conditions for approval, to active substances for which a decision has been adopted in accordance with Article 6(3) of that Directive before 14 June 2011. For Bacillus amyloliquefaciens subsp. plantarum strain D747 the conditions of Article 80(1)(a) of Regulation (EC) No 1107/2009 are fulfilled by Commission Implementing Decision 2011/253/EU (3).
- In accordance with Article 6(2) of Directive 91/414/EEC Germany received on 21 October 2010 an application (2) from Mitsui AgriScience International SA/NV, for the inclusion of the active substance Bacillus amyloliquefaciens subsp. plantarum strain D747 in Annex I to Directive 91/414/EEC. Implementing Decision 2011/253/EU confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.
- For that active substance, the effects on human and animal health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicant. The designated rapporteur Member State submitted a draft assessment report on 14 January 2013.
- The draft assessment report was reviewed by the Member States and the European Food Safety Authority (hereinafter 'the Authority'). The Authority presented to the Commission its conclusion (4) on the pesticide risk assessment of the active substance Bacillus amyloliquefaciens subsp. plantarum strain D747 on 27 March 2014. The draft assessment report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised on 10 October 2014 in the format of the Commission review report for Bacillus amyloliquefaciens subsp. plantarum strain D747.

⁽¹) OJ L 309, 24.11.2009, p. 1. (²) 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,

^(*) Commission Implementing Decision 2011/253/EU of 26 April 2011 recognising in principle the completeness of the dossier submitted for detailed examination in view of the possible inclusion of metobromuron, S-Abscisic acid, Bacillus amyloliquefaciens subsp. plantarum D747, Bacillus pumilus QST 2808 and Streptomyces lydicus WYEC 108 in Annex I to Council Directive 91/414/EEC (OJ L 106, 27.4.2011,

⁽⁴⁾ EFSA Journal (2014);12(4):3624. Available online: www.efsa.europa.eu.

- (5) It has appeared from the various examinations made that plant protection products containing Bacillus amyloliquefaciens subsp. plantarum strain D747 may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve Bacillus amyloliquefaciens subsp. plantarum strain D747.
- A reasonable period should be allowed to elapse before approval in order to permit Member States and the inter-(6) ested parties to prepare themselves to meet the new requirements resulting from the approval.
- (7) Without prejudice to the obligations provided for in Regulation (EC) No 1107/2009 as a consequence of approval, taking into account the specific situation created by the transition from Directive 91/414/EEC to Regulation (EC) No 1107/2009, the following should, however, apply. Member States should be allowed a period of six months after approval to review authorisations of plant protection products containing Bacillus amyloliquefaciens subsp. plantarum strain D747. Member States should, as appropriate, vary, replace or withdraw authorisations. By way of derogation from that deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier, as set out in Directive 91/414/EEC, of each plant protection product for each intended use in accordance with the uniform principles.
- The experience gained from inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 (1) has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties, it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the Directives which have been adopted until now amending Annex I to that Directive or the Regulations approving active substances.
- In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing (9) Regulation (EU) No 540/2011 (2) should be amended accordingly.
- (10)It is also appropriate to allow Member States to extend provisional authorisations granted for plant protection products containing Bacillus amyloliquefaciens subsp. plantarum strain D747 in order to provide them with the time necessary to fulfil the obligations set out in this Regulation as regards those provisional authorisations.
- (11)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 Bacillus amyloliquefaciens subsp. plantarum strain D747, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Re-evaluation of plant protection products

Member States shall in accordance with Regulation (EC) No 1107/2009, where necessary, amend or withdraw existing authorisations for plant protection products containing Bacillus amyloliquefaciens subsp. plantarum strain D747 as an active substance by 30 September 2015.

 $^(^{1})$ Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 366, 15.12.1992, p. 10).
(2) Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the Euro-

pean Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

By that date they shall in particular verify that the conditions in Annex I to this Regulation are met, with the exception of those identified in the column on specific provisions of that Annex, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to Directive 91/414/EEC in accordance with the conditions of Article 13(1) to (4) of that Directive and Article 62 of Regulation (EC) No 1107/2009.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747 as either the only active substance or as one of several active substances, all of which were listed in the Annex to Implementing Regulation (EU) No 540/2011 by 31 March 2015 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, on the basis of a dossier satisfying the requirements of Annex III to Directive 91/414/EEC and taking into account the column on specific provisions of Annex I to this Regulation. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 29(1) of Regulation (EC) No 1107/2009.

Following that determination Member States shall:

- (a) in the case of a product containing *Bacillus amyloliquefaciens* subsp. plantarum strain D747 as the only active substance, where necessary, amend or withdraw the authorisation by 30 September 2016 at the latest; or
- (b) in the case of a product containing *Bacillus amyloliquefaciens* subsp. *plantarum* strain D747 as one of several active substances, where necessary, amend or withdraw the authorisation by 30 September 2016 or by the date fixed for such an amendment or withdrawal in the respective act or acts which added the relevant substance or substances to Annex I to Directive 91/414/EEC or approved that substance or those substances, whichever is the latest.

Article 3

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 4

Extension of existing provisional authorisations

Member States may extend existing provisional authorisations for plant protection products containing Bacillus amyloliquefaciens subsp. plantarum strain D747 for a period ending on 30 September 2016 at the latest.

Article 5

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 April 2015.

However, Article 4 shall apply from the date of the entry into force of this Regulation.

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

Done at Brussels, 11 December 2014.

For the Commission
The President
Jean-Claude JUNCKER

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Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
Bacillus amyloliquefaciens subsp. plantarum strain D747 Accession number in the Agricultural Research Culture Collection (NRRL), Peoria, Illinois, USA: B-50405 Deposit number in the International Patent Organism Depositary, Tokyo, Japan: FERM BP-8234.	Not applicable	Minimum concentration: 2,0 × 10 ¹¹ CFU/g	1 April 2015	31 March 2025	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 Bacillus amyloliquefaciens subsp. plantarum strain D747, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 10 October 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that Bacillus amyloliquefaciens subsp. plantarum strain D747 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.

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

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

Number	Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
'83	Bacillus amyloliquefaciens subsp. plantarum strain D747 Accession number in the Agricultural Research Culture Collection (NRRL), Peoria, Illinois, USA: B-50405 Deposit number in the International Patent Organism Depositary, Tokyo, Japan: FERM BP-8234.	Not applicable	Minimum concentration: 2,0 × 10 ¹¹ CFU/g	1 April 2015	31 March 2025	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 <i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747, and in particular Appendices I and II thereof, as finalised in the Standing Committee on Plants, Animals, Food and Feed on 10 October 2014 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of operators and workers, taking into account that <i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747 is to be considered as a potential sensitizer. Conditions of use shall include risk mitigation measures, where appropriate. Strict maintenance of environmental conditions and quality control analysis during the manufacturing process shall be assured by the producer.'

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

COMMISSION IMPLEMENTING REGULATION (EU) No 1317/2014

of 11 December 2014

on the extension of the transitional periods related to own funds requirements for exposures to central counterparties in Regulations (EU) No 575/2013 and (EU) No 648/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 (1), and in particular Article 497(3) thereof,

Whereas:

- In order to avoid disruption to international financial markets and to prevent penalising institutions by subjecting them to higher own funds requirements during the processes of authorisation and recognition of existing central counterparties ('CCPs'), Article 497(1) and (2) of Regulation (EU) No 575/2013 established a transitional period during which all CCPs with which institutions established in the Union clear transactions will be considered OCCPs.
- (2) Regulation (EU) No 575/2013 also amended Regulation (EU) No 648/2012 of the European Parliament and of the Council (2) in respect of certain inputs to the calculation of institutions' own funds requirements for exposures to CCPs. Accordingly, Article 89(5a) of Regulation (EU) No 648/2012 requires certain CCPs to report, for a limited period of time, the total amount of initial margin they have received from their clearing members. That transitional period mirrors the one laid down in Article 497 of Regulation (EU) No 575/2013.
- (3) Both the transitional period for own funds requirements set out in Article 497(1) and (2) of Regulation (EU) No 575/2013 and the transitional period for reporting the initial margin set out in the first and second subparagraphs of Article 89(5a) of Regulation (EU) No 648/2012 were set to expire on 15 June 2014.
- (4)Article 497(3) of Regulation (EU) No 575/2013 empowers the Commission to adopt an implementing act in order to extend the transitional period by six months in exceptional circumstances. That extension should also apply in respect of the time limits laid down in Article 89 (5a) of Regulation (EU) No 648/2012. Commission Implementing Regulation (EU) No 591/2014 (3) has already extended those transitional periods by six months, until 15 December 2014.
- The authorisation process for existing CCPs established in the Union has been taking place but will not be (5) completed by 15 December 2014. With regard to existing CCPs established in third countries that have already applied for recognition, for the time being no recognition has been granted yet to such CCPs. A further extension of the transitional period will therefore enable institutions established in the Union (or their subsidiaries established outside the Union) to avoid significant increase in the own funds requirements due to the lack of recognised CCPs established in each of those relevant third countries and providing, in a viable and accessible way, the specific type of clearing services that those Union institutions require. While such an increase may only be temporary, it could potentially lead to their withdrawal as direct participants in those CCPs and hence cause disruption in the markets in which those CCPs operate. An additional six-month extension of the transitional periods, i.e. until 15 June 2015, is therefore necessary.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the European Banking Committee

⁽¹) OJ L 176, 27.6.2013, p. 1.
(²) Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories (OJL 201, 27.7.2012, p. 1).

Commission Implementing Regulation (EU) No 591/2014 of 3 June 2014 on the extension of the transitional periods related to own funds requirements for exposures to central counterparties in Regulation (EU) No 575/2013 and Regulation (EU) No 648/2012 of the European Parliament and of the Council (OJ L 165, 4.6.2014, p. 31).

HAS ADOPTED THIS REGULATION:

Article 1

The 15-month periods referred to in Article 497(1) and (2) of Regulation (EU) No 575/2013 and in the first and second subparagraph of Article 89(5a) of Regulation (EU) No 648/2012, respectively, as already extended pursuant to Article 1 of Implementing Regulation (EU) No 591/2014, are extended by an additional 6 months.

Article 2

This Regulation shall enter into force on the third 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, 11 December 2014.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) No 1318/2014

of 11 December 2014

amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community

(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 2111/2005 of the European Parliament and the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air passengers of the identity of the operating carrier, and repealing Article 9 of Directive 2004/36/CE (¹), and in particular Article 4(2) thereof,

Whereas:

- (1) Commission Regulation (EC) No 474/2006 (²) established the Community list of air carriers which are subject to an operating ban within the Union, referred to in Chapter II of Regulation (EC) No 2111/2005.
- (2) In accordance with Article 4(3) of Regulation (EC) No 2111/2005, some Member States and the European Aviation Safety Agency (EASA) communicated to the Commission information that is relevant in the context of updating that list. Relevant information was also communicated by certain third countries. On the basis of that information, the Community list should be updated.
- (3) The Commission informed all air carriers concerned, either directly or through the authorities responsible for their regulatory oversight, about the essential facts and considerations which would form the basis for a decision to impose on them an operating ban within the Union or to modify the conditions of an operating ban imposed on an air carrier which is included in the Community list.
- (4) The Commission gave the air carriers concerned the opportunity to consult the documents provided by the Member States, to submit written comments and to make an oral presentation to the Commission and to the Committee established by Council Regulation (EEC) No 3922/1991 (3) (the 'Air Safety Committee').
- (5) The Air Safety Committee has received updates from the Commission about the ongoing joint consultations, in the framework of Regulation (EC) No 2111/2005 and its implementing Commission Regulation (EC) No 473/2006 (4), with competent authorities and air carriers of the states of Angola, Botswana, Georgia, the Republic of Guinea, India, Indonesia, Kazakhstan, the Kyrgyz Republic, Lebanon, Libya, Madagascar, the Islamic Republic of Mauritania, Mozambique, Nepal, the Philippines, São Tomé and Príncipe, Sudan and Zambia. The Air Safety Committee also received information from the Commission on Afghanistan, Ghana, Iran and North Korea. The Air Safety Committee also received from the Commission updates about technical consultations with the Russian Federation.
- (6) The Air Safety Committee has heard presentations by EASA about the results of the analysis of audit reports carried out by the International Civil Aviation Organisation (ICAO) in the framework of ICAO's Universal Safety Oversight Audit Programme (USOAP). Member States were invited to prioritise ramp inspections on air carriers licensed by states in respect of which Significant Safety Concerns (SSC) have been identified by ICAO or in respect of which EASA concluded that there are significant deficiencies in the safety oversight system. In addition to the consultations undertaken by the Commission under Regulation (EC) No 2111/2005, the prioritisation of ramp inspections will allow the acquisition of further information regarding the safety performance of the air carriers licensed in those states.

⁽¹⁾ OJ L 344, 27.12.2005, p. 15.

 ⁽²⁾ Commission Regulation (EC) No 474/2006 of 22 March 2006 establishing the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 84, 23.3.2006, p. 14).
 (3) Council Regulation (EEC) No 3922/1991 of 16 December 1991 on the harmonization of the technical requirements and administrative

⁽³⁾ Council Regulation (EEC) No 3922/1991 of 16 December 1991 on the harmonization of the technical requirements and administrative procedures in the field of civil aviation (OJ L 373, 31.12.1991, p. 4).

^(*) Commission Regulation (EC) No 473/2006 of 22 March 2006 laying down implementing rules for the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 84, 23.3.2006, p. 8).

- (7) The Air Safety Committee has heard presentations by EASA about the results of the analysis of ramp inspections carried out under the Safety Assessment of Foreign Aircraft programme (SAFA) in accordance with Commission Regulation (EU) No 965/2012 (1).
- (8) The Air Safety Committee has also heard presentations by EASA about the technical assistance projects carried out in states affected by measures or monitoring under Regulation (EC) No 2111/2005. It was informed about the plans of EASA and requests for further technical assistance and cooperation to improve the administrative and technical capability of civil aviation authorities with a view to helping resolve any non-compliance with applicable international standards. Member States were also invited to respond to those requests on a bilateral basis in coordination with the Commission and EASA. In this regard, the Commission underlined the usefulness of providing information to the international aviation community, particularly through ICAO's SCAN database, on technical assistance provided by the Union and by its Member States, to improve aviation safety around the world.
- (9) The Air Safety Committee has also heard a presentation by Eurocontrol providing an update on the status of the SAFA alarming function and on the current statistics for alert messages for banned carriers.

Union air carriers

- (10) Following the analysis by EASA of information resulting from ramp inspections carried out on aircraft of Union air carriers or from standardisation inspections carried out by EASA, as well as specific inspections and audits carried out by national aviation authorities, several Member States have taken certain enforcement measures and informed the Commission and the Air Safety Committee about those measures. Greece informed that the Hellenic CAA performed inspections on *Gain Jet Aviation* and *Skygreece Airlines*. On the occasion of the additional inspections no major problems were identified.
- (11) Should any relevant safety information indicate that there are imminent safety risks as a consequence of a lack of compliance by Union air carriers with the appropriate safety standards, Member States reiterated their readiness to act as necessary.

Air carriers from Angola

- (12) Regulation (EC) No 474/2006, as amended by Commission Implementing Regulation (EU) No 1197/2011 (²), allows TAAG Angolan Airlines certified in Angola, to operate into the Union four aircraft of type Boeing 737-700 with registration marks D2-TBF, D2-TBG, D2-TBH and D2-TBJ, three aircraft of type Boeing 777-200 with registration marks D2-TED, D2-TEE and D2-TEF, and two aircraft of type Boeing 777-300 with registration marks D2-TEG and D2-TEH.
- (INAVIC), a request to add a new aircraft of type Boeing 777-300 to Annex B to Regulation (EC) No 474/2006. However, there are persistent difficulties to establish and maintain regular contact with INAVIC as well as with TAAG Angolan Airlines. These difficulties extend also to INAVIC's contacts with ICAO, which has led in the recent past to a number of cancellations of previously scheduled ICAO audits. This indicates that there are internal communication problems within both TAAG Angolan Airlines and INAVIC as well as between them, which makes it difficult to adequately assess whether the granting of the request by TAAG Angolan Airlines would entail safety risks. Therefore, the Commission considers that the most appropriate way to proceed is to request both INAVIC as well as TAAG Angolan Airlines to fully engage with the Commission in the near future, with a view to thoroughly reviewing the current safety situation in all its aspects, including with regard to the addition of new aircraft to the fleet of TAAG Angolan Airlines.
- (14) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that there are at this stage no grounds for amending the Community list of air carriers which are subject to an operating ban within the Union by including additional aircraft operated by TAAG Angolan Airlines.

⁽¹⁾ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down the technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).

⁽²⁾ Commission Implementing Regulation (EU) No 1197/2011 of 21 November 2011 (OJ L 303, 22.11.2011, p. 14). See in particular points 26 to 30 of the recitals of this Regulation.

(15) Member States are to continue to verify effective compliance by TAAG Angolan Airlines with the relevant safety standards, through the prioritisation of ramp inspections to be carried out on aircraft of this air carrier pursuant to Regulation (EU) No 965/2012.

Air carriers from Botswana

- (16) In April 2013, ICAO conducted an ICAO Coordinated Validation Mission (ICVM) in Botswana. The results of that ICVM were partly positive: the Effective Implementation improved. However, there was also a negative result, given that two SSCs were identified. Furthermore, since 2010, two accidents occurred with aircraft registered in Botswana.
- (17) Based on the available information, the current lack of effective implementation of ICAO Standards and Recommended Practices, the two SSCs, the two accidents and the intermittent communication between the Commission and the Civil Aviation Authority Botswana (CAAB), the Commission requested information as regards air carriers certified in Botswana in a letter of 8 July 2014 to CAAB.
- (18) CAAB replied on 3 October 2014, providing the requested information with a view to showing the State's effective implementation of ICAO Standards and Recommended Practices and resolving the two SSCs.
- (19) On the basis of that information, it appears that CAAB would like ICAO to conduct another ICVM before the end of this year, in order to verify that the corrective actions that were taken are sufficient to resolve the two SSCs.
- (20) The assessment of the information provided further indicates that all air carriers were recertified and had been provided with new Air Operator Certificates (AOCs) on the same date. This will lead to a peak in workload for CAAB every time these AOCs need to be renewed. The CAAB has developed a surveillance program for the safety oversight of the air carriers, but the implementation of this program is behind schedule. Finally, during the oversight activities only a limited number of findings is recorded and as a consequence, it is difficult to determine the capacity of the CAAB to resolve emerging safety issues. In order to clarify these issues, additional information will be requested by the Commission and the CAAB will be invited by the Commission to a technical meeting to discuss any further details with respect to the safety oversight situation in Botswana.
- (21) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that there are at this stage no grounds for amending the Community list of air carriers which are subject to an operating ban within the Union by including air carriers from Botswana.

Air carriers from Georgia

- (22) Consultations with the competent authorities of Georgia (GCAA) continue with the aim of monitoring the implementation by GCAA of the corrective action plan developed in response to the SSC identified during the ICAO Comprehensive System Audit (CSA) of Georgia in October 2013.
- (23) On the basis of the information provided by GCAA relating to the actions being taken by GCAA to have the SSC lifted, the Commission did not deem it necessary to ask the GCAA to appear before the Air Safety Committee. The Commission reported to the Air Safety Committee about the implementation of the Corrective Action Plan developed by GCAA.
- (24) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that there are at this stage no grounds for amending the Community list of air carriers which are subject to an operating ban within the Union by including air carriers from Georgia.

Air carriers from the Republic of Guinea

(25) As agreed in the meeting held in Brussels in January 2013, the competent authorities of the Republic of Guinea (DNAC) have regularly provided information on the ongoing implementation of the Corrective Action Plan, which was approved by ICAO in December 2012, as well as all the activities linked to it.

- (26) The latest progress report, received on 21 October 2014, details the most recent activities and developments regarding the implementation of the Corrective Action Plan. The training of staff continues in order to further reinforce the oversight capacity, mainly in the areas of airworthiness and operations. DNAC has continued to address the remaining USOAP findings in terms of the associated protocol questions, through the use of ICAO's Continuous Monitoring Approach (CMA) online tool. Between the beginning of August and the end of September 2014 ICAO has conducted an off-site validation of the protocol questions amenable to remote verification. As a result, the overall effective implementation of the eight critical elements showed a slight improvement.
- (27) A legislative initiative to transform DNAC in an independent, financially and operationally autonomous civil aviation authority, with its own management structure, is in preparation. The Civil Aviation Authority of Guinea (AGAC), fully in line with ICAO requirements, is expected to be enacted by January 2015.
- (28) All previously existing AOCs were suspended at the end of March 2013. The full ICAO-compliant (5-phase) certification of the national air carrier PROBIZ Guinée, with one aircraft of type BE90, is still ongoing, with the help and support of a specific mission of the African Civil Aviation Conference/Banjul Accord Group Aviation Safety Oversight Organisation, including simultaneous on-the-job training of DNAC's inspectors on the whole process. Two other air carriers Eagle Air Guinée and Sahel Aviation Service Guinée have also initiated the certification process. DNAC, with the support of the regional ICAO Dakar office, expects to conclude the certification process for all three air carriers by the end of 2014.
- (29) DNAC requested an ICVM in order to validate the progress in the implementation of the Corrective Action Plan. ICAO had initially planned to conduct the ICVM in May 2014. Senior management changes at the Ministry of Transport caused a delay and the ICVM was tentatively planned for the second half of September 2014. The ongoing Ebola outbreak has now put the ICVM, as well as an ICAO assistance mission initially planned for July 2014, on indefinite hold.
- (30) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that there are at this stage no grounds for amending the Community list of air carriers which are subject to an operating ban within the Union by including air carriers from the Republic of Guinea.
- (31) Should any relevant safety information indicate that there are imminent safety risks as a consequence of lack of compliance with international safety standards, the Commission may be forced to take action in accordance with Regulation (EC) No 2111/2005.

