

**EXPLANATORY MEMORANDUM TO**  
**THE CHANNEL TUNNEL (SAFETY) (AMENDMENT) ORDER 2013**

**2013 No. 407**

1. This explanatory memorandum has been prepared by the Department for Transport and is laid before Parliament by Command of Her Majesty.

**2. Purpose of the instrument**

2.1 The Channel Tunnel (Safety) (Amendment) Order 2013 (“the Order”) implements, in respect of the British section of the Channel Tunnel, European legislation on the safety and interoperability of the European railway system. It does so by giving legal effect, in Great Britain, to a Bi-national Regulation of the Channel Tunnel Intergovernmental Commission (“IGC”).

**3. Matters of special interest to the Joint Committee on Statutory Instruments**

3.1 The coming into force provision in article 1(2) of the Order is necessary to ensure the Bi-national Regulation of the IGC will come into force simultaneously in Great Britain and France as intended by article 2 of that regulation. Article 2 of the Bi-national Regulation states that:

*“Each Government shall notify the other of the completion of its necessary internal procedures to enable this Regulation to enter into force. This Regulation shall enter into force on the date when both Governments have received from one another the documents containing these notifications.”*

3.2 The Department for Transport intends to ensure that the UK Government’s notification to the French Government of the completion of the UK internal procedures will not be given earlier than the expiry of 21 days from the date the Order is laid, so as to respect the “21 day rule”. Notice will be given in the London, Edinburgh and Belfast Gazettes of the date when the Bi-national Regulation, and so also the Order, comes into effect.

**4. Legislative Context**

4.1 The IGC was established by Article 10 of the Treaty of Canterbury of 1986, between the United Kingdom and France, to supervise the construction and operation of the Channel Tunnel. It is comprised of delegations from the authorities of both the United Kingdom and France.

4.2 The IGC has made a Bi-national Regulation (“the new Bi-national Regulation”) to implement, in respect of the Channel Tunnel, European Directives 2008/110/EC and

2009/149/EC, which amend the Railway Safety Directive (2004/49/EC) and a final element of the recast European Interoperability Directive (2008/57/EC) (the other provisions of this later Directive have already been implemented for the Channel Tunnel as explained at **paragraph 4.5** below). The new Bi-national Regulation implements these Directives by amending an earlier bi-national regulation made by the IGC on 24th January 2007 (“the 2007 Bi-national Safety Regulation”).

4.3 The 2007 Bi-national Safety Regulation was given legal effect in Great Britain by the Channel Tunnel (Safety) Order 2007<sup>1</sup>, as amended (“the principal Order”). The Order therefore amends the principal Order so as to give legal effect to the new-Bi-national Regulation in Great Britain.

4.4 The Railways and Other Guided Transport Systems (Safety) (Amendment) Regulations 2011<sup>2</sup> and the Railways (Interoperability) Regulations 2011<sup>3</sup> have already implemented the European legislation mentioned above for the rest of Great Britain (separate legislation exists for Northern Ireland) and in the case of the second of these sets of regulations for the Channel Tunnel also in all respects other than those provisions relating to the additional authorisation of rail vehicles. These latter provisions are now implemented by the new Bi-national Regulation and the Order.

4.5 A transposition note, which explains that the approach taken is predominantly copy out of the relevant provisions and indicates where this policy has not been applied and why, can be found at **Annex A**.

## **5. Territorial Extent and Application**

5.1 Subject to the few exceptions indicated in article 1(5), the Order only extends to Great Britain. These exceptions relate to the repeal of amendments, which did extend to Northern Ireland, that were made by the principal Order to the Channel Tunnel (International Arrangements) Order 2005<sup>4</sup>. Those amendments have since themselves been revoked by the Channel Tunnel (International Arrangements) (Amendment) Order 2009<sup>5</sup>. The amending provisions in the principal Order are therefore obsolete and so are now formally being revoked.

## **6. European Convention on Human Rights**

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

## **7. Policy background**

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<sup>1</sup> S.I. 2007/3531.

<sup>2</sup> S.I. 2011/1860.

<sup>3</sup> S.I. 2011/3066.

<sup>4</sup> S.I. 2005/3207.

<sup>5</sup> S.I. 2009/2081.

