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## Legislation

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<sup>(1)</sup> Text with EEA relevance.

# EN

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<sup>(1)</sup> Text with EEA relevance.

## II

(Non-legislative acts)

## INTERNATIONAL AGREEMENTS

## COUNCIL DECISION (EU) 2018/760

of 14 May 2018

**on the conclusion of an Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway concerning additional trade preferences in agricultural products**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 207(4), in conjunction with point (a)(v) of Article 218(6) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament <sup>(1)</sup>,

Whereas:

- (1) Article 19 of the Agreement on the European Economic Area provides that the Contracting Parties undertake to continue their efforts with a view to achieving progressive liberalisation of agricultural trade.
- (2) In accordance with Council Decision (EU) 2017/2182 <sup>(2)</sup> the Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway concerning additional trade preferences in agricultural products ('the Agreement') was signed on 4 December 2017, subject to its conclusion.
- (3) The Agreement should be approved,

HAS ADOPTED THIS DECISION:

*Article 1*

The Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway concerning additional trade preferences in agricultural products is hereby approved on behalf of the Union.

The text of the Agreement is attached to this Decision.

*Article 2*

The President of the Council shall designate the person(s) empowered to deposit, on behalf of the Union, the instrument of approval provided for in the Agreement <sup>(3)</sup>.

<sup>(1)</sup> Consent of 17 April 2018 (not yet published in the Official Journal).

<sup>(2)</sup> Council Decision (EU) 2017/2182 of 20 November 2017 on the signing, on behalf of the European Union, of an Agreement in the form of an Exchange of Letters between the European Union and the Kingdom of Norway concerning additional trade preferences in agricultural products (OJ L 309, 24.11.2017, p. 1).

<sup>(3)</sup> The date of entry into force of the Agreement will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

*Article 3*

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

Done at Brussels, 14 May 2018.

*For the Council*  
*The President*  
E. ZAHARIEVA

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**AGREEMENT****in the form of an Exchange of Letters between the European Union and the Kingdom of Norway concerning additional trade preferences in agricultural products**

A. Letter from the European Union

Madam,

I have the honour to refer to the negotiations between the European Union and the Kingdom of Norway (‘the Parties’) on bilateral trade in agricultural products, concluded on 5 April 2017.

A new round of agricultural trade negotiations between the European Commission and the Norwegian Government was undertaken on the basis of Article 19 of the Agreement on the European Economic Area (‘the EEA Agreement’) with a view to furthering the progressive liberalisation of agricultural trade between the Parties on a preferential, reciprocal and mutually beneficial basis. The negotiations were carried out on an orderly basis, with due consideration given to developments in the Parties’ respective agricultural policies and circumstances, including developments in bilateral trade and trade conditions with other trading partners.

I hereby confirm that the results of the negotiations were as follows:

1. Norway undertakes to grant duty-free access to products originating in the European Union, listed in Annex I to this Agreement.
2. Norway undertakes to establish tariff quotas for products originating in the European Union, listed in Annex II to this Agreement.
3. The European Union undertakes to grant duty-free access to products originating in Norway, listed in Annex III to this Agreement.
4. The European Union undertakes to establish tariff quotas for products originating in Norway, listed in Annex IV to this Agreement.
5. The tariff codes set out in Annexes I to IV to this Agreement are the tariff codes that apply to the Parties as of 1 January 2017.
6. The existing tariff quotas for imports into Norway of 600 tons of swine meat, 800 tons of poultry meat and 900 tons of bovine meat, as listed in Annex II to the Agreement in the form of an exchange of letters between the European Union and the Kingdom of Norway signed on 15 April 2011 (‘the 2011 Agreement’), will not be affected by the implementation of a possible future WTO agreement on agriculture. Point 7 of the 2011 Agreement is therefore deleted.
7. As regards the additional tariff quota for imports into Norway of 1 200 tons of cheese and curd, the Parties agree that 700 tons will be administered by auction and 500 tons by the licensing system.
8. The Parties will continue efforts to consolidate all bilateral concessions (those already in force and those set out in this Agreement) in a new exchange of letters, which should replace their existing bilateral agricultural agreements.
9. The rules of origin for the purpose of implementing the concessions referred to in Annexes I to IV to this Agreement are set out in Annex IV to the Agreement in the form of an exchange of letters of 2 May 1992 (‘the 1992 Agreement’). However, Annex II to Protocol 4 to the EEA Agreement shall be applied instead of the Appendix to Annex IV to the 1992 Agreement.
10. The Parties will ensure that the concessions that they grant to each other will not be undermined.