Air carriers from India

- (32) On 7 November 2014, a technical meeting took place in Brussels. The Commission and EASA, as well as senior representatives from the Indian Directorate General of Civil Aviation (DGCA) attended the meeting. The meeting was held with respect to India's compliance with international safety and oversight obligations, including the decision by the United States Federal Aviation Administration (FAA) to downgrade India's compliance status from category 1 to category 2, as a result of deficiencies identified during an International Aviation Safety Assessment (IASA) audit. DGCA provided details pertaining to the status of its corrective actions to address the findings that resulted from the FAA compliance category downgrade. DGCA reiterated that it had taken action to address the majority of the FAA findings and that it has established a structured corrective action plan with respect to remaining areas of concern. In addition, in the technical meeting DGCA presented information pertaining to the issue of sustainability and the ongoing improvements in this regard.
- (33) During that technical meeting DGCA gave its commitment to fully engage in a safety dialogue with the Commission, including through additional meetings if and when deemed necessary by the Commission. DGCA also committed to provide the Commission with any relevant safety information, as part of the official consultations with the authorities that have responsibility for regulatory oversight over the air carriers certified in India pursuant to the provisions laid out in Article 3(2) of Commission Regulation (EC) No 473/2006.
- (34) On the basis of the information provided at the technical meeting of 7 November 2014 and the commitments taken by DGCA on that occasion, the Commission does not deem it necessary at this stage to impose operating restrictions on Indian air carriers.
- (35) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that there are at this stage no grounds for amending the Community list of air carriers which are subject to an operating ban within the Union by including air carriers from India.

(36) Member States are to continue to verify the effective compliance with relevant safety standards through the prioritisation of ramp inspections to be carried out on Indian air carriers pursuant to Regulation (EU) No 965/2012.

Air carriers from Indonesia

- (37) Consultations with the competent authorities of Indonesia (DGCA) continue with the aim of monitoring the progress of DGCA in ensuring that the safety oversight of all air carriers certified in Indonesia is in compliance with international safety standards.
- (38) The efforts of DGCA to reach an aviation system fully compliant with ICAO standards are acknowledged. The necessary transparency shown by DGCA, as well as the willingness to share information, has also been noted.
- (39) ICAO performed a CSA in the period 5 to 14 May 2014. The final report of this audit became available on 18 November 2014 and the results of the audit show that the safety oversight system in Indonesia still needs substantial improvement. DGCA has proposed a Corrective Action Plan to ICAO, in order to resolve the findings stemming from this audit.
- (40) In September 2014, the National Transportation Safety Committee of Indonesia published the final report on the Lion Air accident that occurred on 13 April 2013 in Bali. The comprehensive report gives an analysis of the accident and provides safety recommendations to the air carrier and the DGCA, amongst others.
- (41) At present, there is however no objective and conclusive evidence that the implementation of the Corrective Action Plan and safety recommendations are adequate.
- (42) In a letter of 20 October 2014, DGCA informed the Commission that four new air carriers had been certified since the last update, namely AOC No 121-042 had been issued to PT. MY INDO Airlines on 15 August 2014, AOC No 121-054 had been issued to PT Indonesia Air Asia Extra on 28 August 2014, AOC No 135-052 had been issued to PT. Elang Lintas Indonesia on 28 February 2014 and AOC No 135-053 had been issued to PT. Elang Nusantara Air on 12 March 2014. However, DGCA did not provide evidence that the safety oversight of those air carriers is ensured in compliance with international safety standards.
- (43) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that the Community list of air carriers which are subject to an operating ban within the Union should be amended to include those four air carriers in Annex A to Regulation (EC) No 474/2006.

Air carriers from Kazakhstan

- (44) Consultations with the competent authorities of Kazakhstan (CAC) continue with the aim of monitoring the progress of CAC in ensuring that the safety oversight of all air carriers certified in Kazakhstan is in compliance with international aviation safety standards.
- (45) CAC informed the Commission of the developments related to the ICVM that took place from 27 May to 4 June 2014 in Kazakhstan, including the status of the two SSCs identified by ICAO in 2009. In particular, CAC indicated that one SSC pertaining to the issuance of certificates of airworthiness of aircraft was resolved, whilst a second one pertaining to the certification process for the issuance of AOCs was maintained.
- (46) Air Astana also provided its regular update on safety related developments within that air carrier, in particular regarding recent changes in its fleet that is at present allowed to operate in the Union. Most of the new additions are newly manufactured aeroplanes being leased in on a financial leasing basis. There is also a certain increase in the current and planned level of operations.
- (47) On the basis of the available information concerning the safety oversight system of Kazakhstan, it is considered that the Kazakh aviation authorities experience a shortage of sufficiently trained and experienced inspectors to lead certification tasks regarding AOCs and special authorisations and that they cannot at this stage ensure a continued oversight in the area of flight operations. The Kazakh authorities are therefore strongly encouraged to step up their efforts to reach compliance with international safety standards.

- (48) The Commission and EASA intend to closely monitor the progress of CAC to hire, retain and qualify its inspectors as well as the steps taken by the CAC to implement the CAP related to the remaining SSC.
- (49) On 29 September 2014, the Commission requested from CAC updated information regarding air carriers under CAC's oversight, in particular information relating to the revocation of AOCs. In its reply, CAC informed the Commission about the AOCs issued in Kazakhstan and provided evidence on the revocation of three AOCs, namely the AOCs of *Jet One*, *Luk Aero* and *Air Trust Aircompany*.
- (50) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that the Community list of air carriers which are subject to an operating ban within the Union should be amended to remove Jet One, Luk Aero and Air Trust Aircompany from Annex A to Regulation (EC) No 474/2006.
- (51) Member States are to continue to verify the effective compliance with relevant safety standards through the prioritisation of ramp inspections to be carried out on aircraft of *Air Astana* pursuant to Regulation (EU) No 965/2012.

Air carriers from the Kyrgyz Republic

- (52) By letters dated 18 October 2014 and 13 November 2014 the competent authority of the Kyrgyz Republic (KG CAA) provided updated information about the air carriers certified in that country, which are currently subject to an operating ban in the Union. According to these letters and the accompanying documentation, KG CAA has suspended the AOCs of four air carriers, namely Kyrgyz Airlines, SAEMES, Supreme Aviation and Click Airways, and it has revoked the AOC of Kyrgyz Trans Avia. Under the legislation of the Kyrgyz Republic, the suspension of an AOC is equivalent to its revocation, when the holder of the suspended certificate has not applied for a certification procedure within three months following the suspension. Kyrgyz Airlines, SAEMES, Supreme Aviation and Click Airways have not applied for such certification since the suspension of their AOC. Consequently, their AOCs can be deemed revoked.
- (53) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that the Community list of air carriers which are subject to an operating ban within the Union should be amended to remove Kyrgyz Airlines, SAEMES, Supreme Aviation, Click Airways and Kyrgyz Trans Avia from Annex A to Regulation (EC) No 474/2006.

Air carriers from Lebanon

- (54) Consultations with the competent authorities of Lebanon (DGCA Lebanon) continue with the aim of confirming that Lebanon is addressing the deficiencies established by ICAO during the ICVM performed in Lebanon from 5 to 11 December 2012. DGCA Lebanon has established a Corrective Action Plan and is in the process of carrying out those actions, particularly in relation to the SSC with respect to the certification of air carriers in Lebanon.
- (55) During a technical meeting on 14 July 2014, DGCA Lebanon provided information on the change in its management, the appointment of new staff both employed by DGCA Lebanon and seconded by Middle East Airlines, improved identification of the root causes for the SSC and the awareness at political level with respect to the improvements that need to be made in Lebanon. DGCA Lebanon provided the full list of current AOCs in Lebanon and information with respect to the renewal of AOC of two air carriers.
- (56) DGCA Lebanon informed the Commission that the report on the resolution of the SSC was sent to ICAO. However, at present, those corrective actions still have to be verified.
- (57) On 14 and 15 October 2014, an informal visit by the Commission to DGCA Lebanon took place. During this visit, Lebanon highlighted the progress made at the DGCA since July 2014, due in particular to good communication with the Union. Lebanon is taking seriously the SSC that was raised by the International Civil Aviation Organisation, and checked all AOCs. DGCA Lebanon stressed that the Directorate General of Civil Aviation now has full authority to monitor all safety aspects on all airlines, albeit that there is not yet an autonomous and adequately resourced civil aviation authority. Lebanon provided additional information on its Aviation Safety Action Plan on 9 November 2014, including plans for the further development of an autonomous civil aviation authority.

- (58) In light of the foregoing, consultations with the Lebanese authorities are to continue in accordance with Article 3(2) of Regulation (EC) No 473/2006.
- (59) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that at this stage there are no grounds for amending the Community list of air carriers which are subject to an operating ban within the Union by including air carriers from Lebanon.
- (60) Should any relevant safety information indicate that there are imminent safety risks as a consequence of a lack of compliance with international safety standards, the Commission may be forced to take further action in accordance with Regulation (EC) No 2111/2005.

Air carriers from Libya

- (61) In April 2012, the competent authorities of Libya (LYCAA) agreed to restrict all air carriers certified in Libya from operating in the Union. The intention was to allow LYCAA time to re-certify those air carriers and to establish sufficient oversight capabilities to ensure compliance with international safety standards.
- (62) The Commission has monitored the effectiveness of those restrictions. The Commission has also carried out regular consultations with LYCAA on its progress in reforming its civil aviation safety system.
- (63) Until March 2014, some progress had been observed, both at the level of LYCAA as well as at the level of the main air carriers, *Libyan Airlines* and *Afriqiyah Airways*. However, certification of those air carriers took much longer than expected.
- (64) As the Commission stated in April 2014 (¹), before LYCAA could be allowed to issue an authorisation to its carriers to operate in the Union, it should be demonstrated to the satisfaction of the Commission that the re-certification process has been effectively completed and that there is sustainable continued oversight in accordance with ICAO standards.
- (65) However, the security situation in Libya deteriorated significantly in the course of June and July 2014, notably following the outbreak of violence on and around Tripoli International Airport. This unstable security situation continues to prevail. The violence has resulted in severe destruction of and damage to buildings, infrastructure and aircraft on the ground at Tripoli International Airport, rendering the airport as well as the local airspace unusable.
- (66) In view of the unclear status of the capabilities of LYCAA to properly oversee its air carriers following the violence and the lack of a stable and effective government, the Commission does no longer have the necessary confidence that LYCAA still has the authority to restrict Libyan air carriers from operating in the Union. In addition, the Commission is not convinced of the ability of LYCAA to fulfil its international obligations with regard to safety oversight of its air carriers. The Commission is further concerned about the large number of aircraft damaged during the violence and questions whether their continuing airworthiness is being appropriately accounted for.
- (67) The oral presentation to the Commission and the Air Safety Committee, given by LYCAA on 25 November 2014, on its actions to ensure aviation safety in Libya made it clear that, despite the efforts undertaken by LYCAA under its current leadership, substantial concerns remain about imminent aviation safety risks not being sufficiently contained. Those concerns are substantially reinforced by the ongoing instability.
- (68) Due to the unclear status of the capabilities of LYCAA to adequately oversee Libyan air carriers and to control imminent safety risks, it is assessed that LYCAA cannot fulfil its international obligations in relation to aviation safety.
- (69) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that the Community list of air carriers which are subject to an operating ban within the Union should be amended to include all air carriers certified in Libya in Annex A to Regulation (EC) No 474/2006.

⁽i) Commission Implementing Regulation (EU) No 368/2014 of 10 April 2014 (OJ L 108, 11.4.2014, p. 16). See in particular recital 64 of this Regulation.

Air carriers from Madagascar

- (70) Consultations with the competent authorities of Madagascar have continued actively with the purpose of monitoring the progress of these authorities in ensuring that the safety oversight of all air carriers certified in Madagascar is in compliance with international safety standards.
- (71) The Commission, assisted by EASA, held a consultation meeting on 23 October 2014 with the competent authorities of Madagascar and representatives of the air carrier Air Madagascar. At this meeting, the air carrier provided information about its fleet evolution and in particular informed that two aircraft of type Boeing 737, which are mentioned in Annex B to Regulation (EU) No 474/2006, will be gradually replaced as of 2015 by aircraft of the same type, and that an aircraft of type ATR 72-600 will be added to the fleet during the first quarter of 2015.
- (72) On 10 November 2014, the air carrier Air Madagascar made the request to have Annex B modified, in order to allow operations of the new aircraft of type Boeing 737 that will replace the existing aircraft of type Boeing 737 in its fleet, as well as the operations of the aircraft of type ATR 72-600 that will be added to the fleet.
- (73) Air Madagascar provided evidence that the safety performance of its fleet has improved. The competent authorities of Madagascar stated that, with regard to the operations conducted with the aircraft of type Boeing B737, they are satisfied with the current level of compliance demonstrated by Air Madagascar with respect to ICAO requirements. Member States and EASA confirmed that no specific concern arose from ramp checks carried out at Union airports in the framework of the SAFA programme.
- (74) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that the Community list of air carriers which are subject to an operating ban within the Union should be amended with regard to Air Madagascar. Annex B to Regulation (EC) No 474/2006 should be amended to allow the operation of aircraft of type B737 series as well as aircraft of type ATR 72/42 series, that are or will be listed on the AOC of Air Madagascar.
- (75) Member States will continue to verify the effective compliance with relevant safety standards through the prioritisation of ramp inspections to be carried out on aircraft of *Air Madagascar* pursuant to Regulation (EU) No 965/2012.

Air carriers from the Islamic Republic of Mauritania

- (76) EASA informed the Commission about reports showing serious safety deficiencies and a persistent failure by the air carrier *Mauritania Airlines International* (MAI) to address deficiencies identified by ramp inspections performed under the SAFA programme. Those deficiencies are related to flight preparation and performance calculations. Despite some improvement as regards the condition of aircraft, the nature and severity of the recent findings have a direct impact on the safety of operations and require corrective actions.
- (77) The Commission has directly informed the competent national authorities (ANAC) and Mauritania Airlines International (MAI) about those deficiencies, in order for them to swiftly take mitigating actions. ANAC acknowledged receipt by reporting on a number of corrective actions and on the latest ICAO audit results in the areas of aerodromes and air navigation services.
- (78) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that at this stage there are no grounds for amending the Community list of air carriers which are subject to an operating ban within the Union by including air carriers from the Islamic Republic of Mauritania.
- (79) Should any relevant safety information indicate that there are imminent safety risks as a consequence of a lack of compliance with international safety standards, the Commission may be forced to take further action in accordance with Regulation (EC) No 2111/2005.

Air carriers from Mozambique

- (80) The competent authorities of Mozambique (IACM) have reported on the ongoing implementation of the Corrective Action Plan submitted to, and approved by, ICAO. The latest progress report and its supporting documents received by the Commission and EASA on 26 September 2014 indicate that IACM has continued to work on the update of the legal framework by submitting legislative proposals to further align the civil aviation act with ICAO requirements, to have its role upgraded from one of a mere regulator to that of an authority and to further pursue the alignment of its existing regulations with the amended ICAO Standards and Recommended Practices (SARPS). The recruitment and training of staff continues, in order to further reinforce the oversight capacity, mainly in the areas of operations and licencing, aerodromes, airworthiness, rulemaking and enforcement. The internal capacity building efforts are strengthened through partnerships with African and European authorities, as well as with regional organisations. A gap analysis of the aerodrome certification has been conducted for all airports and a detailed plan for the certification of the international airports (Maputo, Beira and Nacala) has been requested, with a view to initiating the process in 2015. The State Safety Programme is being established and is expected to be completed by 2017.
- (81) IACM has continued to address the outstanding USOAP findings in terms of the associated protocol questions. In addition, many of the required regulations and procedures to support the replies have been produced and the associated documentation uploaded, through the use of ICAO's CMA online tool. The validation of these actions by ICAO is currently pending.
- (82) IACM has requested an ICVM in order to validate the progress in the implementation of its Corrective Action Plan, which is now scheduled to take place from 26 November until 4 December 2014, covering the areas of legislation, CAA organisation, aerodromes and air navigations services.
- (83) The significant progress reported by IACM in the rectification of the deficiencies identified by ICAO has been noted and its efforts towards completing their work of establishing an aviation system fully compliant with international standards are encouraged. Recognising the significant progress already achieved, and the expected further progress, a Union safety assessment mission might take place in the first quarter of 2015. However, for the time being, the fact remains that several important aviation safety-related issues still need to be fully and adequately addressed.
- (84) The investigation into the crash of the air carrier *Linhas Aéreas de Moçambique SA* (LAM) on 29 November 2013 is still ongoing. The final accident investigation report is expected by the end of 2014. Following the accident, LAM has conducted an extensive review of internal safety and security training, mechanisms and procedures, resulting in the implementation of more demanding organisational and operational requirements. In parallel, the work has continued to further improve the Safety Management System (SMS), with a particular attention to flight data analysis and exchange.
- (85) IACM also reported that it has continued the certification process of air carriers in compliance with ICAO SARPS. According to the list provided by IACM, a new air carrier has been certified, namely Makond Lda. However, IACM was not able to provide evidence that the safety oversight of that air carrier is ensured in compliance with international safety standards.
- (86) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that the Community list of air carriers which are subject to an operating ban within the Union should be amended to add the air carrier Makond Lda to Annex A to Regulation (EC) No 474/2006.

Air carriers from Nepal

- (87) The Commission has continued consultations with the competent authority of Nepal (CAAN) to establish its capabilities to sufficiently implement and enforce the relevant international safety standards.
- (88) On the basis of a request by the Commission, CAAN submitted documentation relating to progress made with regard to safety oversight activities, including the deficiencies noted by the Union assessment visit to Nepal in February 2014, the ICAO SSC, as well as ICAO audits.

- (89) The Commission and EASA had a meeting with CAAN on 24 September 2014. The meeting focussed in particular on the progress made in the areas of licencing of aircrew, certification of air carriers and oversight of air operations.
- (90) However, it appears that the progress is insufficient and that more time is needed. In particular, there are concerns that the requirements for aircrew operating in a multi-crew environment have so far been inadequately addressed by CAAN, especially since lack of proper crew training is indicated as a probable cause in the accident report of the fatal accident on 16 February 2014.
- (91) In addition, concerns remain that the re-certification by CAAN of air carriers is inadequate and may be unsuitable to ensure that all Nepalese air carriers comply with international air safety requirements. CAAN is therefore encouraged to seek the assistance of appropriate subject matter experts to assess the process and verify its appropriateness and take actions as necessary.
- (92) A meeting between the Commission, EASA and Nepal Airlines Corporation, Buddha Air, Shree Airlines, Tara Air and Yeti Airlines was held on 11 November 2014 to review progress with regard to the observations of the Union onsite assessment visit, as well as other issues relating to improvement of air safety in Nepal.
- (93) The ability of certain air carriers to manage the risks of their operations, at a level which could indicate an ability to mitigate risks raised by insufficient oversight by CAAN, is considered encouraging. However, the Commission considers that at present the competent authorities of Nepal are unable to sufficiently implement and enforce the relevant international safety standards to a level which could justify an alleviation of the current operating ban.
- (94) It should also be noted that on 25 August 2014, the Commission wrote to CAAN to obtain updated information regarding air carriers under its oversight. In a letter of 10 September 2014, CAAN informed the Commission that one new air carrier had been certified since the last update, namely AOC No 082/2014 had been issued to Manang Air Pvt. Ltd. on 3 July 2014. However, CAAN did not provide the evidence that the safety oversight of this air carrier is ensured in compliance with international safety standards.
- (95) Air carriers which in the past had a separate AOC issued only for their international operations have now been issued with only one AOC covering all operations. For this reason, AOC No 058/2010 for Buddha Air (International Operations) and AOC No 059/2010 for Shree Airlines (International Operations) have been revoked by CAAN.
- (96) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that the Community list of air carriers which are subject to an operating ban within the Union should be amended to include Manang Air Pvt. in Annex A to regulation (EC) No 474/2006 and to remove Buddha Air (International Operations) and Shree Airlines (International Operations) from Annex A to Regulation (EC) No 474/2006.

Air carriers from the Philippines

- (97) On 9 April 2014, the FAA announced its decision to upgrade the Philippines compliance status from category 2 to category 1 in respect to its IASA audit programme. In a letter of 24 July 2014 to the Commission, the Civil Aviation Authority of the Philippines (CAAP) referred to the decision by the FAA to upgrade the Philippines compliance category. This letter also referred to the communication from ICAO that the Philippines had resolved the previously identified SSCs. Finally, the CAAP stated in this letter that its next objective was to have the operating ban lifted on the air carriers certified in the Philippines that were still subject to an operating ban within the Union.
- (98) In a letter of 22 September 2014 to CAAP, the Commission reiterated that any decision to remove air carriers certified in the Philippines from the Community list of air carriers which are subject to an operating ban within the Union must be based on an evidence-based approach. In this respect a technical meeting was held on 4 November 2014 with experts from the Commission and EASA as well as senior representatives from CAAP.
- (99) The evidence presented by CAAP before and during the technical meeting of 4 November 2014 included details of the current CAAP organisational structure as well as proposed improvements that would enhance its oversight capabilities. Information was also provided on the current surveillance activity which CAAP conducts on air carriers certified in the Philippines. CAAP also cited ongoing infrastructure improvements and provided an update on the further proposed development of its State Safety Programme (SSP).

- (100) In its letter of 22 September 2014, the Commission also proposed that EASA would conduct an on-site technical assistance visit to the Philippines. This visit was conducted during the week of 10 November 2014.
- (101) The discussion and evidence provided by CAAP at the technical meeting of 4 November 2014 is deemed encouraging with regard to the progress that the competent authorities of the Philippines have made with respect to the oversight of air carriers certified in the Philippines. This opens the possibility for the organisation of an on-site Union verification mission in the future.
- (102) However, with regard to the CAAP objective to apply for a total lifting of the operating ban on air carriers certified in the Philippines, it needs to be underlined that this will necessitate a full evaluation of all relevant information and that the outcome of the on-site Union verification will need to be satisfactory.
- (103) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that there are at this stage no grounds for amending the Community list of air carriers which are subject to an operating ban within the Union with respect to air carriers from the Philippines.
- (104) Member States are to continue to verify effective compliance by *Philippine Airlines* and *Cebu Pacific Air* with the relevant safety standards, through the prioritisation of ramp inspections pursuant to Regulation (EU) No 965/2012.