7.1 The objective of the European Union in introducing revisions to the Railway Safety Directive (2004/49/EC) through Directive 2008/110/EC and Directive 2009/149/EC and a recast Interoperability Directive (2008/57/EC), both of which the Order implements for the British section of the Channel Tunnel, was to assist in the creation of a harmonised European railway system that allows for the safe and uninterrupted movement of trains and therefore to promote the single market in the rail sector. The intention was to achieve this through the introduction of a common system of safety requirements and the harmonisation of the standards to which railway equipment is built and the processes by which equipment designs are verified and authorised to be placed into service.

7.2 This harmonisation is intended to bring economic benefits through economies of scale thereby improving the competitive position of the rail industry in comparison with other modes of transport. The introduction of common authorisation processes is intended to open up the European market for both the manufacture of railway equipment and the operation of railway services.

7.3 The provisions the Order implements for the British section of the Channel Tunnel are already in force for the rest of mainland Great Britain (see **Section 4**). However, the Channel Tunnel's cross-border nature and bi-national governance mean that it cannot be treated entirely in the same manner as the rest of the UK rail network. The IGC was established to provide a mechanism to ensure that the Governments of the United Kingdom and France could meet and discuss matters relating to the Channel Tunnel and provide a structure for decision making.

7.4 Implementation for the Channel Tunnel has been negotiated and agreed between the Governments of the United Kingdom and France and a new Bi-national Regulation made by the IGC under the authority of the Treaty of Canterbury to give effect to this implementation was signed by the two heads of delegation at a meeting of the IGC on 6 February 2013. The Order is now required to give legal force to this new Bi-national Regulation in Great Britain by amending the principle Order.

7.5 The key changes which the new Bi-nation Regulation will introduce for the Channel Tunnel are:

- a requirement for an entity in charge of maintenance to be identified in the National Vehicle Register for each rail vehicle used in the Channel Tunnel;
- a requirement for each entity in charge of maintenance to establish an appropriate maintenance regime for all vehicles assigned to it to ensure they are in a safe state of running;
- a revision of the methodology to calculate Common Safety Indicators (statistical measures which are used to assess safety performance and the economic impact of accidents); and
- provisions relating to the re-authorisation of rail vehicles for operation in the Channel Tunnel in particular:

- placing restrictions on when an additional authorisation can be required and on the scope of the verifications which can be required by the IGC (in its role as safety authority) before it issues authorisations;
- requiring the safety authority to deal with applications for safety authorisations for railway undertakings within certain time limits; and
- providing for the authorisation of trains to cover types of train as well as individual vehicles.

7.6 To give effect to these changes, the Order will amend the schedule to the principle Order (which sets out the text of the 2007 Bi-national Safety Regulation which has now been amended) with a revised schedule setting out the consolidated text of the 2007 Bi-national Regulation. The key amendments will:

- introduce a number of new and revised definitions including “Entity in Charge of Maintenance” and “Vehicle”;
- update the duties and responsibilities of the IGC in its role as safety authority for the Channel Tunnel;
- ensure that no vehicles can be placed in service or used in the Channel Tunnel unless they have an entity in charge of maintenance assigned to them;
- make the required changes concerning vehicle authorisations; and
- reflect the revised methodology to calculate Common Safety Indicators.

7.7 A minimal copy out approach has been adopted wherever possible to avoid placing additional regulatory burdens or costs on business. The level of public interest in the matters addressed by the Order is low. Primarily those affected by the Order are railway operators and manufacturers and suppliers of railway equipment; media interest is therefore usually limited to the specialist trade press for the railway industry. The Order is therefore primarily an economic measure and is not of any particular legal or political importance.

- **Consolidation**

7.8 The Order revokes and replaces the Schedule to the principle Order in its entirety. The new Bi-national Regulation itself does not consolidate its amendments with the 2007 Bi-national Safety Regulation, but except in relation to the points noted above, the majority of the provisions set out in the Schedule have not changed. In the United Kingdom, a consolidated version has been produced (as now set out in the amended Schedule to the principle Order) to maintain regulatory clarity. The consolidated text in the Schedule therefore reflects the 2007 Bi-national Safety Regulation with the changes made by the new Bi-national Regulation.