11. The Parties agree to ensure that tariff quotas will be managed in such a way that imports can take place regularly and that the agreed quantities can actually be imported.
12. The Parties agree to exchange at regular intervals information on traded products, tariff quota management, price quotations and any useful information concerning their respective domestic markets and the implementation of the results of these negotiations.
13. Consultations will be held at the request of either Party on any question relating to the implementation of the results of these negotiations. If difficulties with implementation arise, such consultations will be held as promptly as possible, with a view to adopting appropriate corrective measures.
14. The Parties reaffirm their commitment, in accordance with Article 19 of the EEA Agreement, to continue their efforts with a view to achieving progressive liberalisation of agricultural trade. To this end, the Parties agree to carry out, in two years' time, a new review of the conditions of trade in agricultural products, with a view to exploring possible concessions.
15. In the event of the further enlargement of the European Union, the Parties will assess the impact on bilateral trade, with a view to adapting bilateral preferences so that pre-existing preferential trade flows between Norway and acceding countries can continue.

This Agreement shall enter into force on the first day of the third month following the date of the deposit of the last instrument of approval.

I would be grateful if you could confirm the agreement of your Government with the above.

Please accept, Madam, the assurance of my highest consideration.

Съставено в Брюксел на  
Hecho en Bruselas, el  
V Bruselu dne  
Udfærdiget i Bruxelles, den  
Geschehen zu Brüssel am  
Brüssel,  
Έγινε στις Βρυξέλλες, στις  
Done at Brussels,  
Fait à Bruxelles, le  
Sastavljeno u Bruxellesu  
Fatto a Bruxelles, addì  
Briselē,  
Priimta Briuselyje,  
Kelt Brüsszelben,  
Magħmul fi Brussell,  
Gedaan te Brussel,  
Sporządzono w Brukseli, dnia  
Feito em Bruxelas,  
Întocmit la Bruxelles,  
V Bruseli  
V Bruslju,  
Tehty Brysselissä  
Utfärdat i Bryssel den  
Utferdiget i Brussel,

04 -12- 2017

За Европейския съюз  
 Por la Unión Europea  
 Za Evropskou unii  
 For Den Europæiske Union  
 Für die Europäische Union  
 Euroopa Liidu nimel  
 Για την Ευρωπαϊκή Ένωση  
 For the European Union  
 Pour l'Union européenne  
 Za Europsku uniju  
 Per l'Unione europea  
 Eiropas Savienības vārdā –  
 Europos Sąjungos vardu  
 Az Európai Unió részéről  
 Ghall-Unjoni Ewropea  
 Voor de Europese Unie  
 W imieniu Unii Europejskiej  
 Pela União Europeia  
 Pentru Uniunea Europeană  
 Za Európsku úniu  
 Za Evropsko unijo  
 Euroopan unionin puolesta  
 För Europeiska unionen  
 For Den europeiske union

## ANNEX I

**DUTY FREE ACCESS FOR IMPORTS INTO NORWAY OF PRODUCTS ORIGINATING IN THE EUROPEAN UNION**

Norwegian customs tariff code	Description of products
01.01.2100	Live horses, asses, mules and hinnies; Horses; Pure-bred breeding animals
01.01.2902	Live horses, asses, mules and hinnies; Other horses; of weight less than 133 kg
01.01.2908	Live horses, asses, mules and hinnies; Other horses; Other
02.07.4300	Meat and edible offal, of the poultry of heading 01.05, fresh, chilled or frozen; of ducks; fatty livers, fresh or chilled
02.07.5300	Meat and edible offal, of the poultry of heading 01.05, fresh, chilled or frozen; of geese; fatty livers, fresh or chilled
05.06.9010	Bones and horn-cores, unworked, defatted, simply prepared (but not cut to shape), treated with acid or degelatinised; powder and waste of these products; Other; for feed purpose
05.11.9911	Animal products not elsewhere specified or included; dead animals of Chapter 1 or 3, unfit for human consumption; other; Blood powder, unfit for human consumption; for feed purpose