Air carriers from the Russian Federation

- (105) The Commission, EASA and the Member States have continued to closely monitor the safety performance of air carriers certified in the Russian Federation and operating in the Union, including through prioritisation of the ramp inspections to be carried out on certain Russian air carriers in accordance with Regulation (EU) No 965/2012.
- (106) On 15 July 2014, the Commission met with representatives of the air carrier *Kogalymavia*, in order to confirm the effectiveness of the measures taken by that air carrier to improve its safety record. Overall, the progress made by *Kogalymavia* appeared sustainable. That air carrier is encouraged to continue to establish a positive safety culture inside its organisation, including reporting of essential safety-related information.
- (107) On 6 November 2014, the Commission, assisted by EASA and a Member State, met with representatives of the Russian Federal Air Transport Agency (FATA). The purpose of this meeting was to ensure that findings that have been raised against Russian air carriers during SAFA ramp inspections in the past 12 months are adequately addressed by those air carriers. During the meeting, FATA committed to further investigate the reasons for certain serious findings and to follow up on those cases where non-compliances have not yet been properly rectified.
- (108) On 21 November 2014 FATA informed the Commission that it had advised its air carriers to timely address all open findings in the SAFA database and to apply corrective actions on a continuous basis, in order to avoid problems with regard to SAFA inspections and findings.
- (109) Based on the available information, it was concluded that a hearing before the Air Safety Committee of the Russian aviation authorities or of air carriers certified in the Russian Federation was not necessary.
- (110) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that there are at this stage no grounds for amending the Community list of air carriers which are subject to an operating ban within the Union by including air carriers from the Russian Federation.
- (111) However, Member States are to continue to verify effective compliance by the air carriers for the Russian Federation with the international safety standards, through the prioritisation of ramp inspections in accordance with Regulation (EU) No 965/2012. Should those inspections point to an imminent safety risk as a consequence of non-compliance with the relevant safety standards, the Commission may be forced to take action against air carriers from the Russian Federation in accordance with Regulation (EC) No 2111/2005.

Air carriers from São Tomé and Príncipe

- (112) After a long period without communication, on 22 September 2014 the competent authorities of São Tomé and Príncipe (INAC) reported on the progress achieved over that period of time.
- (113) ICAO announced on 28 May 2014 the resolution of the SSCs pertaining to the air operator certification process and surveillance, and the ensuring of protection provided by aerodrome operators. As a consequence, São Tomé and Príncipe has now resolved all the previously identified SSCs.
- (114) The Corrective Action Plan submitted by INAC is currently being implemented. The summary of its execution in mid-April 2014 shows that 20 % of the activities planned for implementation before the end of November 2014 have been carried out as planned, while 25 % of those activities are still ongoing and the remaining 55 % have not yet started and have seen their target date significantly delayed.
- (115) INAC has revoked the AOCs of eight air carriers, namely British Gulf International Company Ltd, Executive Jet Services, Global Aviation Operation, Goliaf Air, Island Oil Exploration, Transafrik International Ltd, Transcargo and Transliz Aviation. INAC has provided written proof of the revocation of the AOCs of those air carriers.
- (116) The Commission takes note of the positive developments reported by INAC and commends in particular the revocation of the AOCs of the air carriers which had their principal place of business outside of the country, as well as the removal of all their aircraft from the registry of São Tomé and Príncipe.
- (117) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that the Community list of air carriers which are subject to an operating ban within the Union should be amended to remove those air carriers from Annex A to Regulation (EC) No 474/2006.
- (118) INAC also reported that AOCs have been issued to the air carriers STP Airways and Africa's Connection. However, INAC was not able to provide evidence that the safety oversight of those two air carriers is ensured in compliance with international safety standards.
- (119) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that the Community list of air carriers which are subject to an operating ban within the Union should be amended to include the air carriers STP Airways and Africa's Connection in Annex A to Regulation (EC) No 474/2006.

Air carriers from Sudan

- (120) The Sudan Civil Aviation Authority (SCAA) submitted to the Commission information on four air carriers, namely BADR Airlines (BDR), Nova Airlines (NOV), Sudan Airways (SUD) and Tarco Air (TRQ). The supporting documents indicate that those airlines have different levels in managing safety. Those documents nonetheless suggest that good progress has been made with a view to preparing a possible Union verification mission in 2015
- (121) SCAA also informed the Commission of the results of the latest ICAO audit in the areas of aerodromes and air navigation services. Although those audits address areas that are mostly unrelated to the technical domains of the Union's primary concerns relating to the air carriers registered in Sudan, namely personnel licences, operations and airworthiness, this has shown that SCAA has endeavoured to tackle all issues of aviation safety in a holistic approach.
- (122) It appears that SCAA has enacted sustainable improvements in a realistic and progressive manner. However, a thorough assessment still needs to be carried out in order to identify whether the international safety standards are met by the SCAA and the air carriers certified in Sudan. In addition, further verification through a Union verification mission needs to take place before any proposals for amendments to the Community list of air carriers, which are subject to an operating ban within the Union, might be considered.
- (123) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that there are at this stage no grounds for amending the Community list of air carriers which are subject to an operating ban within the Union with respect to air carriers from Sudan.

Air carriers from Zambia

- (124) By letter of 15 May 2014, the Zambian Department of Civil Aviation reported to the Commission that the Zambia Civil Aviation Authority (ZCAA) is operational and that its administrative capacity is being reinforced. That letter also provided an update on the corrective actions taken to address the existing deficiencies, including a Safety Plan, which the Commission received on 5 August 2014. That Safety Plan sets out the additional actions that need to be taken to establish an efficient and effective safety regulatory and oversight system in Zambia and contains clear goals for the short, medium and long term.
- (125) It appears that the Zambian Department of Civil Aviation has made progress and the Zambian authorities are encouraged to continue to make further improvements, with a view to the current restrictions being reconsidered at the appropriate moment after the necessary verification. However, for the time being, a number of important deficiencies remain, notably regarding the establishment of the ZCAA, including an adequate number of properly trained staff, and the update of legislation and regulations to implement the provisions of the ICAO Annexes which have been identified in the Safety Plan and in respect of which the corresponding actions are still to be carried out.
- (126) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, it is therefore assessed that there are at this stage no grounds for amending the Community list of air carriers which are subject to an operating ban within the Union with respect to air carriers from Zambia.
- (127) Article 8(2) of Regulation (EC) No 2111/2005 recognises the need for decisions to be taken swiftly and, where appropriate, urgently, given the safety implications. It is therefore essential, for the protection of sensitive information and for minimising commercial impacts, that the decisions in the context of updating the list of air carriers which are subject to an operating ban or restriction within the Union, are published and enter into force immediately after their adoption.
- (128) Regulation (EC) No 474/2006 should therefore be amended accordingly,
- (129) The measures provided for in this Regulation are in accordance with the opinion of the Air Safety Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 474/2006 is amended as follows:

- (1) Annex A is replaced by the text set out in Annex A to this Regulation;
- (2) Annex B is replaced by the text set out in Annex B 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, 11 December 2014.

For the Commission,
On behalf of the President,
Violeta BULC
Member of the Commission

ANNEX A

LIST OF AIR CARRIERS OF WHICH ALL OPERATIONS ARE SUBJECT TO A BAN WITHIN THE EU, WITH EXCEPTIONS $(^{\rm l})$

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
BLUE WING AIRLINES	SRBWA-01/2002	BWI	Suriname
MERIDIAN AIRWAYS LTD	AOC 023	MAG	Republic of Ghana
All air carriers certified by the authorities with responsibility for regulatory oversight of Afghanistan, including			Islamic Republic of Afghanistan
ARIANA AFGHAN AIRLINES	AOC 009	AFG	Islamic Republic of Afghanistan
KAM AIR	AOC 001	KMF	Islamic Republic of Afghanistan
PAMIR AIRLINES	Unknown	PIR	Islamic Republic of Afghanistan
SAFI AIRWAYS	AOC 181	SFW	Islamic Republic of Afghanistan
All air carriers certified by the authorities with responsibility for regulatory oversight of Angola, with the exception of TAAG Angola Airlines put in Annex B, including			Republic of Angola
AEROJET	AO 008-01/11	ТЕЈ	Republic of Angola
AIR GICANGO	009	Unknown	Republic of Angola
AIR JET	AO 006-01/11-MBC	MBC	Republic of Angola
AIR NAVE	017	Unknown	Republic of Angola
AIR26	AO 003-01/11-DCD	DCD	Republic of Angola
ANGOLA AIR SERVICES	006	Unknown	Republic of Angola
DIEXIM	007	Unknown	Republic of Angola
FLY540	AO 004-01 FLYA	Unknown	Republic of Angola
GIRA GLOBO	008	GGL	Republic of Angola
HELIANG	010	Unknown	Republic of Angola

⁽¹) Air carriers listed in Annex A could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
HELIMALONGO	AO 005-01/11	Unknown	Republic of Angola
MAVEWA	016	Unknown	Republic of Angola
SONAIR	AO 002-01/10-SOR	SOR	Republic of Angola
All air carriers certified by the authorities with responsibility for regulatory oversight of Benin, including			Republic of Benin
AERO BENIN	PEA No 014/MDCTTTATP- PR/ANAC/DEA/SCS	AEB	Republic of Benin
AFRICA AIRWAYS	Unknown	AFF	Republic of Benin
ALAFIA JET	PEA No 014/ANAC/ MDCTTTATP-PR/DEA/SCS	Unknown	Republic of Benin
BENIN GOLF AIR	PEA No 012/MDCTTP-PR/ ANAC/DEA/SCS.	BGL	Republic of Benin
BENIN LITTORAL AIRWAYS	PEA No 013/MDCTTTATP- PR/ANAC/DEA/SCS.	LTL	Republic of Benin
COTAIR	PEA No 015/MDCTTTATP- PR/ANAC/DEA/SCS.	СОВ	Republic of Benin
ROYAL AIR	PEA No 11/ANAC/ MDCTTP-PR/DEA/SCS	BNR	Republic of Benin
TRANS AIR BENIN	PEA No 016/MDCTTTATP- PR/ANAC/DEA/SCS	TNB	Republic of Benin
All air carriers certified by the authorities with responsibility for regulatory oversight of the Republic of Congo, including			Republic of Congo
AERO SERVICE	RAC06-002	RSR	Republic of Congo
CANADIAN AIRWAYS CONGO	RAC06-012	Unknown	Republic of Congo
EMERAUDE	RAC06-008	Unknown	Republic of Congo
EQUAFLIGHT SERVICES	RAC 06-003	EKA	Republic of Congo
EQUAJET	RAC06-007	EKJ	Republic of Congo
EQUATORIAL CONGO AIRLINES S.A.	RAC 06-014	Unknown	Republic of Congo
MISTRAL AVIATION	RAC06-011	Unknown	Republic of Congo
TRANS AIR CONGO	RAC 06-001	TSG	Republic of Congo



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
All air carriers certified by the authorities with responsibility for regulatory oversight of Democratic Republic of Congo (DRC), including			Democratic Republic of Congo (DRC)
AFRICAN AIR SERVICE COMMUTER	104/CAB/MIN/TVC/2012	Unknown	Democratic Republic of Congo (DRC)
AIR BARAKA	409/CAB/MIN/TVC/002/ 2011	Unknown	Democratic Republic of Congo (DRC)
AIR CASTILLA	409/CAB/MIN/TVC/007/ 2010	Unknown	Democratic Republic of Congo (DRC)
AIR FAST CONGO	409/CAB/MIN/TVC/0112/ 2011	Unknown	Democratic Republic of Congo (DRC)
AIR KASAI	409/CAB/MIN/TVC/0053/ 2012	Unknown	Democratic Republic of Congo (DRC)
AIR KATANGA	409/CAB/MIN/TVC/0056/ 2012	Unknown	Democratic Republic of Congo (DRC)
AIR MALEBO	409/CAB/MIN/TVC/0122/ 2012	Unknown	Democratic Republic of Congo (DRC)
AIR TROPIQUES	409/CAB/MIN/TVC/00625/ 2011	Unknown	Democratic Republic of Congo (DRC)
ARMI GLOBAL BUSINESS AIRWAYS	409/CAB/MIN/TVC/029/ 2012	Unknown	Democratic Republic of Congo (DRC)
BIEGA AIRWAYS	409/CAB/MIN/TVC/051/ 2012	Unknown	Democratic Republic of Congo (DRC)
BLUE AIRLINES	106/CAB/MIN/TVC/2012	BUL	Democratic Republic of Congo (DRC)
BLUE SKY	409/CAB/MIN/TVC/0028/ 2012	Unknown	Democratic Republic of Congo (DRC)
BUSINESS AVIATION	409/CAB/MIN/TVC/048/09	ABB	Democratic Republic of Congo (DRC)
BUSY BEE CONGO	409/CAB/MIN/TVC/0064/ 2010	Unknown	Democratic Republic of Congo (DRC)
CETRACA	105/CAB/MIN/TVC/2012	CER	Democratic Republic of Congo (DRC)
CHC STELLAVIA	409/CAB/MIN/TVC/0078/ 2011	Unknown	Democratic Republic of Congo (DRC)
COMPAGNIE AFRICAINE D'AVIATION (CAA)	409/CAB/MIN/TVC/0050/ 2012	Unknown	Democratic Republic of Congo (DRC)
CONGO EXPRESS AIRLINES	409/CAB/MIN/TVC/059/ 2012	CXR	Democratic Republic of Congo (DRC)
DOREN AIR CONGO	102/CAB/MIN/TVC/2012	Unknown	Democratic Republic of Congo (DRC)



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
EAGLES SERVICES	409/CAB/MIN/TVC/0196/ 2011	Unknown	Democratic Republic of Congo (DRC)
EPHRATA AIRLINES	409/CAB/MIN/TVC/040/ 2011	Unknown	Democratic Republic of Congo (DRC)
FILAIR	409/CAB/MIN/TVC/037/ 2008	Unknown	Democratic Republic of Congo (DRC)
FLY CONGO	409/CAB/MIN/TVC/0126/ 2012	Unknown	Democratic Republic of Congo (DRC)
GALAXY KAVATSI	409/CAB/MIN/TVC/0027/ 2008	Unknown	Democratic Republic of Congo (DRC)
GILEMBE AIR SOUTENANCE (GISAIR)	409/CAB/MIN/TVC/0082/ 2010	Unknown	Democratic Republic of Congo (DRC)
GOMA EXPRESS	409/CAB/MIN/TVC/0051/ 2011	Unknown	Democratic Republic of Congo (DRC)
GOMAIR	409/CAB/MIN/TVC/011/ 2010	Unknown	Democratic Republic of Congo (DRC)
GTRA	409/CAB/MIN/TVC/0060/ 2011	Unknown	Democratic Republic of Congo (DRC)
INTERNATIONAL TRANS AIR BUSINESS (ITAB)	409/CAB/MIN/TVC/0065/ 2010	Unknown	Democratic Republic of Congo (DRC)
JET CONGO AIRLINES	409/CAB/MIN/TVC/0011/ 2012	Unknown	Democratic Republic of Congo (DRC)
KATANGA EXPRESS	409/CAB/MIN/TVC/0083/ 2010	Unknown	Democratic Republic of Congo (DRC)
KATANGA WINGS	409/CAB/MIN/TVC/0092/ 2011	Unknown	Democratic Republic of Congo (DRC)
KIN AVIA	409/CAB/MIN/TVC/0059/ 2010	Unknown	Democratic Republic of Congo (DRC)
KORONGO AIRLINES	409/CAB/MIN/TVC/001/ 2011	KGO	Democratic Republic of Congo (DRC)
LIGNES AERIENNES CONGOLAISES (LAC)	Ministerial signature (ordonnance No. 78/205)	LCG	Democratic Republic of Congo (DRC)
MANGO AIRLINES	409/CAB/MIN/TVC/009/ 2011	Unknown	Democratic Republic of Congo (DRC)
MAVIVI AIR TRADE	409/CAB/MIN/TVC/00/ 2011	Unknown	Democratic Republic of Congo (DRC)
OKAPI AIRLINES	409/CAB/MIN/TVC/086/ 2011	OKP	Democratic Republic of Congo (DRC)
PATRON AIRWAYS	409/CAB/MIN/TVC/0066/ 2011	Unknown	Democratic Republic of Congo (DRC)

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
PEGASUS	409/CAB/MIN/TVC/021/ 2012	Unknown	Democratic Republic of Congo (DRC)
SAFE AIR	409/CAB/MIN/TVC/021/ 2008	Unknown	Democratic Republic of Congo (DRC)
SERVICES AIR	103/CAB/MIN/TVC/2012	Unknown	Democratic Republic of Congo (DRC)
SION AIRLINES	409/CAB/MIN/TVC/0081/ 2011	Unknown	Democratic Republic of Congo (DRC)
STELLAR AIRWAYS	409/CAB/MIN/TVC/056/ 2011	Unknown	Democratic Republic of Congo (DRC)
SWALA AVIATION	409/CAB/MIN/TVC/0084/ 2010	Unknown	Democratic Republic of Congo (DRC)
TRACEP CONGO	409/CAB/MIN/TVC/0085/ 2010	Unknown	Democratic Republic of Congo (DRC)
TRANSAIR CARGO SERVICES	409/CAB/MIN/TVC/073/ 2011	Unknown	Democratic Republic of Congo (DRC)
WALTAIR AVIATION	409/CAB/MIN/TVC/004/ 2011	Unknown	Democratic Republic of Congo (DRC)
WILL AIRLIFT	409/CAB/MIN/TVC/0247/ 2011	Unknown	Democratic Republic of Congo (DRC)
WIMBI DIRA AIRWAYS	409/CAB/MIN/TVC/039/ 2008	WDA	Democratic Republic of Congo (DRC)
All air carriers certified by the authorities with responsibility for regulatory oversight of Djibouti, including			Djibouti
DAALLO AIRLINES	Unknown	DAO	Djibouti
All air carriers certified by the authorities with responsibility for regulatory oversight of Equatorial Guinea, including			Equatorial Guinea
CEIBA INTERCONTINENTAL	2011/0001/MTTCT/DGAC/ SOPS	CEL	Equatorial Guinea
CRONOS AIRLINES	2011/0004/MTTCT/DGAC/ SOPS	Unknown	Equatorial Guinea
PUNTO AZUL	2012/0006/MTTCT/DGAC/ SOPS	Unknown	Equatorial Guinea
TANGO AIRWAYS	Unknown	Unknown	Equatorial Guinea
All air carriers certified by the authorities with responsibility for regulatory oversight of Eritrea, including			Eritrea



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
ERITREAN AIRLINES	AOC No 004	ERT	Eritrea
NASAIR ERITREA	AOC No 005	NAS	Eritrea
All air carriers certified by the authorities with responsibility for regulatory oversight of the Republic of Gabon, with the exception of Gabon Airlines, Afrijet and SN2AG put in Annex B, including			Republic of Gabon
AFRIC AVIATION	010/MTAC/ANAC-G/DSA	EKG	Republic of Gabon
AIR SERVICES SA	004/MTAC/ANAC-G/DSA	RVS	Republic of Gabon
AIR TOURIST (ALLEGIANCE)	007/MTAC/ANAC-G/DSA	LGE	Republic of Gabon
NATIONALE ET REGIONALE TRANSPORT (NATIONALE)	008/MTAC/ANAC-G/DSA	NRG	Republic of Gabon
SCD AVIATION	005/MTAC/ANAC-G/DSA	SCY	Republic of Gabon
SKY GABON	009/MTAC/ANAC-G/DSA	SKG	Republic of Gabon
SOLENTA AVIATION GABON	006/MTAC/ANAC-G/DSA	SVG	Republic of Gabon
All air carriers certified by the authorities with responsibility for regulatory oversight of Indonesia, with the exception of Garuda Indonesia, Airfast Indonesia, Mandala Airlines, Ekspres Transportasi Antarbenua and Indonesia Air Asia, including			Republic of Indonesia
AIR BORN INDONESIA	135-055	Unknown	Republic of Indonesia
AIR PACIFIC UTAMA	135-020	Unknown	Republic of Indonesia
ALFA TRANS DIRGANTATA	135-012	Unknown	Republic of Indonesia
ANGKASA SUPER SERVICES	135-050	LBZ	Republic of Indonesia
ASCO NUSA AIR	135-022	Unknown	Republic of Indonesia
ASI PUDJIASTUTI	135-028	sQs	Republic of Indonesia
AVIASTAR MANDIRI	121-043	Unknown	Republic of Indonesia



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
AVIASTAR MANDIRI	135-029	VIT	Republic of Indonesia
BATIK AIR	121-050	ВТК	Republic of Indonesia
CITILINK INDONESIA	121-046	CTV	Republic of Indonesia
DABI AIR NUSANTARA	135-030	Unknown	Republic of Indonesia
DERAYA AIR TAXI	135-013	DRY	Republic of Indonesia
DERAZONA AIR SERVICE	135-010	DRZ	Republic of Indonesia
DIRGANTARA AIR SERVICE	135-014	DIR	Republic of Indonesia
EASTINDO	135-038	ESD	Republic of Indonesia
ELANG LINTAS INDONESIA	135-052	Unknown	Republic of Indonesia
ELANG NUSANTARA AIR	135-053	Unknown	Republic of Indonesia
ENGGANG AIR SERVICE	135-045	Unknown	Republic of Indonesia
ERSA EASTERN AVIATION	135-047	Unknown	Republic of Indonesia
GATARI AIR SERVICE	135-018	GHS	Republic of Indonesia
HEAVY LIFT	135-042	Unknown	Republic of Indonesia
INDONESIA AIR ASIA EXTRA	121-054	Unknown	Republic of Indonesia
INDONESIA AIR TRANSPORT	121-034	IDA	Republic of Indonesia
INTAN ANGKASA AIR SERVICE	135-019	Unknown	Republic of Indonesia
JAYAWIJAYA DIRGANTARA	121-044	JWD	Republic of Indonesia
JOHNLIN AIR TRANSPORT	135-043	JLB	Republic of Indonesia
KAL STAR	121-037	KLS	Republic of Indonesia
KARTIKA AIRLINES	121-003	KAE	Republic of Indonesia
KOMALA INDONESIA	135-051	Unknown	Republic of Indonesia
KURA-KURA AVIATION	135-016	KUR	Republic of Indonesia
LION MENTARI AIRLINES	121-010	LNI	Republic of Indonesia
MANUNGGAL AIR SERVICE	121-020	MNS	Republic of Indonesia
		1	1