## **8. Consultation outcome**

8.1 A consultation on a draft of the Order was published on 15 November 2012 and ran until 14 December 2012. A four-week consultation period was chosen since equivalent provisions implementing the changes to the European Union railway safety

and interoperability regimes have been in force for some time in the whole of the United Kingdom except for the Channel Tunnel. The industry is therefore already familiar with them as are the small number of stakeholders who will be directly affected by the Order's provisions. There was also an urgent need to complete implementation of the Directives to the Channel Tunnel since the original transposition deadlines had passed and there was potential for formal infraction proceedings by the European Commission. A consultation workshop was organised during the consultation period but was cancelled due to a lack of uptake.

8.2 Eleven consultation responses were received and all of these broadly supported the proposals with many welcoming the additional transparency that their introduction would bring to the legislative framework. A number suggested that the provisions needed further clarity in certain areas and some minor drafting changes were made to address these. Many respondents also took the opportunity to raise broader issues surrounding the Channel Tunnel's current governance arrangements which are being addressed through other work programmes.

8.3 A summary of responses to the consultation is available from [www.gov.uk/government/consultations/channel-tunnel-transposition-of-railway-safety-and-interoperability-directives](http://www.gov.uk/government/consultations/channel-tunnel-transposition-of-railway-safety-and-interoperability-directives).

## **9. Guidance**

9.1 The Office of Rail Regulation has already updated its guidance on the Railways and Other Guided Transport Systems (Safety) Regulations 2006 to reflect the amendments to Directive 2004/49/EC. The Department for Transport has published a series of helpnotes on the Railways (Interoperability) Regulations 2011. The IGC has also published guidance on the 2007 Bi-national Safety Regulation and will revise this to incorporate the amendments introduced by the new Bi-national Regulation and the Order before these come into force.

## **10. Impact**

10.1 Since the provisions contained within the Order have already been in force in both the United Kingdom and France (except the Channel Tunnel) for some time, they are well already understood within the industry. We therefore anticipate that the only costs which the Order will create are one-off and related to familiarisation. Given the small number of operators affected, these have been assessed as negligible (£576). The Order will not impact on charities or voluntary bodies.

10.2 The impact on the public sector is minor and expected to be limited to undertaking the statutory review of provisions within five years of coming into force. This is expected to take 0.33 person-years to complete with an estimated cost, including publication as a Command Paper, of £20,000.

10.3 An Impact Assessment is attached to this explanatory memorandum and will be published alongside it on the [legislation.gov.uk](http://legislation.gov.uk) website.

## **11. Regulating small business**

11.1 The Order does not apply to small business. It is only applicable to those companies operating, or seeking to operate, through the Channel Tunnel and does not go beyond what is required to transpose the requirements of the European directives with which these companies would, in any event, have to comply in the United Kingdom and France (outside the Channel Tunnel) – in a coherent manner for the Channel Tunnel environment.

## **12. Monitoring & review**

12.1 The Order requires the Secretary of State to review, at least every five years, the principal Order, and publish a report about his conclusions.

## **13. Contact**

**13.1** Christopher Angell at the Department for Transport (**Tel:** 020 7944 0082 or **e-mail:** [Christopher.Angell@dft.gsi.gov.uk](mailto:Christopher.Angell@dft.gsi.gov.uk)) can answer any queries regarding the instrument.

## Transposition Note

**Transposition note for: (i) provisions of Directive 2008/57/EC relating to additional authorisations for the Channel Tunnel; (ii) Directive 2008/110/EC amending Directive 2004/49/EC on safety on the Community's railways; and (iii) Commission Directive 2009/149/EC amending Directive 2004/49/EC as regards Common Safety Indicators and common methods to calculate accident costs.**

## Background and explanation of the transposition note

### Directive 2008/57/EC

The Railways (Interoperability) Regulations 2011 [S.I. 2011/3066] implemented Directive 2008/57/EC (as amended by Directives 2009/131/EC and 2011/18/EC) for the UK. Those regulations apply to the UK side of the Channel Tunnel as well as to the rest of the UK. But regulation 6, which deals with the additional authorisation of rail vehicles used in the UK where a rail vehicle has already been authorised in another Member State, does not apply to the Channel Tunnel because the additional authorisation of rail vehicles used in the Channel Tunnel is governed by chapter 5 of 2007 Bi-national Safety Regulation for the Channel Tunnel. The 2007 Bi-national Safety Regulation is made under the Treaty of Canterbury 1986 and is applicable to both the UK and French sections of the Channel Tunnel. It is given force of law in Great Britain by the Channel Tunnel (Safety) Order 2007 [S.I. 2007/3531]. Chapter 5 of the 2007 Bi-national Safety Regulation, which implemented the additional authorisation provisions in Directive 2004/49/EC in its original form, needs to be amended in order to reflect the revised European Union additional authorisation provisions which are now contained in articles 23 and 25 of Directive 2008/57/EC.