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
MARTABUANA ABADION	135-049	Unknown	Republic of Indonesia
MATTHEW AIR NUSANTARA	135-048	Unknown	Republic of Indonesia
MERPATI NUSANTARA AIRLINES	121-002	MNA	Republic of Indonesia
MIMIKA AIR	135-007	Unknown	Republic of Indonesia
MY INDO AIRLINES	121-042	Unknown	Republic of Indonesia
NAM AIR	121-058	Unknown	Republic of Indonesia
NATIONAL UTILITY HELICOPTER	135-011	Unknown	Republic of Indonesia
NUSANTARA AIR CHARTER	121-022	SJK	Republic of Indonesia
NUSANTARA BUANA AIR	135-041	Unknown	Republic of Indonesia
PACIFIC ROYALE AIRWAYS	121-045	PRQ	Republic of Indonesia
PEGASUS AIR SERVICES	135-036	Unknown	Republic of Indonesia
PELITA AIR SERVICE	121-008	PAS	Republic of Indonesia
PENERBANGAN ANGKASA SEMESTA	135-026	Unknown	Republic of Indonesia
PURA WISATA BARUNA	135-025	Unknown	Republic of Indonesia
RIAU AIRLINES	121-016	RIU	Republic of Indonesia
SAYAP GARUDA INDAH	135-004	Unknown	Republic of Indonesia
SKY AVIATION	121-028	Unknown	Republic of Indonesia
SKY AVIATION	135-044	Unknown	Republic of Indonesia
SMAC	135-015	SMC	Republic of Indonesia
SRIWIJAYA AIR	121-035	SJY	Republic of Indonesia
SURVEI UDARA PENAS	135-006	PNS	Republic of Indonesia
SURYA AIR	135-046	Unknown	Republic of Indonesia
TRANSNUSA AVIATION MANDIRI	121-048	TNU	Republic of Indonesia



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
TRANSWISATA PRIMA AVIATION	135-021	TWT	Republic of Indonesia
TRAVEL EXPRESS AVIATION SERVICE	121-038	XAR	Republic of Indonesia
TRAVIRA UTAMA	135-009	TVV	Republic of Indonesia
TRI MG INTRA ASIA AIRLINES	121-018	TMG	Republic of Indonesia
TRIGANA AIR SERVICE	121-006	TGN	Republic of Indonesia
UNINDO	135-040	Unknown	Republic of Indonesia
WING ABADI AIRLINES	121-012	WON	Republic of Indonesia
All air carriers certified by the authorities with responsibility for regulatory oversight of Kazakhstan, with the exception of Air Astana, including			Republic of Kazakh- stan
AIR ALMATY	AK-0483-13	LMY	Republic of Kazakhstan
ATMA AIRLINES	AK-0469-12	AMA	Republic of Kazakhstan
AVIA-JAYNAR/AVIA-ZHAYNAR	AK-0467-12	SAP	Republic of Kazakhstan
BEK AIR	AK-0463-12	BEK	Republic of Kazakhstar
BEYBARS AIRCOMPANY	AK-0473-13	BBS	Republic of Kazakhstar
BURUNDAYAVIA AIRLINES	KZ-01/001	BRY	Republic of Kazakhstan
COMLUX-KZ	KZ-01/002	KAZ	Republic of Kazakhstan
EAST WING	KZ-01/007	EWZ	Republic of Kazakhstar
EURO-ASIA AIR	AK-0472-13	EAK	Republic of Kazakhstar
FLY JET KZ	AK-0477-13	FJK	Republic of Kazakhstar
INVESTAVIA	AK-0479-13	TLG	Republic of Kazakhstar
IRTYSH AIR	AK-0468-13	MZA	Republic of Kazakhstar



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
JET AIRLINES	KZ-01/003	SOZ	Republic of Kazakhstan
KAZAIR JET	AK-0474-13	KEJ	Republic of Kazakhstan
KAZAIRTRANS AIRLINE	AK-0466-12	KUY	Republic of Kazakhstan
KAZAVIASPAS	AK-0484-13	KZS	Republic of Kazakhstan
PRIME AVIATION	AK-0478-13	PKZ	Republic of Kazakhstan
SCAT	KZ-01/004	VSV	Republic of Kazakhstan
ZHETYSU AIRCOMPANY	AK-0470-12	JTU	Republic of Kazakhstan
All air carriers certified by the authorities with responsibility for regulatory oversight of the Kyrgyz Republic, including			Kyrgyz Republic
AIR BISHKEK (formerly EASTOK AVIA)	15	EAA	Kyrgyz Republic
AIR MANAS	17	MBB	Kyrgyz Republic
AVIA TRAFFIC COMPANY	23	AVJ	Kyrgyz Republic
CENTRAL ASIAN AVIATION SERVICES (CAAS)	13	СВК	Kyrgyz Republic
HELI SKY	47	HAC	Kyrgyz Republic
AIR KYRGYZSTAN	03	LYN	Kyrgyz Republic
MANAS AIRWAYS	42	BAM	Kyrgyz Republic
S GROUP INTERNATIONAL (formerly S GROUP AVIATION)	45	INT	Kyrgyz Republic
SKY BISHKEK	43	BIS	Kyrgyz Republic
SKY KG AIRLINES	41	KGK	Kyrgyz Republic
SKY WAY AIR	39	SAB	Kyrgyz Republic



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
TEZ JET	46	TEZ	Kyrgyz Republic
VALOR AIR	07	VAC	Kyrgyz Republic
All air carriers certified by the authorities with responsibility for regulatory oversight of Liberia.			Liberia
All air carriers certified by the authorities with responsibility for regulatory oversight of Libya, including			Libya
AFRIQIYAH AIRWAYS	007/01	AAW	Libya
AIR LIBYA	004/01	TLR	Libya
BURAQ AIR	002/01	BRQ	Libya
GHADAMES AIR TRANSPORT	012/05	GHT	Libya
GLOBAL AVIATION AND SERVICES	008/05	GAK	Libya
LIBYAN AIRLINES	001/01	LAA	Libya
PETRO AIR	025/08	PEO	Libya
All air carriers certified by the authorities with responsibility for regulatory oversight of the Republic of Mozambique, including			Republic of Mozambique
AERO-SERVIÇOS SARL	MOZ-08	Unknown	Republic of Mozam- bique
CFM — TRABALHOS E TRANSPORTES AÉREOS LDA	MOZ-07	Unknown	Republic of Mozam- bique
COA — COASTAL AVIATION	MOZ-15	Unknown	Republic of Mozambique
CPY — CROPSPRAYERS	MOZ-06	Unknown	Republic of Mozam- bique
CRA — CR AVIATION LDA	MOZ-14	Unknown	Republic of Mozam- bique
EMÍLIO AIR CHARTER LDA	MOZ-05	Unknown	Republic of Mozam- bique
ETA — EMPRESA DE TRANSPORTES AÉREOS LDA	MOZ-04	Unknown	Republic of Mozambique



Name of the legal entity of the air carrier as	Air Operator Certificate ('AOC')	ICAO airline	
indicated on its AOC (and its trading name, if different)	Number or Operating Licence Number	designation number	State of the Operator
HCP — HELICÓPTEROS CAPITAL LDA	MOZ-11	Unknown	Republic of Mozambique
KAY — KAYA AIRLINES, LDA	MOZ-09	KYY	Republic of Mozambique
LAM — LINHAS AÉREAS DE MOÇAMBIQUE S.A.	MOZ-01	LAM	Republic of Mozambique
MAKOND, LDA	MOZ-20	Unknown	Republic of Mozambique
MEX — MOÇAMBIQUE EXPRESSO, SARL MEX	MOZ-02	MXE	Republic of Mozam- bique
OHI — OMNI HELICÓPTEROS INTERNA- TIONAL LDA	MOZ-17	Unknown	Republic of Mozam- bique
SAF — SAFARI AIR LDA	MOZ-12	Unknown	Republic of Mozam- bique
SAM — SOLENTA AVIATION MOZAM- BIQUE, SA	MOZ-10	Unknown	Republic of Mozam- bique
TTA — TRABALHOS E TRANSPORTES AÉREOS LDA	MOZ-16	TTA	Republic of Mozam- bique
UNIQUE AIR CHARTER LDA	MOZ-13	Unknown	Republic of Mozambique
All air carriers certified by the authorities with responsibility for regulatory oversight of Nepal, including			Republic of Nepal
AIR DYNASTY HELI. S.	035/2001	Unknown	Republic of Nepal
AIR KASTHAMANDAP	051/2009	Unknown	Republic of Nepal
BUDDHA AIR	014/1996	ВНА	Republic of Nepal
FISHTAIL AIR	017/2001	Unknown	Republic of Nepal
GOMA AIR	064/2010	Unknown	Republic of Nepal
MAKALU AIR	057A/2009	Unknown	Republic of Nepal
MANANG AIR PVT LTD	082/2014	Unknown	Republic of Nepal
MOUNTAIN HELICOPTERS	055/2009	Unknown	Republic of Nepal
MUKTINATH AIRLINES	081/2013	Unknown	Republic of Nepal



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
NEPAL AIRLINES CORPORATION	003/2000	RNA	Republic of Nepal
SHREE AIRLINES	030/2002	SHA	Republic of Nepal
SIMRIK AIR	034/2000	Unknown	Republic of Nepal
SIMRIK AIRLINES	052/2009	RMK	Republic of Nepal
SITA AIR	033/2000	Unknown	Republic of Nepal
TARA AIR	053/2009	Unknown	Republic of Nepal
YETI AIRLINES DOMESTIC	037/2004	NYT	Republic of Nepal
All air carriers certified by the authorities with responsibility for regulatory oversight of the Philippines, with the exception of Philippine Airlines and Cebu Pacific Air, including:			Republic of the Philippines
AEROEQUIPEMENT AVIATION	2010037	Unknown	Republic of the Philippines
AIR ASIA PHILIPPINES	2012047	APG	Republic of the Philip- pines
AIR JUAN AVIATION	2013053	Unknown	Republic of the Philip- pines
AIR PHILIPPINES CORPORATION	2009006	GAP	Republic of the Philip- pines
ASIA AIRCRAFT OVERSEAS PHILIPPINES INC.	2012048	Unknown	Republic of the Philip- pines
ASIAN AEROSPACE CORPORATION	2012050	Unknown	Republic of the Philip- pines
ASTRO AIR INTERNATIONAL	2012049	AAV	Republic of the Philip- pines
AYALA AVIATION CORP.	4AN9900003	Unknown	Republic of the Philip- pines
CANADIAN HELICOPTERS PHILIPPINES INC.	2010026	Unknown	Republic of the Philippines
CM AERO SERVICES	20110401	Unknown	Republic of the Philippines
CYCLONE AIRWAYS	2010034	Unknown	Republic of the Philippines



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
FAR EAST AVIATION SERVICES	2009013	Unknown	Republic of the Philip- pines
INAEC AVIATION CORP.	2010028	Unknown	Republic of the Philip- pines
INTERISLAND AIRLINES	2010023	ISN	Republic of the Philip- pines
ISLAND AVIATION	2009009	SOY	Republic of the Philip- pines
ISLAND TRANSVOYAGER	2010022	ITI	Republic of the Philip- pines
LION AIR	2009019	Unknown	Republic of the Philip- pines
MACRO ASIA AIR TAXI SERVICES	2010029	Unknown	Republic of the Philip- pines
MAGNUM AIR	2012051	MSJ	Republic of the Philippines
MISIBIS AVIATION & DEVELOPMENT CORP	2010020	Unknown	Republic of the Philippines
NORTHSKY AIR INC.	2011042	Unknown	Republic of the Philippines
OMNI AVIATION CORP.	2010033	Unknown	Republic of the Philip- pines
ROYAL AIR CHARTER SERVICES INC.	2010024	Unknown	Republic of the Philip- pines
ROYAL STAR AVIATION, INC.	2010021	Unknown	Republic of the Philip- pines
SOUTH EAST ASIAN AIRLINES	2009 004	SRQ	Republic of the Philip- pines
SOUTH EAST ASIAN AIRLINES (SEAIR) INTERNATIONAL	2012052	SGD	Republic of the Philippines
SOUTHERN AIR FLIGHT SERVICES	2011045	Unknown	Republic of the Philippines
SUBIC SEAPLANE, INC.	2011035	Unknown	Republic of the Philippines
WCC AVIATION COMPANY	2009015	Unknown	Republic of the Philippines
ZEST AIRWAYS INCORPORATED	2009003	EZD	Republic of the Philippines



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator	
All air carriers certified by the authorities with responsibility for regulatory oversight of Sao Tome and Principe, including			Sao Tome and Principe	
AFRICA'S CONNECTION	10/AOC/2008	ACH	Sao Tome and Principe	
STP AIRWAYS	03/AOC/2006	STP	Sao Tome and Principe	
All air carriers certified by the authorities with responsibility for regulatory oversight of Sierra Leone, including			Sierra Leone	
AIR RUM, LTD	UNKNOWN	RUM	Sierra Leone	
DESTINY AIR SERVICES, LTD	UNKNOWN	DTY	Sierra Leone	
HEAVYLIFT CARGO	UNKNOWN	Unknown	Sierra Leone	
ORANGE AIR SIERRA LEONE LTD	UNKNOWN	ORJ	Sierra Leone	
PARAMOUNT AIRLINES, LTD	UNKNOWN	PRR	Sierra Leone	
SEVEN FOUR EIGHT AIR SERVICES LTD	UNKNOWN	SVT	Sierra Leone	
TEEBAH AIRWAYS	UNKNOWN	Unknown	Sierra Leone	
All air carriers certified by the authorities with responsibility for regulatory oversight of Sudan, including			Republic of Sudan	
ALFA AIRLINES	54	AAJ	Republic of the Sudan	
ALMAJAL AVIATION SERVICE	15	MGG	Republic of the Sudan	
BADER AIRLINES	35	BDR	Republic of the Sudan	
BENTIU AIR TRANSPORT	29	BNT	Republic of the Sudan	
BLUE BIRD AVIATION	11	BLB	Republic of the Sudan	
DOVE AIRLINES	52	DOV	Republic of the Sudan	
ELIDINER AVIATION	8	DND	Republic of the Sudan	
FOURTY EIGHT AVIATION	53	WHB	Republic of the Sudan	



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO airline designation number	State of the Operator
GREEN FLAG AVIATION	17	Unknown	Republic of the Sudan
HELEJETIC AIR	57	НЈТ	Republic of the Sudan
KATA AIR TRANSPORT	9	KTV	Republic of the Sudan
KUSH AVIATION	60	KUH	Republic of the Sudan
MARSLAND COMPANY	40	MSL	Republic of the Sudan
MID AIRLINES	25	NYL	Republic of the Sudan
NOVA AIRLINES	46	NOV	Republic of the Sudan
SUDAN AIRWAYS	1	SUD	Republic of the Sudan
SUN AIR COMPANY	51	SNR	Republic of the Sudan
TARCO AIRLINES	56	TRQ	Republic of the Sudan
All air carriers certified by the authorities with responsibility for regulatory oversight of Zambia, including			Zambia
ZAMBEZI AIRLINES	Z/AOC/001/2009	ZMA	Zambia

ANNEX B

LIST OF AIR CARRIERS OF WHICH OPERATIONS ARE SUBJECT TO OPERATIONAL RESTRICTIONS WITHIN THE EU $(^{!})$

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number	ICAO airline designation number	State of the Operator	Aircraft type restricted	Registration mark(s) and, when available, construction serial number(s) of restricted aircraft	State of registry
TAAG ANGOLA AIRLINES	001	DTA	Republic of Angola	All fleet with the exception of: 5 aircraft of type Boeing B777 and 4 aircraft of type Boeing B737-700.	All fleet with the exception of: D2-TED, D2-TEE, D2-TEF, D2-TEG, D2-TEH, D2-TBF, D2-TBG, D2-TBH, D2-TBJ.	Republic of Angola
AIR ASTANA (¹)	AK-0475-13	KZR	Kazakhstan	All fleet with the exception of: aircraft of type Boeing B767, aircraft of type Boeing B757, aircraft of type Airbus A319/320/321.	All fleet with the exception of: aircraft within the Boeing B767 fleet, as mentioned on the AOC; aircraft within the Boeing B757 fleet, as mentioned on the AOC; aircraft within the Airbus A319/320/321 fleet, as mentioned on the AOC.	Aruba (Kingdom of the Nether- lands)
AIR SERVICE COMORES	06-819/TA- 15/DGACM	KMD	Comoros	All fleet with the exception of: LET 410 UVP.	All fleet with the exception of: D6-CAM (851336).	Comoros
AFRIJET (²)	002/MTAC/ ANAC-G/ DSA	ABS	Republic of Gabon	All fleet with the exception of: 2 aircraft of type Falcon 50, 2 aircraft of type Falcon 900.	All fleet with the exception of: TR-LGV; TR-LGY; TR-AFJ; TR-AFR.	Republic of Gabon
GABON AIRLINES (³)	001/MTAC/ ANAC	GBK	Republic of Gabon	All fleet with the exception of: 1 aircraft of type Boeing B767-200.	All fleet with the exception of: TR-LHP.	Republic of Gabon
NOUVELLE AIR AFFAIRES GABON (SN2AG)	003/MTAC/ ANAC-G/ DSA	NVS	Republic of Gabon	All fleet with the exception of: 1 aircraft of type Challenger CL-601, 1 aircraft of type HS-125-800.	All fleet with the exception of: TR-AAG, ZS-AFG.	Republic of Gabon; Republic of South Africa
AIRLIFT INTER- NATIONAL (GH) LTD	AOC 017	ALE	Republic of Ghana	All fleet with the exception of: 2 aircraft of type DC8-63F.	All fleet with the exception of: 9G-TOP and 9G-RAC.	Republic of Ghana

⁽¹) Air carriers listed in Annex B could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.



Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number	ICAO airline designation number	State of the Operator	Aircraft type restricted	Registration mark(s) and, when available, construction serial number(s) of restricted aircraft	State of registry
IRAN AIR (4)	FS100	IRA	Islamic Republic of Iran	All fleet with the exception of: 14 aircraft of type Airbus A300, 8 aircraft of type Airbus A310, 1 aircraft Boeing B737.	All fleet with the exception of: EP-IBA, EP-IBB, EP-IBC, EP-IBD, EP-IBG, EP-IBH, EP-IBI, EP-IBJ, EP-IBN, EP-IBO, EP-IBS, EP-IBT, EP-IBV, EP-IBZ, EP-ICE, EP-ICE, EP-ICF, EP-IBL, EP-IBL, EP-IBL, EP-IBC, EP-IBL, EP-IBC, EP-IBC, EP-IBC, EP-ICE, EP-IC	Islamic Republic of Iran
AIR KORYO	GAC-AOC/ KOR-01	KOR	Democratic People's Republic of Korea	All fleet with the exception of: 2 aircraft of type TU- 204.	All fleet with the exception of: P-632, P-633.	Democratic People's Republic of Korea
AIR MADA- GASCAR	5R-M01/ 2009	MDG	Madagascar	All fleet with the exception of: aircraft of type Boeing B737, aircraft of type ATR 72/42 and 3 aircraft of type DHC 6-300.	All fleet with the exception of: aircraft within the Boeing B737 fleet, as mentioned on the AOC, aircraft within the ATR 72/42 fleet, as mentioned on the AOC; 5R-MGC, 5R-MGD, 5R-MGF.	Republic of Madagascar

⁽¹⁾ Air Astana is only allowed to use the specific aircraft types mentioned, provided that they are registered in Aruba and that all changes to the AOC are timely submitted to the Commission and to Eurocontrol.

Afrijet is only allowed to use the specific aircraft mentioned for its current level of operations within the Union.

Gabon Airlines is only allowed to use the specific aircraft mentioned for its current level of operations within the Union.

Iran Air is allowed to operate to the Union using the specific aircraft under the conditions set out in Recital (69) of Regulation (EU) No 590/2010, OJ L 170, 6.7.2010, p. 15.

COMMISSION IMPLEMENTING REGULATION (EU) No 1319/2014

of 11 December 2014

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (1),

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors (²), and in particular Article 136(1) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.
- (2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the Official Journal of the European Union,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 11 December 2014.

For the Commission,

On behalf of the President,

Jerzy PLEWA

Director-General for Agriculture and Rural Development

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²) OJ L 157, 15.6.2011, p. 1.

 $\label{eq:annex} ANNEX$ Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	AL	62,5
	IL	107,2
	MA	81,6
	TN	139,2
	TR	112,1
	ZZ	100,5
0707 00 05	AL	63,5
	EG	191,6
	MA	164,1
	TR	138,7
	ZZ	139,5
0709 93 10	MA	64,0
	TR	122,0
	ZZ	93,0
0805 10 20	AR	35,3
	MA	68,6
	SZ	37,7
	TR	61,9
	UY	32,9
	ZA	34,5
	ZW	33,9
	ZZ	43,5
0805 20 10	MA	61,0
	ZZ	61,0
0805 20 30, 0805 20 50,	IL	102,5
0805 20 70, 0805 20 90	TR	77,8
	ZZ	90,2
0805 50 10	TR	71,9
	ZZ	71,9
0808 10 80	BR	51,7
	CA	135,6
	CL	79,6
	NZ	90,6
	US	117,2
	ZA	143,4
	ZZ	103,0

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0808 30 90	CN	82,9
	TR	174,9
	US	173,2
	ZZ	143,7

⁽¹) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DIRECTIVES

COMMISSION DIRECTIVE 2014/106/EU

of 5 December 2014

amending Annexes V and VI to Directive 2008/57/EC of the European Parliament and of the Council on the interoperability of the rail system within the Community

(Text with EEA relevance)

THE EUROPEAN COMMISSION.

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

Having regard to 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 (1), and in particular Article 30(3) thereof,

Whereas:

- (1) The scope and the content of the 'EC' declaration of verification for subsystems should be better defined in Annex V to Directive 2008/57/EC. In particular, the responsibility of the signatory of such declaration should be clearly stated.
- (2) The procedures concerning the declaration of verification in case of modifications of existing subsystems and in case of additional verifications carried out by the notified bodies should be clarified in Annex V to Directive 2008/57/EC;
- (3) The aim of the verification procedure for subsystems should be clarified in Annex VI to Directive 2008/57/EC. Furthermore, the principles concerning the verification procedure in case of modifications of existing subsystems should be defined in the same Annex.
- (4) The measures provided for in this Directive are in accordance with the opinion of the Committee established in accordance with Article 29(1) of Directive 2008/57/EC.

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes V and VI to Directive 2008/57/EC are replaced by the text set out in Annexes I and II to this Directive respectively.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 January 2016 at the latest. They shall forthwith communicate to the Commission the text of those acts.

When Member States adopt those acts, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

- 2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.
- 3. The obligations for transposition and implementation of this Directive shall not apply to the Republic of Cyprus and the Republic of Malta for as long as no railway system is established within their territories.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 5 December 2014.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

'ANNEX V

"EC" DECLARATION OF VERIFICATION OF SUBSYSTEMS

1. "EC" DECLARATION OF VERIFICATION OF SUBSYSTEMS

The "EC" declaration of verification of a subsystem is a declaration established by the "applicant" within the meaning of Article 18 in which he declares on his sole responsibility that the subsystem concerned, which has been subject to the relevant verifications procedures, satisfies the requirements of the relevant Union legislation, including any relevant national rules.

The "EC" declaration of verification and the accompanying documents must be dated and signed.

The "EC" declaration of verification must be based on the information resulting from the "EC" verification procedure for subsystems set out in Annex VI. It must be written in the same language as the technical file accompanying the "EC" declaration of verification and must contain at least the following:

- (a) the reference to this Directive, TSIs and applicable national rules,
- (b) the reference to the TSI(s) or their parts to which conformity has not been examined during EC verification procedure and to the national rules which have been applied in case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case,
- (c) name and address of the "applicant" within the meaning of Article 18 (specifying the trade name and full address; in the case of the authorised representative, specifying also the trade name of the contracting entity or the manufacturer),
- (d) a brief description of the subsystem,
- (e) name(s) and address(es) and the identification number(s) of the notified body(ies) which conducted the "EC" verification(s) referred to in Article 18,
- (f) name(s) and address(es) and the identification number(s) of the notified body(ies) which conducted the assessment of conformity with other regulations deriving from the Treaty,
- (g) name(s) and address(es) of the designated body(ies) which conducted the verification(s) of conformity with national rules referred to in Article 17(3),
- (h) name and address of the assessment body(ies) which established the safety assessment reports related to the use of the CSM on risk assessment where required by this Directive,
- (i) the references of the documents contained in the technical file accompanying the "EC" declaration of verification,
- (j) all the relevant temporary or final provisions to be complied with by the subsystems and in particular, where appropriate, any operating restrictions or conditions,
- (k) the identity of the signatory (i.e. the physical person or persons authorised to sign the declaration)

Where reference is made in Annex VI to the "intermediate statement of verification" (ISV), the provisions of this Section shall apply to that declaration.

2. "EC" DECLARATION OF VERIFICATION OF SUBSYSTEMS IN THE CASE OF MODIFICATIONS

In a case of a modification, which is not a substitution in the framework of maintenance, of a subsystem covered by an "EC" declaration of verification, without prejudice to Article 20, the following provisions apply.

- 2.1. If the entity introducing the modification demonstrates that the modification does not affect the basic design characteristics of the subsystem which are relevant for the compliance with the requirements concerning the basic parameters:
 - (a) the entity introducing the modification shall update the references of the documents contained in the technical file accompanying the "EC" declaration of verification;
 - (b) no new "EC" declaration of verification needs to be established.
- 2.2. If the entity introducing the modification demonstrates that the modification affects the basic design characteristics of the subsystem which are relevant for the compliance with the requirements concerning some basic parameters:
 - (a) the entity introducing the modification shall establish a complementary "EC" declaration of verification with reference to the basic parameters concerned;
 - (b) the complementary "EC" declaration of verification shall be accompanied by a list of documents of the original technical file accompanying the original "EC" declaration of verification that are no more valid;
 - (c) the technical file accompanying the "EC" declaration of verification shall include a demonstration that the impact of modifications is limited to the basic parameters referred to in point (a);
 - (d) provisions of Section 1 of this Annex shall apply mutatis mutandis to this complementary "EC" declaration of verification;
 - (e) the original "EC" declaration of verification shall be considered valid for the basic parameters not concerned by the modification.
- 3. "EC" DECLARATION OF VERIFICATION OF SUBSYSTEMS IN THE CASE OF ADDITIONAL VERIFICATIONS

An "EC" declaration of verification of a subsystem may be complemented in the case of additional verifications carried out, in particular when such additional verifications are necessary for an additional authorisation for placing in service. In this case the scope of the complementary declaration shall be limited to the scope of the additional verifications.'

ANNEX II

'ANNEX VI

"EC" VERIFICATION PROCEDURE FOR SUBSYSTEMS

GENERAL PRINCIPLES

""EC" verification" means a procedure carried out by the applicant within the meaning of Article 18 to demonstrate that the requirements of the relevant Union legislation including any relevant national rules relating to a subsystem have been fulfilled and the subsystem may be authorised to be placed in service.

2. CERTIFICATE OF VERIFICATION ISSUED BY A NOTIFIED BODY

2.1. Introduction

For the purpose of this Directive, the verification by reference to TSIs is the procedure whereby a notified body checks and certifies that the subsystem complies with the relevant technical specifications for interoperability (TSI).

This is without prejudice of the obligations of the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18) to comply with the other applicable legislation deriving from the Treaty, including any verifications by the assessment bodies required by the other legislation.

2.2. Intermediate statement of verification (ISV)

2.2.1. Principles

At the request of the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18), the verifications may be done for parts of a subsystem or may be limited to certain stages of the verification procedure. In these cases, the results of verification may be documented in an "intermediate statement of verification" (ISV) issued by the notified body chosen by the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18).

The ISV must provide reference to the TSIs with which the conformity has been assessed.

2.2.2. Parts of the subsystem

The applicant within the meaning of Article 18 may apply for an ISV for any part into which he decides to split the subsystem. Each part shall be checked at each stage as set out in point 2.2.3.

2.2.3. Stages of the verification procedure

The subsystem, or certain parts of the subsystem, shall be checked at each of the following stages:

- (a) overall design,
- (b) production: construction, including, in particular, civil-engineering activities, manufacturing, constituent assembly and overall adjustment,
- (c) final testing.

The applicant (within the meaning of Article 18) may apply for an ISV for the design stage (including the type tests) and for the production stage for the whole subsystem or for any part into which the applicant decided to split it (see paragraph 2.2.2).

2.3. Certificate of verification

2.3.1. The notified bodies responsible for the verification assesses the design, production and final testing of the subsystem and draw up the certificate of verification intended for the contracting entity or manufacturer (i.e. the applicant in the meaning of Article 18), who in turn draws up the "EC" declaration of verification. The certificate of verification must provide reference to the TSIs with which the conformity has been assessed.

Where a subsystem has not been assessed for its conformity with all relevant TSI(s) (e.g. in the case of a derogation, partial application of TSIs for upgrade or renewal, transitional period in a TSI or specific case), the certificate of verification shall give the precise reference to the TSI(s) or their parts whose conformity has not been examined by the notified body during the verification procedure.

- 2.3.2. Where ISV have been issued, the notified body responsible for the verification of the subsystem takes these ISV into account, and, before issuing its certificate of verification:
 - (a) verifies that the ISV cover correctly the relevant requirements of the TSI(s),
 - (b) checks all aspects that are not covered by the ISV, and
 - (c) checks the final testing of the subsystem as a whole.
- 2.3.3. In the case of a modification to a subsystem already covered by a certificate of verification, the notified body shall perform only those examinations and tests that are relevant and necessary, i.e. assessment shall relate only to the parts of the subsystem that are changed and their interfaces to the unchanged parts of the subsystem.
- 2.3.4. Each notified body involved in the verification of a subsystem shall draw up a technical file in accordance with Article 18(3) covering the scope of its activities.

2.4. Technical file accompanying the EC declaration of verification

The technical file accompanying the EC declaration of verification shall be assembled by the applicant (in the meaning of Article 18) and must contain the following:

- (a) technical characteristics linked to the design including general and detailed drawings with respect to execution, electrical and hydraulic diagrams, control-circuit diagrams, description of data-processing and automatic systems to the level of detail sufficient for documenting the verification of conformity carried out, documentation on operation and maintenance, etc., relevant for the subsystem concerned;
- (b) a list of interoperability constituents, referred to in Article 5(3)(d), incorporated into the subsystem;
- (c) the technical files referred to in Article 18(3), compiled by each of the notified bodies involved in the verification of the sub-system, which shall include:
 - copies of the "EC" declarations of conformity and, where applicable, "EC" declarations of suitability for use established for interoperability constituents referred to in Article 5(3)(d) and accompanied, where appropriate, by the corresponding calculation notes and a copy of the records of the tests and examinations carried out by the notified bodies on the basis of the common technical specifications,
 - where available, the ISV that accompany the certificate of verification, including the result of verification by the notified body of the ISV validity,
 - the certificate of verification, accompanied by corresponding calculation notes and signed by the notified body responsible for the verification, stating that the subsystem complies with the requirements of the relevant TSI(s) and mentioning any reservations recorded during performance of the activities and not withdrawn; the certificate of verification should also be accompanied by the inspection and audit reports drawn up by the same body in connection with its task, as specified in points 2.5.2 and 2.5.3;
- (d) certificates of verification issued in accordance with other legislation deriving from the Treaty;
- (e) when verification of safe integration is required pursuant to Article 15, the relevant technical file shall include the assessors' report(s) on the common safety methods (CSM) on risk assessment referred to in Article 6(3) of Directive 2004/49/EC.

2.5. Surveillance by notified bodies

2.5.1. The notified body responsible for checking production must have permanent access to building sites, production workshops, storage areas and, where appropriate, prefabrication or testing facilities and, more generally, to all premises which it considers necessary for its task. The notified body must receive from the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18) all the documents needed for that purpose and, in particular, the implementation plans and technical documentation concerning the subsystem.

- 2.5.2. The notified body responsible for checking implementation must periodically carry out audits in order to confirm compliance with the relevant TSI(s). It must provide those responsible for implementation with an audit report. Its presence may be required at certain stages of the building operations.
- 2.5.3. In addition, the notified body may pay unexpected visits to the worksite or to the production workshops. At the time of such visits the notified body may conduct complete or partial audits. It must provide those responsible for implementation with an inspection report and, if appropriate, an audit report.
- 2.5.4. The notified body shall be able to monitor a subsystem on which an interoperability constituent is mounted in order to assess, where required by the corresponding TSI, its suitability for use in its intended railway environment.

2.6. Submission

A copy of the technical file accompanying the EC declaration of verification must be kept by the manufacturer or contracting entity (i.e. by the applicant in the meaning of Article 18) throughout the service life of the subsystem. It must be sent to any Member State which so requests.

The documentation submitted for an application for an authorisation for placing in service shall be submitted to the national safety authority of the Member State where the authorisation is sought. The national safety authority may request that part(s) of the documents submitted together with the authorisation is/are translated into its own language.

2.7. Publication

Each notified body must periodically publish relevant information concerning:

- (a) requests for verification and ISV received,
- (b) request for assessment of conformity and suitability for use of ICs,
- (c) ISV issued or refused,
- (d) certificates of conformity and "EC" certificates for suitability for use issued or refused,
- (e) certificates of verification issued or refused.

2.8. Language

The files and correspondence relating to the "EC" verification procedure must be written in a Union official language of the Member State in which the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18) is established or in a Union official language accepted by the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18).

3. CERTIFICATE OF VERIFICATION ISSUED BY A DESIGNATED BODY

3.1. Introduction

In the case where national rules apply, the verification shall include a procedure whereby the body designated pursuant to Article 17(3), third subparagraph, (the designated body) checks and certifies that the subsystem complies with the national rules notified in accordance with Article 17(3) for each Member State in which the subsystem is intended to be authorised to be placed in service.

3.2. Certificate of verification

The designated body draws up the certificate of verification intended for the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18).

The certificate shall contain a precise reference to the national rule(s) whose conformity has been examined by the designated body in the verification process.

In the case of national rules related to the subsystems composing a vehicle, the designated body shall divide the certificate into two parts, one part including the references to those national rules strictly related to the technical compatibility between the vehicle and the network concerned, and the other part for all other national rules.

3.3. Technical file

The technical file compiled by the designated body and accompanying the certificate of verification in the case of national rules must be included in the technical file accompanying the "EC" declaration of verification referred to in point 2.4 and shall contain the technical data relevant for the assessment of the conformity of the subsystem with those national rules.

3.4. Language

The files and correspondence relating to the "EC" verification procedure must be written in a Union official language of the Member State in which the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18) is established or in a Union official language accepted by the contracting entity or manufacturers (i.e. the applicant in the meaning of Article 18).

4. VERIFICATION OF PARTS OF SUBSYSTEMS IN ACCORDANCE WITH ARTICLE 18(5)

If a certificate of verification is to be issued for certain parts of a subsystem, provisions for this Annex shall apply mutatis mutandis for those parts.'

DECISIONS

POLITICAL AND SECURITY COMMITTEE DECISION EUTM MALI/4/2014

of 9 December 2014

on the acceptance of a third State contribution to the European Union military mission to contribute to the training of the Malian Armed Forces (EUTM Mali)

(2014/894/CFSP)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular the third subparagraph of Article 38 thereof,

Having regard to Council Decision 2013/34/CFSP of 17 January 2013 on a European Union military mission to contribute to the training of Malian Armed Forces (EUTM Mali) (1), and in particular Article 8(2) thereof,

Whereas:

- (1) Pursuant to Article 8(2) of Decision 2013/34/CFSP, the Council authorised the Political and Security Committee (PSC) to invite third States to offer contributions and to take the relevant decisions on acceptance of the proposed contributions by third States.
- (2) Following recommendation on a contribution from Serbia by the EU Mission Commander and the advice from the European Union Military Committee (EUMC), the contribution from Serbia should be accepted.
- (3) In accordance with Article 5 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark does not participate in the elaboration and implementation of decisions and actions of the Union which have defence implications,

HAS ADOPTED THIS DECISION:

Article 1

- 1. The contribution from Serbia to the European Union military mission to contribute to the training of the Malian Armed Forces (EUTM Mali) is accepted and is considered to be significant.
- 2. Serbia is exempted from financial contributions to the budget of EUTM Mali.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 9 December 2014.

For the Political and Security Committee
The Chairperson
W. STEVENS

COMMISSION IMPLEMENTING DECISION

of 10 December 2014

establishing the format for communicating the information referred to in Article 21(3) of Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances

(notified under document C(2014) 9334)

(Text with EEA relevance)

(2014/895/EU)

THE EUROPEAN COMMISSION.

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

Having regard to Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (1), and in particular Article 21(5) thereof,

Whereas:

- Article 21(3) of Directive 2012/18/EU requires the Member States to supply the Commission with information regarding establishments covered by that Directive using a specific report form.
- (2)The report form should allow the communication of streamlined information by the Member States, in order to maximise the usefulness and comparability of the information provided and minimise the administrative burden for Member States, whilst also respecting the requirements of Directive 2007/2/EC of the European Parliament and of the Council (2) establishing an Infrastructure for Spatial Information in the European Community (INSPIRE).
- (3)The measures provided for in this Decision are in accordance with the opinion of the Committee established by Council Directive 96/82/EC (3),

HAS ADOPTED THIS DECISION:

Article 1

Member States shall supply the Commission with the information referred to in Article 21(3) of Directive 2012/18/EU using the reporting format laid down in the Annex to this Decision.

For existing entries in the database the information will be reviewed by 31 December 2016.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 10 December 2014.

For the Commission Karmenu VELLA Member of the Commission

⁽¹⁾ OJ L 197, 24.7.2012, p. 1.

⁽²⁾ Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Informa-

tion in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1)
Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances (OJ L 10, 14.1.1997, p. 13).

ANNEX

FORMAT FOR PROVIDING INFORMATION IN ACCORDANCE WITH ARTICLE 21(3) OF DIRECTIVE 2012/18/EU

All fields with an asterisk are mandatory.

Confidential information shall be marked as such with an indication for each type of data, of the grounds for refusal in accordance with Article 4 of Directive 2003/4/EC of the European Parliament and of the Council (¹).

1. Part 1 — European Commission Authentication System (ECAS)

For security purposes, the Member State user will only be able to access eSPIRS by registering in ECAS, the European Commission Authentication System, by providing the following mandatory user information:

- (a) Name*: name of user
- (b) Surname*: surname of user
- (c) E-mail*: e-mail address of user
- (d) User role*: National Reporter (NR) or National Administrator (NA)

Once the user has been authenticated, (s)he will be directed to the Major Accident Hazard Bureau's MINERVA portal where eSPIRS is housed. The user rights for the eSPIRS database will be granted according to the user role.

2. Part 2 — Information to be reported in eSPIRS

The user shall provide the information listed below using either the online reporting format allowing to import data for each establishment separately, or a national exporting tool using the eSPIRS XML template for automatic import of the information included in its national/regional/local establishment database(s) into eSPIRS.

2.1. Reporting Competent Authority

- (a) Name*: Official name of Reporting Competent Authority
- (b) Address*: Street name where the Reporting Competent Authority is located
- (c) City*: City, town, village where the Reporting Competent Authority is located
- (d) Post code*: Postal code where the Reporting Competent Authority is located
- (e) Country*: Country where the Reporting Competent Authority is located
- (f) Comments: Comments the user may want to add regarding the Reporting Competent Authority

2.2. Establishment name and activities

- (a) Seveso status*: [According to Seveso III there are two establishment tier statuses: upper tier and lower tier]
- (b) Name*: Name of Seveso establishment reported in eSPIRS
- (c) Parent Company: Holding company/parent company of the establishment
- (d) Personalized code: Code the user can enter if (s)he wants to still use the old code system in eSPIRS
- (e) Industry type and/or NACE Code*: Where an establishment relates to more than one SPIRS and/or NACE code, a distinction shall be made between primary activity and secondary activities.
 - (1) Industry type to be indicated in accordance with the Seveso SPIRS Codes:
 - (1) Agriculture
 - (2) Leisure and sport activities (e.g. ice rink)
 - (3) Mining activities (tailings and physicochemical processes)

⁽¹) Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).

- (4) Processing of metals
- (5) Processing of ferrous metals (foundries, smelting, etc.)
- (6) Processing of non-ferrous metals (foundries, smelting, etc.)
- (7) Processing of metals using electrolytic or chemical processes
- (8) Petrochemical/Oil Refineries
- (9) Power generation, supply and distribution
- (10) Fuel storage (including heating, retail sale, etc.)
- (11) Production, destruction and storage of explosives
- (12) Production and storage of fireworks
- (13) LPG production, bottling and bulk distribution
- (14) LPG storage
- (15) LNG storage and distribution
- (16) Wholesale and retail storage and distribution (excluding LPG)
- (17) Production and storage of pesticides, biocides, fungicides
- (18) Production and storage of fertilizers
- (19) Production of pharmaceuticals
- (20) Waste storage, treatment and disposal
- (21) Water and sewage (collection, supply, treatment)
- (22) Chemical installations
- (23) Production of basic organic chemicals
- (24) Plastic and rubber manufacture
- (25) Production and manufacturing of pulp and paper
- (26) Wood treatment and furniture
- (27) Textiles manufacturing and treatment
- (28) Manufacture of food products and beverages
- (29) General engineering, manufacturing and assembly
- (30) Shipbuilding, shipbreaking, ship repair
- (31) Building and works of engineering construction
- (32) Ceramics (bricks, pottery, glass, cement, etc.)
- (33) Manufacture of glass
- (34) Manufacture of cement, lime and plaster
- (35) Electronics and electrical engineering
- (36) Handling and transportation centres (ports, airports, lorry parks, marshalling yards, etc.)
- (37) Medical, research, education (including hospitals, universities, etc.)
- (38) General chemicals manufacture (not otherwise specified in the list)
- (39) Other activity (not otherwise specified in the list)

- (2) NACE code: NACE is the European industry standard related to a statistical classification of economic activities, consisting of a 6-digit code. The user may want to relate the Seveso establishment to this classification scheme, referring to the first 4 digits, in addition or as an alternative to the SPIRS codes.
- (f) Link to the website including further information on the establishment*
- (g) E-PRTR ID: Where the establishment is, fully or partly, covered by Regulation (EC) No 166/2006 of the European Parliament and of the Council (¹), provide the national unique identifier used for the reporting of the facility under that Regulation, as well as the link to the relevant website.
- (h) IED ID (from 2016 data onwards): Where the establishment is, fully or partly, covered by Directive 2010/75/EU of the European Parliament and of the Council (²) (http://ec.europa.eu/environment/air/pollutants/stationary/ied/legislation.htm), provide all relevant national unique installation identifiers for the purposes of that Directive, as well as the link to the relevant website.
- (i) Establishment comments: comments the user may want to add regarding the reported establishment
- 2.3. Establishment location* full address or latitudinal/longitudinal coordinates
 - (a) Address*: Street name, street number and city where the establishment is located
 - (b) Latitude*: Latitudinal coordinates of the establishment (if no address is given)
 - (c) Longitude*: Longitudinal coordinates of the establishment (if no address is given)
 - (d) Address comments: comments the user may want to add regarding the establishment address

2.4. Establishment substances

- (a) Substance (according to Seveso III): The common name or the generic name or the hazard classification
- (b) CAS Number: A CAS Registry Number is a unique numeric identifier, is designated to only one substance, has no chemical significance and is a link to a wealth of information about a specific chemical substance. It can contain up to 10 digits, divided by hyphens into three parts. (http://www.cas.org/content/chemical-substances)
- (c) Quantity: Amount of substance in tonnes
- (d) Physical properties: Storage conditions under which the substance is maintained, such as state (solid, liquid, gas), granularity (powder, pellets, etc.), pressure, temperature, etc.
- (e) Substances comments: comments the user may want to add regarding the establishment substances reported

(¹) Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 33, 4.2.2006, p. 1).