The Order will therefore give force of law in Great Britain to the necessary revisions to the 2007 Bi-national Safety Regulation (made by a new IGC Bi-national Regulation of 6 February 2013) which will implement articles 23 and 25 of Directive 2008/57/EC. The revisions to the 2007 Bi-national Safety Regulation also implement other provisions of Directive 2008/57/EC to the extent those provisions need to apply to additional authorisations for the Channel Tunnel.

### Directive 2008/110/EC

The Railways and Other Guided Transport Systems (Safety) (Amendment) Regulations 2011 [S.I 2011/1860] ("the 2011 Regulations") implemented Directive 2008/110/EC for mainland Great Britain (there are separate regulations for Northern Ireland). The 2011 Regulations do not apply to the UK side of the Channel Tunnel because Directive 2004/49/EC, which Directive 2008/110/EC amends, was implemented separately for the Channel Tunnel by the 2007 Bi-national Safety Regulation, given force of law in the UK by the Channel Tunnel (Safety) Order 2007 [S.I 2007/3531]. Directive 2008/110/EC introduces requirements for ensuring that entities in charge of maintenance of rail vehicles



perform maintenance safely. The 2007 Bi-national Safety Regulation needs to be amended to implement Directive 2008/110/EC for the Channel Tunnel and the Order will give such amendments force of law in Great Britain.

### Directive 2009/149/EC

The Railways and Other Guided Transport Systems (Safety) (Amendment) Regulations 2011 [S.I. 2011/1860] implemented Directive 2009/149/EC for mainland Great Britain (again there were separate regulations for Northern Ireland), but for the same reasons as above, this does not include the UK side of the Channel Tunnel. Directive 2009/149/EC introduces new common safety indicators, common definitions for these indicators and methods for calculating them. The 2007 Bi-national Safety Regulation needs to be amended to implement Directive 2009/149/EC for the Channel Tunnel, and the Order will give those amendments force of law in the UK.

### Further explanation

The transposition note below indicates that the approach taken is predominately one of copy out. For these purposes we have regarded a provision as being copied out if either (i) the text is implemented by cross-reference or (ii) the language of the Directive is used with modifications to the text being limited to necessary changes to fit specific circumstances of the Channel Tunnel or the drafting approach of the 2007 Bi-national Safety Regulation, and without elaborating the text for policy reasons.

The articles referred to in the national provision column of the table refer to the articles in the text of the 2007 Bi-national Safety Regulation, which is set out in a schedule to the Order.

Article	Copy out (Yes/No)	If No – reason for elaboration	National Provision
<b>Directive 2008/57/EC</b>			
Article 21 (to the extent applicable to additional authorisations)	Yes		Articles 5A and 63
Articles 23(1)	Yes		Article 62
Articles 23(2) and 25(1) - Member States decide whether additional authorisation is mandatory.	No	The agreement reached with the French authorities is that additional authorisation will be mandatory for the Channel Tunnel.	Article 61
Articles 23(3)-(7) and 25(2)-(5)	Yes		Articles 5A, 63 and



Article	Copy out (Yes/No)	If No – reason for elaboration	National Provision
			64 (The last sentence of Article 64 (concessionaires' fees for tests) is not copied out but is carried over from the 2007 Bi-national Safety Regulation).
Articles 26 and 34(3) (to the extent applicable to additional authorisations)	Yes		Articles 63 and 65
Last two sentences of paragraph 2.6 of Annex VI (as amended by Directive 2011/18/EC)	Yes		Last two sentences of paragraph 2 of Article 63
<b>Directive 2008/110/EC</b>			
Article 1(1) – The following exclusions from scope are added to the exclusions in Article 2(2) of Directive 2004/49/EC. Both exclusions are discretionary:  (i) heritage vehicles that run on the national network (subject to compliance with national safety rules), and	No	These exclusions are not relevant to the types of operation carried out in the Channel Tunnel.	