⁽²⁾ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (OJ L 334, 17.12.2010, p. 17).

COMMISSION IMPLEMENTING DECISION

of 10 December 2014

establishing the format for communicating information from Member States on the implementation of Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances

(notified under document C(2014) 9335)

(Text with EEA relevance)

(2014/896/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC (¹), and in particular Article 21(5) thereof,

Whereas:

- (1) Article 21(2) of Directive 2012/18/EU requires the Member States to report on the implementation of this Directive by 30 September 2019, and every four-years thereafter.
- (2) The Commission has developed a questionnaire to define the set of information to be made available by the Member States for the purposes of reporting on the implementation of the Directive.
- (3) The first reporting period should cover the period between 1 June 2015, date at which the Directive becomes fully applicable in the Member States, and 31 December 2018, to allow Member States the time necessary to assess the information collected and submit it to the Commission by 30 September 2019. The subsequent four-yearly reporting periods will cover the periods between 1 January of the first year of the reporting period and 31 December of the fourth year of the reporting period.
- (4) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 22 of Council Directive 96/82/EC (²),

HAS ADOPTED THIS DECISION:

Article 1

Member States shall report on the implementation of Directive 2012/18/EU in accordance with Article 21(2) of that Directive by replying to the questionnaire set out in the Annex to this Decision (3).

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 10 December 2014.

For the Commission Karmenu VELLA Member of the Commission

⁽¹⁾ OJ L 197, 24.7.2012, p. 1.

⁽²⁾ Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances (OJ L 10, 14.1.1997, p. 13).

⁽³⁾ Available also at this website of the European Commission: http://ec.europa.eu/environment/seveso/

ANNEX

QUESTIONNAIRE

GENERAL INFORMATION

- 1. Provide information regarding the main competent authorities responsible for the enforcement of Directive 2012/18/EU. Information should cover, as a minimum, contact information and main tasks (monitoring of safety reports, land-use planning, domino effects, establishment and implementation of external emergency plans, inspections, information to the public, sanctions). Alternatively: refer to the previous report if no significant changes have taken place.
- 2. Indicate when the last update of information on establishments in view of its inclusion in the (e)SPIRS database took place.

2. DOMINO EFFECTS (ARTICLE 9 OF DIRECTIVE 2012/18/EU)

At the end of the reporting period, how many groups of establishments were identified where the risk or consequences of a major accident may be increased because of the geographical position and the proximity of such establishments, and their inventories of dangerous substances, pursuant to Article 9 of Directive 2012/18/EU?

3. SAFETY REPORTS (ARTICLE 10 OF DIRECTIVE 2012/18/EU)

- 1. Have all upper-tier establishments for which this was required during the reporting period, submitted a safety report? If not, how many have not done so?
- 2. Have all safety reports been updated in the course of the previous five years? If not, how many upper-tier establishments for which this was required have not updated their safety report?

4. EMERGENCY PLANS (ARTICLE 12 OF DIRECTIVE 2012/18/EU)

- 1. Have external emergency plans been established for all upper-tier establishments for which this was required during the reporting period? If not, for how many upper-tier establishments has no external emergency plan been established?
- 2. For how many of the upper-tier establishments have the authorities decided that it was not necessary to draw up an external emergency plan in accordance with Article 12(8) of Directive 2012/18/EU?
- 3. Where the answer to question 4.2 is one or more, provide the justification submitted by the relevant competent authority in each instance.
- 4. Have external emergency plans been tested over the last three years for all upper-tier establishments? If not, in how many cases has the external emergency plan not been tested?
- 5. Provide information about the main arrangements for consulting the public concerned on external emergency plans.
- 6. Give a brief explanation of the way external emergency plans are tested (e.g. part test, full test, involving emergency services, desk top etc.). Specify the criteria used when considering whether an external emergency plan is adequate.

5. LAND-USE PLANNING (ARTICLES 13 AND 15 OF DIRECTIVE 2012/18/EU)

1. Over the reporting period, has the public concerned been consulted on all specific individual projects (new establishments, significant modifications to existing establishments, new developments around existing establishments) and has the public been consulted on general plans or programmes related to new establishments or new developments around existing establishments? If not, provide a summary report on the major reasons for cases in which the public was not consulted.

- 2. Optional: Does your national legislation provide for coordinated or joint procedures in order to fulfil the requirements on land-use planning under Seveso and requirements stemming from other legislation, such as Directives 2011/92/EU (1) and 2001/42/EC of the European Parliament and of the Council (2)?
- INFORMATION ON SAFETY MEASURES (ARTICLE 14 AND ANNEX V OF DIRECTIVE 2012/18/EU)
 - 1. Has information on safety measures and requisite behaviour in the event of a major accident been made actively available to the public during the last five years for all upper-tier establishments? If not, for how many upper-tier establishments has this not been the case?
 - 2. Indicate by whom (operator, authorities) and, where possible, by which means (for example operators' or authorities leaflets, flyers, emails, SMS), the information under 6.1 is made available.
 - 3. Is the information listed in Annex V to Directive 2012/18/EU being kept permanently available for all establishments, including electronically, and updated where necessary? If not, indicate the percentage of establishments for which this is not the case and the measures taken to address shortcomings.
 - 4. Indicate by whom (operator, authorities) and, where possible, by which means (for example operators' or authorities notices, websites), the information under 6.3 is kept permanently available.
 - 5. At the end of the reporting period, how many establishments are considered to have a major accident potential with transboundary effects? In how many cases has relevant information been supplied to a potentially affected Member State.
- 7. INSPECTIONS (ARTICLE 20 OF DIRECTIVE 2012/18/EU)
 - 1. At what level or levels have inspection plans been drawn up? Have they been made publicly available, or has the public been electronically informed of where more detailed information about the inspection plan can be obtained upon request? Optional: If published on the internet, provide a link.
 - 2. Have programmes for routine inspections, including the frequency of site visits, been established for all establishments? Has the date of the last site visit, or reference to where that information can be accessed electronically been made publicly available? Optional: If published on the internet, provide a link.
 - 3. For how many upper-tier establishments is the inspection programme including the frequency of site visits based on a systematic appraisal of the major-accident hazard of the establishment concerned? How many are subject to yearly site visits?
 - 4. For how many lower-tier establishments is the inspection programme including the frequency of site visits based on a systematic appraisal of major-accident hazards of the establishment concerned? How many are subject to site visits at least every three years?
 - 5. Does national legislation or administrative guidance provide for coordinated or joint inspections with inspections carried out under other Union legislation (e.g. under the Industrial Emissions Directive or IED)?
- PROHIBITION OF USE, PENALTIES AND OTHER COERCIVE INSTRUMENTS (ARTICLE 19 AND 28 OF DIRECTIVE 2012/18/EU)
 - 1. For how many establishments the use or bringing into use has been prohibited during the reporting period?
 - 2. How many other types of coercive measures have been taken during the reporting period? Provide an indication of the types of actions that are most frequently used (e.g. prohibition of use, administrative sanction, penalty or other measure). If possible, provide a statistical breakdown.

⁽¹) Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain

public and private projects on the environment (OJ L 26, 28.1.2012, p. 1).

Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment (OJ L 197, 21.7.2001, p. 30).

9. ACCESS TO JUSTICE (ARTICLE 23 OF DIRECTIVE 2012/18/EU)

Explain how compliance with Article 23 of Directive 2012/18/EU on access to justice has been ensured and describe experience of applying this Article during the reporting period.

10. FURTHER INFORMATION

Optional: Provide any additional Seveso-related general information, implementation experience, reports etc. that could be of interest and can be shared with the public on the following points:

- (a) Lessons learned from accidents and incidents to prevent a recurrence;
- (b) IT tools used for monitoring the implementation of the Directive and for data sharing;
- (c) If relevant, any Seveso-like (in terms of notification of activities, requirements regarding safety management, safety reports, information to the public, emergency planning and inspections), applied to installations and activities not covered by Directive 2012/18/EU, for example on pipelines, ports, marshalling yards, offshore installations, gas exploration, exploitation, etc.

RECOMMENDATIONS

COMMISSION RECOMMENDATION

of 5 December 2014

on matters related to the placing in service and use of structural subsystems and vehicles under Directives 2008/57/EC and 2004/49/EC of the European Parliament and of the Council

(Text with EEA relevance)

(2014/897/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

- (1) In accordance with Article 30(1) of Directive 2008/57/EC of the European Parliament and of the Council (¹), the Commission may submit to the Committee referred to in Article 29 of the same Directive any matter related to the implementation of that Directive;
- (2) Since 2005 the European Railway Agency ('the Agency') has been carrying out several activities supporting the development of an integrated, safe and interoperable EU railway system. Following the adoption of Directive 2008/57/EC, the Agency has had regular meetings with stakeholders and national safety authorities, particularly in the field of cross-acceptance of railway vehicles, i.e. mutual recognition of authorisations for the placing in service of railway vehicles. These meetings have shown that there are different understandings of the authorisation for placing in service of structural subsystems and vehicles as provided for in Chapters IV and V of that Directive.
- (3) Without a common understanding, national implementing rules could lead to Member States applying the requirements in different ways which compounds the difficulties for manufacturers and railway undertakings. A common understanding of the process for the placing in service of structural subsystems and vehicles is also needed to ensure consistency between the various recommendations issued by the Agency in relation to several tasks set out by Directive 2004/49/EC of the European Parliament and of the Council (²) and Directive 2008/57/EC.
- (4) The Commission adopted its Recommendation 2011/217/EU (³). The aim of the latter was to clarify the procedure for authorising the placing in service of structural subsystems and vehicles as set out in Directive 2008/57/EC.
- (5) In order to discuss and analyse questions related to the placing in service of structural subsystems and vehicles which have arisen following the adoption of Recommendation 2011/217/EU, the Commission set up a task force on the vehicle authorisation process in 2011. This task force's final report was published on the Agency website in July 2012.
- (6) On 30 January 2013, the Commission adopted its legislative proposals for a fourth railway package. These proposals take into account the results of the above-mentioned task force and include an improved process for the authorisation of vehicles and sub-systems. The clarifications in this Recommendation are needed to optimise the implementation of the current legal framework.

⁽¹) 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 (OJ L 191, 18.7.2008, p. 1).

⁽²⁾ 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).

⁽²⁾ Commission Recommendation 2011/217/EU of 29 March 2011 on the authorisation for the placing in service of structural subsystems and vehicles under Directive 2008/57/EC of the European Parliament and of the Council (OJ L 95, 8.4.2011, p. 1).

- (7) It is therefore necessary to broaden Recommendation 2011/217/EU to cover other aspects related to the authorisation process and to further clarify the following issues:
 - relationship between essential requirements, technical specifications for interoperability (TSI) and national rules,
 - use of the common safety methods for authorisation purposes,
 - integrity of TSIs and national rules,
 - verifications which are outside the scope of authorisation for placing in service,
 - testing,
 - manufacturer's or contracting entity's declaration of verification,
 - mutual recognition,
 - technical file,
 - roles and responsibilities before, during and after authorisation,
 - role of the safety management system, and
 - management of modifications.
- (8) For the sake of clarity and simplification, it is preferable to replace Recommendation 2011/217/EU by this Recommendation.
- (9) After consulting the Committee referred to in Article 29 of Directive 2008/57/EC,

HAS ADOPTED THIS RECOMMENDATION:

1. Member States should ensure that national safety authorities, railway undertakings, infrastructure managers, assessment bodes, entities in charge of maintenance, manufacturers, applicants for authorisation for placing in service and other players involved in the authorisation for placing in service and use of structural subsystems and vehicles are aware of and take into account the principles and guidelines set out in paragraphs 2 to 116.

DEFINITIONS

- 2. For the purpose of this Recommendation, the definitions of Directive 2008/57/EC and 2004/49/EC should apply. In particular the terms 'railway undertakings', 'infrastructure managers', 'keepers of vehicles', and 'entity in charge of maintenance' are used based upon their roles and responsibilities as defined in Articles 3 and 4 of Directive 2004/49/EC. Any entity fulfilling one of the roles mentioned in these Articles might also fulfil another role (e.g. a railway undertaking or an infrastructure manager can also be a keeper of vehicles). The following definitions should also apply:
 - (a) 'design operating state' means the normal operating mode and the foreseeable degraded conditions (including wear) within the range and conditions of use specified in the technical and maintenance files. It covers all conditions under which the subsystem is intended to operate and its technical boundaries;
 - (b) 'basic design characteristics' means the characteristics of a subsystem as defined in the type or design examination certificate;
 - (c) 'safe integration' means the action to ensure the incorporation of an element (e.g. a new vehicle type, network project, subsystem, part, component, constituent, software, procedure, organisation) into a bigger system, does not create an unacceptable risk for the resulting system;

- (d) 'establishment of technical compatibility with the network' means verification and documentation in the technical file accompanying the EC declaration of verification of the vehicle type's parameters that are relevant for the technical compatibility with the given network and, where applicable, conformity with the limit values specified for this network; the parameters include physical characteristics and functions; the verification needs to be done according to the rules applicable for the given network;
- (e) 'technical compatibility' means an ability of two or more structural subsystems or parts of them which have at least one common interface, to interact with each other while maintaining their individual design operating state and their expected level of performance;
- (f) 'assessment body' means the notified body, designated body or risk assessment body;
- (g) 'notified body' means a body as defined by Article 2(j) of Directive 2008/57/EC;
- (h) 'designated body' means a body designated by a Member State in accordance with Article 17(3) of Directive 2008/57/EC for verification of compliance of a subsystem with the national rules;
- (i) 'risk assessment body' means a body as defined by Article 3(14) of Commission Implementing Regulation (EU) No 402/2013 (¹);
- (j) 'EC declaration of verification' means, for a subsystem, the 'EC' declaration of verification established pursuant to Article 18 and Annex V to Directive 2008/57/EC which is a declaration that the subsystem satisfies the requirements of the relevant European legislation including any national rules that are used to implement the essential requirements of Directive 2008/57/EC;
- (k) 'network project' means a project to place in service new, renewed or upgraded fixed equipment composed of more than one structural subsystem;
- (l) 'network characteristics' means the characteristics of a network as described by the TSIs and, where relevant, by national rules;
- (m) 'technical file accompanying the "EC" declaration of verification' means the combination of all files and documentation gathered by the applicant as required by all applicable EU legislation for a subsystem;
- (n) 'documentation submitted for authorisation' means the file presented by the applicant to the national safety authority at the time of applying for authorisation;
- (o) 'applicant' means the signatory of the 'EC' declaration of verification in accordance with Article 18 of Directive 2008/57/EC and asking for an authorisation for placing in service of a subsystem. Where the CSM RA is required under Article 15 of Directive 2008/57/EC, the role of the 'proposer' according to the CSM RA should be taken by the applicant for authorisation.
- (p) 'applicant for vehicle/network project authorisation' means the entity asking for an authorisation for placing in service of a vehicle or network project respectively. Where the CSM RA is required under Article 15 of Directive 2008/57/EC, the role of the 'proposer' according to the CSM RA should be taken by the applicant for authorisation.

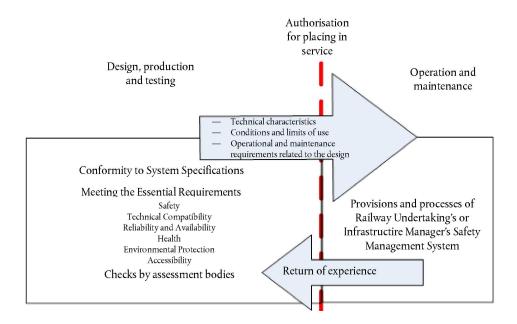
AUTHORISATION FOR THE PLACING IN SERVICE OF SUBSYSTEMS

3. The authorisation for placing in service of a subsystem is the recognition by the Member State that the applicant for this subsystem has demonstrated that it meets, in its design operating state, all the essential requirements of Directive 2008/57/EC (²) when integrated into the rail system. According to Article 17(1) of the

⁽¹⁾ 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. 11).

⁽²⁾ Directive 2008/57/EC sets out in Annex III the essential requirements for the rail system (Article 3(1)). These requirements are specific to the rail sector. The rail system, the subsystems, the interoperability constituents, and all interfaces must meet these essential requirements (Article 4(1)). Meeting the essential requirements is a prerequisite before a structural subsystem can be placed in service. Compliance with the essential requirements of Directive 2008/57/EC is without prejudice of the application of other EU provisions (Article 3(2)).

same Directive, this is provided in the form of an 'EC' declaration of verification. The following diagram summarises the activities before and after an authorisation for placing in service of a structural subsystem:



AUTHORISATION FOR THE PLACING IN SERVICE OF VEHICLES AND AUTHORISATION OF VEHICLE TYPES

- 4. For the purposes of authorisation, a vehicle is composed of the rolling stock subsystem and, where applicable, the on-board control-command and signalling subsystem. A vehicle type authorisation or individual authorisation to place a vehicle in service is a collective authorisation of the subsystem(s) composing the vehicle.
- 5. Requirements arising from functional subsystems and affecting the vehicle design (operating) state (including for example operational performance requirements) are set out in the relevant structural TSIs or, where allowed by Directive 2008/57/EC, in national rules (e.g. CCS class B systems).
- 6. Since vehicles are composed of one or more subsystems, provisions related to subsystems in Chapter IV of Directive 2008/57/EC are applicable to the vehicle's or vehicle type's relevant subsystems, without prejudice to other provisions of Chapter V.
- 7. For authorisations relating to vehicles composed of more than one subsystem, the applicant for authorisation of the vehicle or vehicle type may combine the 'EC' declarations of verifications for both subsystems into a single 'EC' declaration of verification, as described in Annex V to Directive 2008/57/EC, to demonstrate that vehicles of this type as a whole in their design operating state, when integrated into the rail system, satisfy the requirements of the relevant European legislation including the essential requirements of Directive 2008/57/EC.
- 8. A single authorisation for the vehicle type or an authorisation for the placing in service of individual vehicles should be sufficient for the whole EU rail network when the conditions specified in Directive 2008/57/EC are met. This is the case, for example, of a TSI-compliant vehicle or vehicle type which is to be authorised with the condition of use that it is intended to run only on a TSI-compliant network (but only if the relevant TSIs which were applied at the respective authorisations do not contain open points and specific cases related to the compatibility between the network and the vehicle).
- 9. The procedures for authorising vehicle types and individual vehicles are harmonised and include clear steps with fixed time limits.
- 10. The applicable rules for authorising the placing in service of vehicles and vehicle types should be stable, transparent and non-discriminatory. The rules should be either TSIs, or, when permitted by Directive 2008/57/EC, national rules notified to the Commission and made available through a database set up by the Commission. From the moment a TSI is adopted, Member States should not adopt any national rule related to products or

subsystem parts covered by that TSI (except for those declared as 'open points') In the case of non-TSI-compliant vehicles and vehicle types, the principle of mutual recognition should be applied as far as possible in order to prevent unnecessary requirements and redundant verifications, unless these are strictly necessary for verifying the technical compatibility of a vehicle of this type with the relevant network.

- 11. Authorisations relating to vehicles should refer to the technical characteristics of the vehicles' design operating state, including limits and conditions of use and indicate the network(s) (¹) of the Member State(s) for which the vehicles of that type are authorised. The technical characteristics referred to in the authorisation should be:
 - declared by the manufacturers or contracting entities, in their role as applicant for authorisation of the vehicle or vehicle type,
 - verified and certified by the assessment bodies, and
 - documented in the technical file accompanying the EC declaration of verification.
- 12. The technical characteristics as referred to in recommendation 11 above are the same for any individual vehicle of the same vehicle type.
- 13. Neither the type authorisation nor the authorisation for placing an individual vehicle in service should be related to any particular route, railway undertaking, keeper or entity in charge of maintenance (ECM).
- 14. To ensure that there is no need to authorise vehicle types and placing in service of individual vehicles for specific routes and to avoid the need for re-authorisation if the characteristics of any route changes, any limitations and conditions of use attached to a vehicle related authorisation should be specified in terms of the parameters of the technical design characteristics of the infrastructure and not in terms of geography.

TYPE AUTHORISATION

- The characteristics of a vehicle's design operating state that are assessed for authorisation are the characteristics associated with the vehicle type. A vehicle type may first be authorised according to Article 26(1) of Directive 2008/57/EC and then individual vehicles of that type (including a series of individual vehicles) may be authorised by verification of their conformity to type according to Article 26(3) of Directive 2008/57/EC. Alternatively, the authorisation of the first vehicle of a type will confer an authorisation of the vehicle type according to Article 26(2) of Directive 2008/57/EC. This also allows subsequent individual vehicles of the same type to be authorised by verification of conformity to type according to Article 26(3) of Directive 2008/57/EC. This concept of vehicle type authorisation allows manufacturers to place vehicle types on the market and in their catalogue, and thus to offer customers the benefit of an authorisation, without already having built the individual vehicles of such types that a customer may order. One of the objectives of this concept is to remove much of the authorisation risk from those who procure vehicles of such types.
- 16. The concept of type is also relevant for route compatibility. To assess if the route will support a train, a railway undertaking compares the characteristics of a train composed of vehicles of certain types with the information provided by the infrastructure manager in the register of infrastructure. The obligation of infrastructure managers to make public the nature of infrastructure already exists (Directive 2001/14/EC of the European Parliament and of the Council (²) as far as network access is concerned; Directive 2004/49/EC, 2008/57/EC and TSI related to 'operation and traffic management' as far as operation is concerned). Until the register of infrastructure is established and populated, the infrastructure managers should publish this information in another form. This does not empower the infrastructure managers to impose a sort of second authorisation to the vehicles or trains of the railway undertakings.
- 17. The processes of authorising vehicles and the subsequent operation and maintenance of particular vehicles are two clearly distinct processes regulated by distinct provisions. This separation enables vehicles of the same type to be placed on the market by manufacturers already with an authorisation, to be operated by different railway undertakings, and to be maintained by different entities in charge of maintenance (ECM) in accordance with different maintenance regimes depending on the operational context.

The territory of a Member State may include one or more railway networks.

⁽²⁾ Directive 2001/14/EC of the European Parliament and of the Council of 26 February 2001 on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification (OJ L 75, 15.3.2001, p. 29).

18. For vehicle types intended to be authorised in more than one Member State (e.g. for operation on corridors), the national safety authorities may choose to cooperate in order to issue first and additional authorisations at the same time ('simultaneous' authorisation). This enables the relevant national safety authorities to share the work between them (e.g. each of them might take a subject area) and for the national safety authority issuing the first authorisation to recognise and benefit from work carried out by the other national safety authorities.

AUTHORISATION FOR THE PLACING IN SERVICE OF FIXED INSTALLATION SUBSYSTEMS

- 19. It should be underlined that TSIs for fixed installations do not contain a complete set of requirements to be complied with by the relevant subsystem. The requirements set out in the TSIs include those elements which are relevant for the compatibility of the fixed installation subsystems with a TSI compliant vehicle.
- 20. For fixed installations, apart from the application of the TSIs, in order to satisfy essential requirements of all applicable EU legislation, Member States may require application of other rules which do not need to be harmonised to meet the objectives of Directive 2008/57/EC such as electrical safety, civil engineering, building, sanitary, fire protection codes, etc. These rules should not contradict the provisions of the TSIs.
- 21. For a network project composed of more than one fixed installation subsystem, it is suggested that to simplify the process, the applicant may combine the 'EC' declarations of verifications for each subsystem, as described in Annex V to Directive 2008/57/EC, into a single 'EC' declaration of verification for the network project as a whole to demonstrate that the network project as a whole when integrated into the rail system satisfies the requirements of the relevant European legislation including meeting the essential requirements of Directive 2008/57/EC.
- 22. The applicable national rules for authorising the placing in service of fixed installation subsystems should be stable, transparent and non-discriminatory. Without prejudice to recommendations 19 and 20 above, the rules related the essential requirements of the railway system laid down by Directive 2008/57/EC should be either TSIs, or, when permitted by Directive 2008/57/EC, national rules notified to the Commission and made available through a database set up by the Commission. From the moment a TSI is adopted, Member States should not adopt any national rule related to products or subsystem parts covered by that TSI (except for those aspects duly declared as 'open points' in the relevant TSIs).
- 23. An authorisation for placing in service of fixed installation subsystems should refer to its technical characteristics, including limits and conditions of use. The technical characteristics referred to in the authorisation for placing in service should be:
 - declared by the applicant,
 - verified and certified by the assessment bodies, and
 - documented in the technical file accompanying the EC declaration of verification.
- 24. The process of authorising the placing in service of fixed installation subsystems and the operation and maintenance of those subsystems are two clearly distinct processes regulated by distinct provisions.

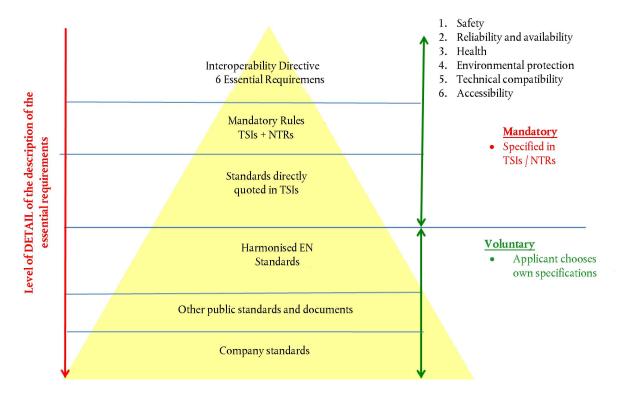
ESSENTIAL REQUIREMENTS, TECHNICAL SPECIFICATIONS FOR INTEROPERABILITY (TSI) AND NATIONAL RULES

- 25. The Interoperability Directive lays down essential requirements for the railway system. These are 'all the conditions set out in Annex III which must be met by the rail system, the subsystems, and the interoperability constituents, including interfaces' (Article 2 point (g) of Directive 2008/57/EC). The essential requirements for the railway system are therefore exhaustive. A Member State or national safety authority may not lay down any requirements or conditions other than as foreseen by Article 17.
- 26. Technical compatibility at the interface between network and vehicles is crucial for safety. Although the safety aspect of this interface could be proven through the use of reference systems or explicit risk estimations in accordance with Commission Regulation (EC) No 352/2009 (¹) (CSM RA), for interoperability reasons, technical compatibility should be proven on the basis of harmonised Union rules, that is the TSIs, or, if no such

⁽¹) Commission Regulation (EC) No 352/2009 of 24 April 2009 on the adoption of a common safety method on risk evaluation and assessment (OJ L 108, 29.4.2009, p. 4). This Regulation will be repealed and replaced as of 21 May 2015 by Implementing Regulation (EU) No 402/2013.

rules exist, on the basis of national rules. Therefore, for the sake of interoperability, interfaces between vehicle and network should be demonstrated using a rule-based approach.

- As a consequence, on one hand, the TSIs should exhaustively specify the interfaces referred to in recommendation 26. Every basic parameter and interface of the target system to be explicitly checked for authorisation should also be fully specified in the TSIs, along with the relevant conformity assessment requirements.
- 28. On the other hand, TSIs should only specify the requirements 'to the extent necessary' to deliver the optimal level of technical harmonisation and mandatory provisions necessary to meet the essential requirements of Directive 2008/57/EC and to achieve the objectives set out in Article 1 of that Directive (Article 5(3)). The TSIs should therefore specify requirements only to the level of detail that needs to be harmonised in order to achieve these objectives while meeting the essential requirements. They also specify the interfaces between subsystems. Each TSI indicates a target subsystem that may be attained gradually within a reasonable time-scale.
- 29. Applicants should have the freedom to use technical solutions of their own choice to meet the essential requirements provided that the specifications of these technical solutions comply with the TSIs and other applicable legislation.
- 30. In order to achieve the goal of the Single European Railway Area without internal frontiers, technical specifications of products meeting the essential requirements may be laid down in harmonised standards (EN). In some cases, harmonised standards that cover the basic parameters of the TSIs provide presumption of conformity with certain clauses of the TSIs. In accordance with the spirit of the new approach to technical harmonisation and standardisation, application of these standards remains voluntary but their references are published on the Official Journal of the European Union (OJEU). These specifications should also be listed in the TSI application guides in order to facilitate their use by the industry. These specifications should remain complementary to TSIs
- 31. The hierarchy and level of detail of the specifications mentioned in recommendations 26 to 30 are illustrated in the following diagram:



- 32. The TSIs should not repeat provisions designed to ensure that a subsystem or vehicle design operating state meets requirements from other applicable Directives.
- 33. Requirements stemming from EU provisions other than Directive 2008/57/EC need also to be applied when a subsystem or a vehicle is designed/planned and placed into its design operating state. The applicant should ensure that these requirements are fulfilled.

- Without prejudice to recommendations 19 and 20, national rules may continue to apply for authorisations only in the cases specified by Article 17(3) of Directive 2008/57/EC. These are
 - the circumstances where no relevant TSI exists i.e.:
 - (a) TSI open points;
 - (b) networks and vehicles not (intended to be) in the scope of the TSIs;
 - (c) requirements for legacy systems (i.e. system interfaces not intended to be covered by the TSIs);
 - (d) requirements for non-TSI-compliant vehicles placed in service before the entry into force of the TSIs or during a transitional period,
 - derogations, for which Article 9 of Directive 2008/57/EC applies,
 - as specific cases defined in TSIs, which include national variations in the target system.
- 35. In the cases listed in recommendation 34, Member States should rely on, make public, and enforce rules covering the essential requirements including technical compatibility between vehicles and their network. In order to preserve the existing level of interoperability and avoid discrimination between applicants, these rules should be at the same level of detail as TSIs and unambiguous in their requirements (i.e. they should specify values for the relevant parameters and conformity assessment methods).
- 36. If an application for an additional authorisation is made for an existing non-TSI-compliant vehicle type or individual vehicles Article 25 of Directive 2008/57/EC would allow the Member State where the additional authorisations is sought, to check only the compatibility with its network. In application of the mutual recognition as described in recommendations 52 to 54, this Member State should recognise the first authorisation for placing in service unless it can demonstrate (to the applicant for the additional authorisation) a significant safety risk. This is consistent with the need to avoid discrimination between vehicles types and individual vehicles that were first authorised in one Member State.
- Therefore, for the purpose of clarity, Member States should state in their national rules which of the provisions apply: only to new vehicles and subsystems at first authorisation; and/or to existing types; and/or to existing vehicles to be given a new authorisation after renewal or upgrade; and/or to all subsystems and vehicles already in service.

USE OF THE COMMON SAFETY METHODS FOR RISK EVALUATION AND ASSESSMENT (CSM RA) AND THE SAFETY MANAGEMENT SYSTEM (SMS)

- 38. The CSM RA is mandatory in the context of the authorisation of placing in service only in the following cases:
 - (a) when required for a particular subject by a TSI or national rule applicable according to Article 17(3) of Directive 2008/57/EC;
 - (b) as required by Article 15(1) of Directive 2008/57/EC to perform safe integration of the subsystems when mandatory rules are not available.

In all other cases the use of the CSM RA is not mandatory in the context of such an authorisation.

- 39. The term 'safe integration' may be used to cover:
 - (a) safe integration between the elements composing a subsystem;
 - (b) safe integration between subsystems that constitute a vehicle or a network project;

and, for vehicles:

- (c) safe integration of a vehicle with the network characteristics;
- (d) safe integration of vehicles into the SMS of railway undertakings. This includes interfaces between vehicles, interfaces with the staff who will operate the subsystem, and maintenance activities by an ECM;

(e) safe integration of a train with the specific routes it operates over;

and for network projects:

- (f) safe integration of a network project with the vehicle characteristics defined in TSIs and national rules;
- (g) safe integration with adjacent parts of the network (line sections);
- (h) safe integration of network project into the SMS of the infrastructure manager. This includes interfaces with the staff who will operate the network project, and maintenance activities by the infrastructure manager or its contractors;
- (i) safe integration of a network project with the specific trains operating over it.
- 40. Regarding the relation between safe integration and the authorisation for placing vehicles in service:
 - points (a), (b), and (c) of recommendation 39 should be carried out before authorisation for placing in service. Any condition and limits of use derived from them (e.g. any limitations for train composition including operation in multiple units or operation of the locomotives together with the vehicles forming the train) should be stated in the technical file accompanying the EC declaration of verification referred to in Article 18(3) of Directive 2008/57/EC in such a way that the user of the authorised subsystem or vehicle can apply these conditions and limits of use according to its SMS,
 - point (d) of recommendation 39 is not part of the authorisation process. It should be carried out by the railway undertaking due account of all the conditions and limits of use that result from points (a), (b) and (c) and verification of conformity with the TSIs and applicable national rules,
 - point (e) of recommendation 39 is not part of the authorisation process. It should be carried out by the railway undertaking on the basis of all the information needed by a railway undertaking to determine train characteristics and establish train-route compatibility (e.g. conditions of use, values of interface parameters) that result from points (a), (b), and (c) and the information contained within the register of infrastructure.
- 40 bis. Regarding the relation between safe integration and the authorisation for placing fixed subsystems and network projects in service:
 - points (a), (b), (f) and (g) of recommendation 39 should be carried out before authorisation for placing in service. Any condition and limits of use derived from them should be stated in the technical file accompanying the EC declaration of verification referred to in Article 18(3) of Directive 2008/57/EC in such a way that the user of the authorised subsystem or network project can apply these conditions and limits of use according to its SMS,
 - point (h) of recommendation 39 is not part of the authorisation process. It should be carried out by the infrastructure manager taking due account of all the conditions and limits of use that result from points (a), (b), (c) and verification of conformity with the TSIs and applicable national rules,
 - point (i) of recommendation 39 is not part of the authorisation process. It should be carried out by the infrastructure manager on the basis of all the information needed to determine route characteristics and establish train-route compatibility (e.g. conditions of use, values of interface parameters) that result from points (a), (b), and (c) and the information contained within the register of vehicle types.
- 41. Regarding the use of the CSM RA to verify safe integration before authorisation for placing in service:
 - point (a) of recommendation 39 is fully in the scope of the TSIs addressing a subsystem; where there are no explicit technical rules covering this matter, the TSI may adopt a risk based approach, require application of the CSM RA and specify to which acceptable level the risk should be controlled,
 - where there are no mandatory rules (TSIs, national rules) covering this interface fully, point (b) of recommendation 39 should be checked by using the CSM RA,

- point (c) of recommendation 39 should be fully covered by TSIs and, where envisaged by Article 17(3) of Directive 2008/57/EC, national rules and this rule-based verification should be carried out by a notified body or designated body as part of its responsibility for 'verification of the interfaces of the subsystem in question with the system into which it is incorporated' (Article 18 of Directive 2008/57/EC), otherwise the requirements for transparency, non-discrimination and interoperability would be compromised.
- The use of the CSM RA is therefore not mandatory for point (c) of recommendation 39 for the cases where TSIs or national rules exist. In the cases where national rules do not specify this interface fully (e.g. some legacy signalling systems and innovative solutions) these national rule(s) may require the application of CSM RA for addressing the risks not covered.

INTEGRITY OF TSIs AND NATIONAL RULES

- 42. It is recognised that the TSIs have been built up by a pool of experts from the sector associations and national safety authorities taking account of national rules and practical experience as their basis. They represent the 'state of the art' or best available knowledge having been developed by the Agency, with these experts and reviewed by the Committee referred to in Article 29 of Directive 2008/57/EC. As such, the TSIs have been recognised by the Member States as fit for purpose (including open points) and are legally binding. It is not part of authorisation to check or validate these mandatory requirements.
- 43. Nevertheless, to preserve the integrity of the TSIs and national rules, it is the responsibility of every entity that at any time becomes aware of a potential deficiency in the TSIs or national rules that, as a matter of urgency, they raise their doubts with full justification through the applicable procedures so that all entities concerned are immediately made aware of the potential deficiency and may take appropriate action.
- 44. Member States should take appropriate measures to amend deficient or incompatible national rules.
- 45. If a TSI is deficient, Article 7 of Directive 2008/57/EC applies and the deficiency should be addressed by:
 - (a) a technical opinion of the Agency; or
 - (b) a TSI amendment;

or both.

Depending on the case, a TSI may be amended by:

- (1) amending the specification of the target system;
- (2) adding specific cases, when they concern only a limited number of Member States and harmonisation at EU level is not deemed necessary;
- (3) adding open points, when harmonisation at EU level is needed, but cannot yet be explicitly covered in the TSI.

VERIFICATIONS WHICH ARE OUTSIDE THE SCOPE OF AUTHORISATION FOR PLACING IN SERVICE

- 46. The verification of train-route compatibility should be independent from the authorisation for placing in service a vehicle type or an individual vehicle. The verification of train-route compatibility is managed by a railway undertaking (or an infrastructure manager if it operates trains) as part of the planning process (for example when bidding for paths) and on a day—to-day basis through its SMS. The railway undertaking should establish compatibility by obtaining information from the infrastructure manager via the register of infrastructure and from the technical file accompanying the EC declaration of verification of the vehicles established at authorisation and maintained thereafter. In the transitional period, i.e. until the register of infrastructure is established and complete with all relevant data for the verification of compatibility with the network, the infrastructure managers should provide necessary information to the railway undertakings by other transparent means.
- 47. Assessing the ability of a railway undertaking to manage the operation and maintenance of the vehicles is not part of the process leading to authorisation. It is covered by the safety certification process and ongoing supervision by the national safety authority.
- 48. Assessing the ability of an infrastructure manager to manage the operation and maintenance of network projects is not part of the process leading to authorisation. It is covered by the safety authorisation process and ongoing supervision by the national safety authority.

- 49. Assessing the ability of an ECM to manage the maintenance of a vehicle is not part of the authorisation process. It is covered by the SMS of the railway undertaking. Where the ECM certification process applies, the SMS of the railway undertaking may take account of this process.
- As a consequence, an applicant for a vehicle type authorisation or for an authorisation for placing an individual vehicle or subsystem in service is not required to assess the significance of the potential changes brought by the vehicle or the subsystem design in the railway system as a whole. If the applicant is the railway undertaking or infrastructure manager that intends to operate this vehicle or subsystem, the application of CSM RA as a railway undertaking or infrastructure manager responsible for the management of change to their part of the railway system is independent from their role as applicant for an authorisation for placing in service
- 51. In practice, where the manufacturer is producing a specific design to the order of a railway undertaking, there is usually an overlap in time between:
 - the verification of conformity of a structural subsystem in order to establish a 'EC' declaration of verification (activity that includes points (a), (b) and (c) of recommendation 39), and
 - the integration of this subsystem into the SMS of the railway undertaking or infrastructure manager (activity that includes points (d) and (e) of recommendation 39).

This is a part of good project management that, in certain circumstances, allows minimising the time gap between the authorisation for placing in service and the actual use of the vehicle or network project in commercial operation. In these circumstances the national safety authority is involved at the same time as:

- an authority in charge of granting an authorisation for vehicle type or for placing an individual vehicle in service, and
- an authority in charge of supervision of safety certificates or safety authorisations.

Even though the two tasks may overlap in time, they should be formally independent, the counterpart in the former being the applicant for authorisation of the vehicle or vehicle type and in the latter the railway undertaking or infrastructure manager that intends to use the subsystem or vehicle.

MUTUAL RECOGNITION OF RULES AND VERIFICATIONS ON VEHICLES

- 52. Member States should mutually recognise verifications carried out according to national rules of other Member States, unless:
 - (a) there is no evidence of compatibility with the network; or
 - (b) a Member State can demonstrate to the applicant a substantial safety risk.
 - (c) The principle of mutual recognition should be applied as far as possible in order to prevent unnecessary requirements and redundant verifications, unless these are strictly necessary to check the technical compatibility of the vehicle with the relevant network and are not equivalent to the rules of the Member State of the first authorisation.
- 53. In the event of additional authorisations, Member States should not call into question national rules applied for a previous authorisation:
 - covering the open points not related to technical compatibility between the vehicle and the network, or
 - classified as belonging to category 'A' in the reference document provided for in Article 27(4) of Directive 2008/57/EC.
- 54. Notwithstanding the absence of generic risk acceptance criteria in the CSM on risk assessment, CSM assessments carried out as part of verifications required by the TSIs should be mutually recognised in accordance with Article 7(4) of CSM RA (1).

⁽¹⁾ This will be replaced by Article 15(5) of the Implementing Regulation (EU) No 402/2013, which shall apply from 21 May 2015.

ROLES AND RESPONSIBILITIES

- 55. Before a subsystem may be authorised to be placed in service, the manufacturer or contracting entity (i. e. the applicant in the meaning of Article 18(1) of Directive 2008/57/EC) must carry out all necessary design, construction and testing or have them carried out under their responsibility and sign an 'EC' declaration of verification.
- The notified bodies verify conformity with TSIs and draw up the certificate(s) of verification intended for the applicant. Article 18(2) of Directive 2008/57/EC states that the notified body's verification 'shall also cover verification of the interfaces of the subsystem in question with the system into which it is incorporated, based on the information available in the relevant TSI and in the registers provided for in Articles 34 and 35'. This implies that the notified body has a role in checking technical compatibility with other subsystems, which is consistent with the fact that technical compatibility is covered by TSIs. The scope of these checks is limited to the relevant TSIs. Each notified body compiles a technical file in respect of the verifications they have carried out
- 57. The provisions of recommendation 56 apply mutatis mutandis to designated bodies and national rules.
- On the basis of Article 15(1) of Directive 2008/57/EC, the role of national safety authorities in authorising the placing in service should be to carry out a check of the documents accompanying the application for placing in service and providing evidence of the adequacy of the verification procedure. This check should consist of checking the completeness, relevance and consistency of the documentation submitted for authorisation. It is limited to matters within the competence of the National (railway) safety authorities as defined in Directive 2004/49/EC.
- If a Member State (or national safety authority) discovers a problem with the application for authorisation for placing in service in that a structural subsystem covered by the 'EC' declaration of verification accompanied by the technical file does not fully comply with Directive 2008/57/EC and in particular does not meet the essential requirements, it should apply Article 19 of Directive 2008/57/EC. This applies *mutatis mutandis* to interoperability constituents in accordance with Article 14 of Directive 2008/57/EC.
- 60. National safety authorities should not repeat any of the checks carried out as part of the verification procedure.
- 61. National safety authorities should not try to carry out or duplicate the work of rule setters, notified bodies, designated bodies or risk assessment bodies.
- 62. National safety authorities should neither carry out an in-depth systematic verification of the work done by the applicant, the notified body, the designated body and the CSM risk assessment body, nor a systematic validation of their results. National safety authorities may call assessment body verifications into question only if there are justifiable doubts. In this case, the principles of proportionality (taking account of the level of risk), non-discrimination, and transparency should be respected. Justified doubts may in particular arise on the basis of the checks referred to in recommendation 58, or when the return of experience has shown that a similar subsystem does not meet the essential requirements as defined in Article 19 of Directive 2008/57/EC.
- 63. In accordance with Article 28(2) of Directive 2008/57/EC for notified bodies (and *mutatis mutandis* for designated bodies), Member States should put in place systems to ensure the competence of assessment bodies and take action to address non-compliance with applicable legislation. To ensure a consistent approach, the Commission, assisted by the Agency, should have a coordination role in this matter.
- 64. Applicants, infrastructure managers and railway undertakings, in conjunction with ECMs should take account of the return of experience with already authorised vehicle types and subsystem designs or identification of unmanaged risks and put in place appropriate corrective actions.
- 65. Applicants should carry out these corrective actions prior to their request for authorisation and should be required to do so as soon as the need is detected.
- 66. For vehicles and subsystems already in use, railway undertakings and infrastructure managers should carry out these corrective actions within their SMS. The SMS of railway undertakings should ensure that the ECMs maintaining vehicles used by them introduce any changes necessary into their system of maintenance.