Article	Copy out (Yes/No)	If No – reason for elaboration	National Provision
(ii) separate heritage, museum and tourist railways,			
Article 1(2) - New definitions of “entity in charge of maintenance”, “keeper” and “vehicle”	Yes		Articles 1(viii)c, 1(xv)a and 1(xxvii)
Article 1(3) - The term “wagon keeper” is replaced with “keeper” in Directive 2004/49/EC.	No	The term “wagon keeper” is not used in the bi-national regulation so no transposition is required.	
Article 1(4) - Amendments are made to Article 5(2) of Directive 2004/49/EC, concerning the adoption of a measure that revises the Annex of Common Safety Indicators.	No	No transposition required. The revised Annex was adopted in Directive 2009/149/EC, transposition of which is described below.	
Article 1(5) - Development of Common Safety Methods (“CSMs”): Directive 2008/110/EC expands on the original text on CSMs in Article 6 of Directive 2004/49/EC.	No	No transposition required as this provision deals with measures required to be adopted by the Commission.	
Article 1(6) - Development of Common Safety Targets (“CSTs”): Directive 2008/110/EC expands on the original text on CSTs in Article 7 of Directive 2004/49/EC.	No	No transposition required as this deals with the process for the adoption of common safety targets by the European Railway Agency and the European Commission.	
Article 1(7)(a) - Wording concerning safety certificates in Directive 2004/49/EC has been amended to	No	This provision is implemented by an amendment to the existing text of article 45 of the 2007 Bi-National Safety Regulation, on Part B Certification and the role of the IGC.	Article 45

Article	Copy out (Yes/No)	If No – reason for elaboration	National Provision
change the emphasis on the role of a railway undertaking as a provider of transport services rather than as an operator.			
Article 1(7)(a) - Minor amendment to wording in Article 10(1) of 2004/49/EC in relation to the matters to be confirmed by a safety certificate.	Yes		Article 45
<b>Article 1(8) – Incorporation of new Article 14a (Maintenance of Vehicles) into Directive 2004/49/EC</b>			
Article 14a(1) - Requirement that, prior to being placed in service or used on the network a vehicle must have an entity in charge of maintenance (“ECM”) assigned to it which is registered on the National Vehicle Register in accordance with Article 33 of Directive 2008/57/EC.	Yes		Article 55A(i)
Article 14a(2) - A railway undertaking, infrastructure manager or keeper may be an ECM.	Yes		Definition of “entity in charge of maintenance”, Article 1(viii)c
Article 14a(3) - Requirement for the ECM to establish a system of maintenance for the vehicles for which it is in charge.	Yes		Article 55B
Article 14a(3) - Requirement for the ECM to carry out maintenance itself or	No	This provision does not require transposition because, as a matter of UK law, an ECM is free to carry out maintenance through its	

Article	Copy out (Yes/No)	If No – reason for elaboration	National Provision
through contractors.		own efforts or by using third party contractors acting on its behalf.	
Article 14a(4) – Requirement for ECMs to be certified by an accredited or recognised body or by the national safety authority to perform maintenance on freight wagon. This includes mention of the accreditation or recognition process if the certifying body appointed by the Member State is not the national safety authority – the accreditation process in such a case is to be in accordance with paragraph 5 of article 14a. Paragraph 5 (see below) provides for a Commission measure to be adopted which will, among other things, provide for accreditation criteria. The relevant measure as adopted was Commission Regulation (EU) 445/2011.	Yes		Article 55A(ii) Article 1(viii)a Article 1(viii)b Article 1(viii)c
Article 14a(4) - Provision for ECMs that are railway undertakings or infrastructure managers to have confirmation of compliance with the ECM certification requirements (in Article 14a(5)) noted on the certificates specified in Articles 10 or 11, as applicable, of Directive 2004/49/EC.	No	Transposition not needed as this will be carried out administratively.	