- Just as prior to authorisation the role of the national safety authority is not to specify a design solution, similarly the supervision role of national safety authorities is not to prescribe corrective action in the event of return of experience. Instead, national safety authorities should monitor the compliance of a railway undertaking or infrastructure manager with its own SMS. National safety authorities should check that railway undertakings and infrastructure managers define, carry out and manage the appropriate corrective actions by means of their own SMS.
- 68. Directive 2004/49/EC makes each of the infrastructure managers and of the railway undertakings responsible for their parts of the system. The railway undertaking is solely responsible for the safe operation of its trains. The infrastructure manager's role is confined to managing the infrastructure and therefore the infrastructure manager has no responsibility for the operation of trains other than to issue permission for train movement. The infrastructure manager has no other authorisation role.
- 69. Assessment of the ability of a subcontractor (e.g. a keeper) to manage its part of operation and maintenance of vehicles is not part of the process leading to an authorisation. This is covered by the obligation on the railway undertaking using authorised vehicles to make sure under its SMS that they have a suitable entity in charge of maintenance, according to Article 14a of Directive 2004/49/EC
- 70. Article 14a(1) of Directive 2004/49/EC as amended by Directive 2008/110/EC states that, before it is placed in service or used on the network, each vehicle should have an ECM assigned to it. The authorisation for placing in service is independent from the operation of a vehicle by a railway undertaking or the maintenance of the vehicle by an ECM; furthermore, Directive 2004/49/EC relates to the operation (use) and maintenance of vehicles. Therefore the ECM may be assigned either before or after a vehicle has been authorised to be placed in service, but always before it is registered in the national vehicle register (ECM is a mandatory field in the NVR) and before it is actually used on the network.
- 71. Organisations should manage the risks created by their activities. Responsibility for managing risks should sit with those who have the greatest capacity to manage them.
- 72. As railway undertakings and infrastructure managers are the only actors required to have safety certifications and safety authorisations, supported by SMSs, these organisations should have a key role for managing the contributions of others, and for taking the right decisions regarding their contributions. When railway undertakings or infrastructure managers take such decisions or actions under their safety management systems, this is without prejudice to the responsibilities of other entities, such as keepers, ECMs, manufacturers.
- 73. The division of operational responsibilities between the railway undertakings and infrastructure managers is defined in the TSI on operation and traffic management.
- 74. Railway undertakings should be held as best placed and most competent to:
 - (a) identify the potential hazards to their planned operations, including maintenance, and implement control measures, such as departure checks;
 - (b) properly specify their operational needs to contractors and suppliers, such as required performance, availability and reliability of vehicles;
 - (c) monitor the performance of vehicles;
 - (d) provide regular and comprehensive feedback on operations and performance to the keeper and ECM, as appropriate; and
 - (e) carry out contract reviews to understand and challenge contract performances.
- 75. On the other hand, railway undertakings and infrastructure managers should not be held as best placed or most competent to directly manage all the risks all the way down the supply chain. In order to fulfil their responsibilities, railway undertakings and infrastructure managers should design contractual obligations for the supply of goods and services in accordance with their safety management systems, taking into account the legal responsibilities of others. Once in use, it is standard practice for vehicles to be modified to correct defects and continuously improve their performance. Managing these changes safely is the responsibility of the railway undertaking. This responsibility should be fulfilled by applying the change management procedures in

its SMS and the Regulation on CSM risk assessment and, when necessary, ensuring that authorisation to place the modified vehicle in service is obtained. The railway undertaking should also ensure that all relevant information is communicated to the ECM for him to up-date the maintenance file.

- 76. Railway undertakings, infrastructure managers, ECMs and keepers should make sure that any support they may need through this process is provided for in the contract with the manufacturer.
- 77. Before the railway undertaking procures access to the network for the train from the infrastructure managers, they should first know the nature of the access that the infrastructure manager has offered for sale. The railway undertaking needs to be sure that the route to which they intend to purchase access is capable of supporting the trains they intend to run.
- 78. Railway undertakings should find in the infrastructure register all information (on the nature of the infrastructure) which they need in order to establish whether the train they intend to run is compatible with the specific route (train/route compatibility). The infrastructure manager should describe in the infrastructure register for each parameter the nominal values and, where applicable, the limit values of the interface parameters to which the route section is maintained. The railway undertakings rely upon the integrity of this information to ensure the safe operation of their trains. The infrastructure manager should inform the railway undertaking of any temporary changes to the nature of the infrastructure not listed in the register of infrastructure.
- 79. Once a railway undertaking has established, by using the infrastructure register and the file accompanying the vehicle authorisation/authorisation for type of vehicle, and considering the conditions of use and other restrictions on the authorisation for placing in service of the vehicle/authorisation for type of vehicle, that the route can support the train it intends to run, it should then refer to the provisions of the TSI related to 'operation and traffic management' (particularly its sections relating to train composition, train braking and running order) to ascertain whether there are any train related restrictions inhibiting operation on the route (e.g. speed limits, length limits, power supply limits).
- 80. If an infrastructure manager or railway undertaking has concerns relating to the use of a specific vehicle or piece of fixed equipment on a specific line, it should bring this to the attention of the other party in order to find a solution. If the party that raises the issue is not satisfied with the response, it should raise the issue with the national safety authority, which should take decisions in accordance with its powers.
- 81. According to Article 4(2) of Commission Regulation (EU) No 1078/2012 (¹), railway undertakings infrastructure managers and entities in charge of maintenance need to inform all the parties involved (including the national safety authorities) about any relevant safety risk as regards defects and construction non-conformities or malfunctions of technical equipment. This obligation of information also concerns the manufacturers and the contracting entities that established the 'EC' declaration of verification after the authorisation for placing in service
- 82. In addition to its task of authorising the placing in service of structural subsystems and in accordance with Article 16 of Directive 2004/49/EC, national safety authorities should also supervise that railway undertakings and infrastructure managers are operating under the requirements of EU legislation and, where allowed by Directive 2008/57/EC, national legislation. This supervision should also cover the management by railway undertakings and infrastructure managers of the risks related to the interface with their suppliers (such as manufacturers, keepers and rolling stock leasing companies), in particular during the procurement of goods and services and their integration into the SMSs of railway undertaking and infrastructure managers
- 83. The nature of the national safety authorities involvement in the use of a subsystem and its maintenance by a railway undertaking or infrastructure manager under the auspices of their SMS is of a supervisory nature. In particular national safety authorities should refuse to take the responsibility for meeting the essential requirements from the manufacturer/contracting entity or railway undertaking/infrastructure manager by specifying or explicitly checking and/or approving particular design solutions, maintenance requirements or corrective actions. The national safety authority should therefore focus on the appropriateness and suitability of the responsible actors management systems and should not act as 'finished work inspector' of the detailed outputs or decisions taken by these actors.

⁽¹) 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).

84. If Member States consider introducing urgent measures as a consequence of accidents or incidents, they should recognise that the safety management system of the railway undertaking is the primary mechanism for managing new risks to the operation of vehicles that may have been discovered in the course of accident/incident investigations or findings in the context of supervision. Even if a Member State believes that a new rule for authorising the placing in service is urgently required, it should follow the procedures specified in applicable Union legislation, including notification of the draft new rule to the Commission under Directive 98/34/EC of the European Parliament and of the Council (¹) or 2004/49/EC.

TESTING

- 85. The only tests that may be required for authorisation, which have to be performed before the authorisation for placing in service and which require the involvement of an assessment body, should be the tests which are:
 - explicitly specified in the TSIs, modules, and, where relevant, in national rules,
 - defined by the applicant for demonstrating the compliance with the requirements of the TSIs and/or national rules,
 - defined in other EU legislation, or
 - defined by the applicant, in accordance with the application of CSM RA as described in recommendation 41.
- 86. The involvement of the notified bodies and/or designated bodies in the verification of compliance with essential requirements is specified by the relevant TSIs and, respectively, national rules.
- 87. Tests not covered by recommendation 85 (e.g. tests needed by a railway undertaking to establish train-route compatibility before using a vehicle type or new subsystem on a particular route, or by a contracting entity to establish compliance with customer requirements) are not part of the authorisation for placing in service.
- 88. If on-track testing is to be carried out in order to verify conformity with requirements for authorisation before authorisation for placing in service has been given by the national safety authority, then any operational and organisational arrangements for carrying out these tests should be defined in each Member State's national legal framework and shall comply with Directives 2008/57/EC and 2004/49/EC. These should cover both the administrative arrangements and any mandatory technical and operational requirements. In general, Member States may adopt either of two approaches:
 - The Member State may include testing competence in a railway undertaking's safety certificate. This can be to the extent that a testing body may be certified as a railway undertaking with its scope of operation confined to only testing.
 - The Member State may require a competent entity (which may or may not be the national safety authority) to give permission to carry out tests. In this case the competent entity (in the absence of verification of conformity with requirements for authorisation by a notified body or designated body) must have sufficient depth of technical knowledge to make such decisions. To fulfil the requirements for transparency and legal certainty, the Member State must ensure that the entity is suitably independent and publish the process for authorising testing in its national legal framework making clear its requirements and the decision criteria to be used by the competent entity for granting authorisation to test.
- 89. The infrastructure managers have a direct role in the context of facilitating the authorisation process. In the case of additional tests required by a national safety authority, Article 23(6) of Directive 2008/57/EC requires that 'the infrastructure manager, in consultation with the applicant, shall make every effort to ensure that any tests take place within 3 months of the applicant's request'.

TECHNICAL FILE

90. According to Article 18 and Annex VI to Directive 2008/57/EC, an 'EC' declaration of verification for a subsystem should be accompanied by a technical file, including the documentation describing the subsystem, the documentation resulting from the verifications carried out by different assessment bodies and the documentation of the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance. The technical file accompanying the EC declaration of verification includes all supporting documents needed for the authorisation for placing in service.

⁽¹) Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 204, 21.7.1998, p. 37).

- 91. A vehicle or network project is covered by the technical file (s) accompanying the EC declaration of verification of the subsystems(s) it is composed of.
- 92. Several assessment bodies may need to intervene in the verification process of a subsystem, each of them according to their scope of competence. The applicant should be held responsible for gathering all files required by all applicable EU legislation. The combination of these technical files, complimented by any other information required by EU legislation (including the items specified in Annex VI 2.4 to Directive 2008/57/EC), is referred to as technical file accompanying the 'EC' declaration of verification for the subsystem.
- 93. The applicant for a type authorisation or an authorisation for placing in service of a vehicle should produce the documentation to be submitted for authorisation.

This documentation should include the technical file accompanying the EC declaration of verification compiled by the applicant for that subsystem.

In the case of a vehicle consisting of two subsystems, the documentation to be submitted for authorisation should include the two technical files accompanying the 'EC' declaration of verification of these two subsystems.

Pending the adoption of a recommendation by the Commission describing the content of the documentation to be submitted by the applicant, a Member State may allow that only a part of the technical file(s) accompanying the 'EC' declaration of verification is included in the documentation accompanying the application for authorisation of a vehicle or vehicle type. This should be clearly indicated in the national legal framework of the Member State published on the website of the European Railway Agency.

The technical file accompanying the 'EC' declaration of verification for a vehicle, vehicle type or subsystem should include all the information listed in Annex V and the documentation supporting the 'EC' declaration(s) of verification (e.g. the certificate(s) of verification and the technical files established by the notified and designated body(ies), calculation notes, records of the tests and examinations carried out, and technical characteristics to be recorded according to applicable TSIs and national rules). Information from the technical file accompanying the 'EC' declaration of verification which is not contained in the documentation submitted for authorisation should be made available to the relevant national safety authority on request.

The documentation accompanying the first authorisation for placing in service of a vehicle is to be submitted to the national safety authority at the time of authorisation and kept by the national safety authority as a record of what was authorised.

- 94. Where the suggestion included in recommendation 21 is followed, recommendation 93 should apply, *mutatis mutandis*, to the documentation to be submitted for authorisation of a network project and the technical files accompanying the relevant EC declaration of verification(s).
- 95. The applicant for an additional authorisation for placing in service of a vehicle should add to the original technical file accompanying the 'EC' declaration of verification the information required in Article 23(3) or 25(3) of Directive 2008/57/EC; this additional information is part of the information to be submitted to the national safety authority. The applicant should however preserve the structure of the technical file accompanying the 'EC' declaration of verification.
- 96. The part of the technical file accompanying the 'EC' declaration of verification defining 'all the elements relating to the conditions and limits of use and to the instructions concerning servicing, constant or routine monitoring, adjustment and maintenance' should be made available, for network projects, to the infrastructure manager and, for vehicles, to the railway undertaking operating the vehicle so that they may provide it to the ECM. For vehicles, this transmission of the information contained in the technical file accompanying the 'EC' declaration of verification may be done via the keeper of vehicles. After the placing in service it is the responsibility of the railway undertaking or infrastructure manager in conjunction with an ECM, to continuously review maintenance interventions and amend this information to ensure that it reflects the duty cycle and return of experience (Articles 4 and 9 of Directive 2004/49/EC).
- 97. The technical file accompanying the 'EC' declaration of verification should include the information needed to manage the design operating state of the vehicle or network project throughout its lifecycle.

98. The technical file accompanying the 'EC' declaration of verification should be updated if additional verifications are carried out (e.g. verification of conformity with national rules for obtaining additional authorisation for placing in service). In the case of an additional authorisation, the applicant should inform the national safety authority that issued the first authorisation.

'EC' DECLARATION OF VERIFICATION

- 99. According to Article 15 of Directive 2008/57/EC and Article 4(3) and (4) of Directive 2004/49/EC, it is the responsibility of the railway undertakings or infrastructure managers to ensure that a vehicle or subsystem meets all the essential requirements when it is in use. This is without prejudice to the responsibility of the other players involved (e.g. the responsibilities of the signatory of the 'EC' declaration of verification). Each manufacturer, maintenance supplier, wagon keeper, service provider and procurement entity must ensure that rolling stock, installations, accessories and equipment and services supplied by them comply with the essential requirements and that the conditions for use are specified in the technical file accompanying the EC declaration of verification so that they can be safely put into operation by the railway undertaking and/or infrastructure manager.
- 100. The responsibility for ensuring that the essential requirements of all applicable EU legislation are fully met in every detail by the subsystems in their design operating state at authorisation rests only with the applicant for authorisation of a subsystem, who issues the 'EC' declaration of verification. On the basis of the verification by the notified body or designated body and, where applicable, an overall assessment of the subsystem or vehicle, the applicant declares that all essential requirements are fulfilled. Therefore, if the compliance of the subsystem in its design operating state with the essential requirements at the time of authorisation is called into question at a later stage, the applicant, who has signed the relevant 'EC' declaration of verification should be considered as bearing the primary responsibility.
- 101. As a consequence, neither a type authorisation nor an authorisation for placing in service should be considered as handover of the responsibility to ensure or verify that the subsystem meets all essential requirements from the applicant to the authorising national safety authority.
- 102. If the compliance with the essential requirements of a subsystem in its design operating state is called into question, the authorising national safety authority should only be held accountable for the specific tasks allocated by Article 16 of Directive 2004/49/EC to the authorising or supervising national safety authority. The national law should reflect this principle in line with recommendations 58 to 62 and 67.
- 103. Independently from the verification of compliance with TSIs and national rules and the verification of safe integration carried out under Article 15(1) of Directive 2008/57/EC, the applicant signs the 'EC' declaration of verification on his sole responsibility. Therefore, the applicant should have a process in place to make sure that it has captured and fulfilled all the essential requirements and complied with all applicable EU legislation.
- 104. Although the CSM RA was originally not developed for that purpose, the applicant may choose to use the methodology in the CSM RA as a tool to fulfil part of his responsibility to ensure that all parts of the subsystem/vehicle meet in all respects and in every detail the essential requirements for the railway system set out in Annex III to Directive 2008/57/EC.
- Equally, the applicant may choose to use any other means allowed by the relevant legislation to ensure that all parts of the subsystem or vehicle meet the essential requirements for the railway system.
- 106. The 'EC' declaration of verification covers all applicable EU legislation. It is the responsibility of the signatory of the 'EC' declaration to comply with that legislation, including the corresponding conformity assessment and to involve, where necessary, assessment bodies required by that legislation.
- 107. In the case of an authorisation relating to vehicles or a network project consisting of more than one subsystem:
 - (a) there may be more than one applicant (one for each subsystem), each establishing an 'EC' declaration of verification for his part including its interfaces. In this case each applicant takes responsibility for the relevant subsystem in accordance with the scope of his 'EC' declaration of verification. A manufacturer or contracting entity may combine these two declarations in an application for a vehicle or network project;
 - (b) the manufacturer or contracting entity for the vehicle type, individual vehicle or network project may combine the 'EC' declarations of verification for each subsystem, as described in Annex V to Directive

2008/57/EC, into a single 'EC' declaration of verification for the vehicle type, individual vehicle or network project. In this case he declares on his sole responsibility that the subsystems comprising the vehicle type, individual vehicle or network project concerned have been subject to the relevant verification procedures, and satisfy the requirements of the relevant European Union legislation including any applicable national rules and that the vehicle or network project itself therefore satisfies the requirements of the relevant European Union legislation including any applicable national rules.

- To the end of establishing an 'EC' declaration of verification, the relevant TSIs may allow partial conformity to a TSI only if the TSI itself provides that specific functions, performances and interfaces required to fulfil the essential requirements are not mandatory in specific circumstances.
- 109. Only when all the preceding evidence and declarations have been compiled is the applicant in a position to formally apply to the competent national safety authority for an authorisation for placing in service of the subsystem. However it is recognised as a good practice for applicants to engage informally with national safety authorities as early as possible so that the process, requirements, roles and responsibilities, scope of application and limitations and conditions of use are clear and that there are no difficulties at a later stage.

MANAGEMENT OF MODIFICATIONS

- 110. Concerning the application of Articles 5(2), 15(3) and Article 20 of Directive 2008/57/EC, any modification of an existing structural subsystem should be analysed and categorised as only one of the following modifications:
 - 1. 'Substitution in the framework of maintenance' and other changes that do not introduce a deviation from the technical file accompanying the 'EC' declaration of verification. In this case there is no need for verification by an assessment body, the Member State does not need to be informed, and the initial 'EC' declaration of verification remains valid and unchanged;
 - 2. Changes that introduce a deviation from the technical file accompanying the 'EC' declaration of verification which may require new checks (and therefore require verification according to the applicable conformity assessment modules) but do not have any impact on the basic design characteristics of the subsystem. In this case, the technical file accompanying the 'EC' declaration of verification needs to be updated, and the relevant information should be made available upon request by the national safety authority;
 - 3. Renewal or upgrading (i.e. a major substitution or change that requires informing the Member State) which do not require a new authorisation for the placing in service; modifications that include a change in the basic design characteristics of the subsystem fall into this category;
 - 4. Renewal or upgrading (i.e. a major substitution or change that requires informing the Member State) which require a new authorisation for placing in service.

It should be noted that decisions by a contracting entity or manufacturer on the changes of a subsystem based on the four categories above must be completely independent from the decision on the significance of a change in the meaning of the CSM RA to the railway system to be made by a railway undertaking or infrastructure manager making a change to their part of the system. The decisions involve different actors in different circumstances with different decision criteria.

Categories 3 and 4 above introduce a deviation from the technical file accompanying the 'EC' declaration of verification with an impact on the basic design characteristics of the subsystem.

- 111. For both subsystems placed in service according to Directive 2008/57/EC and subsystem placed in service earlier for the sake of legal certainty and mutual recognition the TSIs should provide criteria to determine if a modification has an impact on the basic design characteristics of the subsystem and if it fits into category 3 or 4. Until the TSIs provide these criteria, Member States may specify them on national level.
- 112. The modification should always be considered by reference to the subsystem or vehicle at the moment of authorisation. An accumulation of minor modifications may result in a major modification.

- 113. The manufacturers or contracting entities should manage modifications to existing structural subsystems on the basis of the following:
 - (a) On the basis of recommendation 110, the manufacturer or contracting entity evaluates to which category the change belongs and whether the conformity assessment bodies or Member State authorities need to be informed. In the event of modifications of categories 2 to 4 of recommendation 110 resulting in an amendment of the technical file accompanying the 'EC' declaration of verification or affecting the validity of the verifications already carried out, the manufacturer or contracting entity, when introducing a change, should assess the need of a new 'EC' declaration of verification according to the criteria defined in paragraph 2 of Annex V to Directive 2008/57/EC (¹). For modifications in category 4, the Member State should decide to what extent the TSIs need to be applied to the project.
 - (b) Where the use of the CSM RA is required by a TSI for a particular parameter, the TSI should specify the circumstances in which a significance test is to be carried out in respect of this parameter.
 - (c) Similarly, for parameters which are relevant to perform the safe integration as part of authorisation according to recommendation 40 above, a significance test should be carried out for each parameter taking account of the extent of the change concerning the design operating state.
- 114. Railway undertakings and infrastructure managers are each responsible for their part of the railway system. In accordance with Article 4 of Directive 2004/49/EC, they should manage their part of the railway system using an SMS. The SMS should, where appropriate, make use of the CSM RA.
- 115. When a railway undertaking or infrastructure manager brings a vehicle or subsystem into use, it must use the CSM RA starting with an assessment of the significance of the change to the part of the railway system for which it is responsible. As part of this process, railway undertakings and infrastructure managers should address the following questions:
 - (a) concerning vehicles or subsystems to be brought (back) into use after modification and, where required, authorisation: railway undertaking and infrastructure managers should assess using their SMS whether the bringing into use of the vehicle or subsystem represents a change which is significant for the railway system as a whole;
 - (b) concerning any change to the operation of a subsystem or vehicle: railway undertaking and infrastructure managers should assess whether the change is significant in respect to their SMS and, if it is significant, whether the control of all relevant risks is covered by the SMS or the SMS needs to be adapted;
 - (c) concerning any changes to the maintenance of a subsystem or vehicle: railway undertakings and infrastructure managers should assess using their SMS whether the change is significant and if it significant ensure that the systems of maintenance of ECMs and SMS of the railway undertaking and infrastructure manager are appropriately adapted.
- 116. The national safety authorities should supervise the changes introduced in the subsystems in service through the supervision of the safety authorisations and safety certificates of the infrastructure managers and railway undertakings respectively. For this the national safety authorities should supervise if indent (a), (b) and (c) of recommendation 115 is applied correctly.
- 117. Recommendation 2011/217/EU is repealed.

This Recommendation is addressed to the Member States.

Done at Brussels, 5 December 2014.

For the Commission
Violeta BULC
Member of the Commission

⁽¹⁾ See separate proposal to amend Annex V to Directive 2008/57/EC.