Article	Copy out (Yes/No)	If No – reason for elaboration	National Provision
<p>Article 14a(5) - Measure to be adopted by the Commission by 24 December 2010 setting out the details and scope of the ECM certification system. This will include the date of application of the certification system and transition period, as well as details of the maintenance system and the format and validity of the certificate.</p> <p>Commission to review the measure, based on a recommendation by the European Railway Agency, by 24<sup>th</sup> December 2018.</p>	No	No transposition required – these are European Commission obligations, the first of which was fulfilled by Commission Regulation (EC) 445/2011 on a system of certification of entities in charge of maintenance.	
Article 14a(6) - ECM certificates to be valid throughout the Community.	Yes		Article 55A read with definition of an ECM certificate at Article 1(viii)a
Article 14a(7) - European Railway Agency to evaluate certification process and submit a report to the Commission within three years of the entry into force of the Commission’s measure on ECM certification.	No	No transposition required. This is a European Railway Agency obligation.	
Article 14a(8) - Permitted derogations from the obligations to: (a) identify the entity in charge of maintenance; and (b)	No	No transposition required. These derogations are not relevant in the Channel Tunnel.	

Article	Copy out (Yes/No)	If No – reason for elaboration	National Provision
certify it through alternative measures. The derogations are discretionary.			
<b>Other provisions</b>			
<p>Article 1(9) - Amendments to Article 16(2)(a), and (g) and deletion of Article 16(2)(b) of Directive 2004/49/EC requiring the safety authority to authorise the placing in service of structural subsystems within the scope of Directive 2008/57/EC, and that vehicles are duly registered on the National Vehicle register and that safety information therein is kept up-to-date.</p> <p>These amendments and the deletion update references to earlier interoperability directives that were consolidated by Directive 2008/57/EC.</p>	No	The wording in article 4(i) has been agreed with the French delegation to the IGC and recognises that authorisation is only required (consistently with article 15 of Directive 2008/57/EC and the rest of that Directive) where new or substantially modified sub-systems are put in place and not otherwise. This therefore makes clear that any obligation to obtain an authorisation is limited to those circumstances.	Article 4(i)
Article 1(10) - Obligation on national safety authority for any derogations adopted under Article 14a(8) to be reported in its annual safety report.	No	These derogations have not been implemented in respect of the Tunnel.	
Article 1(11) and (12) - Amends Article 26 which allows the annexes of Directive 2004/49/EC to be adapted to technical and scientific progress, with	No	No transposition required – these are European Commission obligations.	

Article	Copy out (Yes/No)	If No – reason for elaboration	National Provision
reference to EU Committee rules and procedures.			
Article 1(13) - Deletion of paragraph 3 from the requirements in Annex II for Member States to notify the Commission of national safety rules relating to the authorisation of placing in service and maintenance of new and substantially altered rolling stock that is not yet covered by a Technical Specification for Interoperability. This requirement is now included in Article 17(3) of Directive 2008/57/EC.	No	Unified safety rules are defined in Article 1(xxvi) as meaning both safety and technical requirements consistently with the wording of article 17(3) of Directive 2008/57/EC. In addition Article 18 (of the amended Bi-national Safety Regulation) now refers to unified safety rules as being made in accordance with article 17 of Directive 2008/57/EC and article 8 of Directive 2004/49/EC. Under Article 20 of the amended Bi-national Safety Regulation the IGC advises the UK and French Governments when unified safety rules or modifications to existing rules are required to be notified to the Commission. Such notifications are then handled administratively.	Article 1(xxvi) Article 18
Article 2 - Requires Member States to introduce provisions to implement the requirements contained in the amending Directive and notify the Commission of transposition by 24 December 2010.	No	No transposition required.	
Article 3 - States the entry into force date of the Directive	No	No transposition required.	
Article 4 - Addresses the Directive to Member States	No	No transposition required.	
<b>Directive 2009/149</b>			
Article 1 - Annex I of Directive	Yes		Article 1(iii) – the



Article	Copy out (Yes/No)	If No – reason for elaboration	National Provision
2004/49 is replaced by the Annex in the CSI Directive.			definition of “Common Safety Indicators” cross-refers to the new Annex to 2004/49/EC.
Article 2 - Requires Member States to introduce provisions to implement the CSI Directive and notify the Commission of transposition.	No	No transposition required.	
Article 3 - States the entry into force date of the Directive	No	No transposition required.	
Article 4 - Addresses the Directive to Member States	No	No transposition required.	
Annex - This is the text of the new Annex of Common Safety Indicators and common methods to calculate accident costs.	Yes		Article 1(iii) – the definition of “Common Safety Indicators” cross-refers to the new Annex to 2004/49/EC.