Norwegian customs tariff code	Description of products
05.11.9930	Animal products not elsewhere specified or included; dead animals of Chapter 1 or 3, unfit for human consumption; other; Meat and blood; for feed purpose
05.11.9980	Animal products not elsewhere specified or included; dead animals of Chapter 1 or 3, unfit for human consumption; other; other; for feed purpose
06.02.1021	Other live plants (including their roots), cuttings and slips; mushroom spawn; unrooted cuttings and slips; cuttings for nursery or horticultural purposes, except of green plants from 15 December - 30 April; <i>Begonia</i> , all sorts, <i>Campanula isophylla</i> , <i>Eupharboria pulcherrima</i> , <i>Poinsettia pulcherrima</i> , <i>Fuchsia</i> , <i>Hibiscus</i> , <i>Kalanchoe</i> and <i>Petunia</i> -hanging ( <i>Petunia hybrida</i> , <i>Petunia atkinsiana</i> )
06.02.1024	Other live plants (including their roots), cuttings and slips; mushroom spawn; unrooted cuttings and slips; cuttings for nursery or horticultural purposes, except of green plants from 15 December - 30 April; <i>Pelargonium</i>
06.02.9032	Other live plants (including their roots), cuttings and slips; mushroom spawn; Other; with balled roots or other culture media; other pot plants or bedding plants, including fruit- and vegetable plants for ornamental purposes; green pot plants from 1 May to 14 December; <i>Asplenium</i> , <i>Begonia x rex-cultorum</i> , <i>Chlorophytum</i> , <i>Euonymus japonicus</i> , <i>Fatsia japonica</i> , <i>Aralia sieboldii</i> , <i>Ficus elastica</i> , <i>Monstera</i> , <i>Philodendron scandens</i> , <i>Radermachera</i> , <i>Stereospermum</i> , <i>Syngonium</i> and <i>X-Fatshedera</i> , also when imported as part of mixed groups of plants
ex 07.08.2009 <sup>(1)</sup>	Leguminous vegetables, shelled or unshelled, fresh or chilled; beans; fresh or chilled beans ( <i>Vigna</i> spp., <i>Phaseolus</i> spp.), other than green beans, asparagus beans, wax beans and string beans
07.09.9930	Other vegetables, fresh or chilled; other; other; sweet corn; for feed purpose
ex 07.10.2209 <sup>(1)</sup>	Vegetables (uncooked or cooked by steaming or boiling in water), frozen; leguminous vegetables, shelled or unshelled; beans ( <i>Vigna</i> spp., <i>Phaseolus</i> spp.); other than green beans, asparagus beans, wax beans and string beans
07.11.5100	Vegetables provisionally preserved (for example, by sulphur dioxide gas, in brine, in sulphur water or in other preservative solutions), but unsuitable in that state for immediate consumption; mushrooms and truffles; mushrooms of the genus <i>Agaricus</i>
07.11.5900	Vegetables provisionally preserved (for example, by sulphur dioxide gas, in brine, in sulphur water or in other preservative solutions), but unsuitable in that state for immediate consumption; mushrooms and truffles; other
07.14.3009	Manioc, arrowroot, salep, Jerusalem artichokes, sweet potatoes and similar roots and tubers with high starch or inulin content, fresh, chilled, frozen or dried, whether or not sliced or in the form of pellets; sago pith; yams ( <i>Dioscorea</i> spp.); not for feed purpose
ex 07.14.4000 <sup>(1)</sup>	Manioc, arrowroot, salep, Jerusalem artichokes, sweet potatoes and similar roots and tubers with high starch or inulin content, fresh, chilled, frozen or dried, whether or not sliced or in the form of pellets; sago pith; taro ( <i>Colocasia</i> spp.)
07.14.5009	Manioc, arrowroot, salep, Jerusalem artichokes, sweet potatoes and similar roots and tubers with high starch or inulin content, fresh, chilled, frozen or dried, whether or not sliced or in the form of pellets; sago pith; yautia ( <i>Xanthosoma</i> spp.); not for feed purpose
08.11.2011	Fruit and nuts, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter; blackberries, mulberries or loganberries



Norwegian customs tariff code	Description of products
08.11.2012	Fruit and nuts, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter; containing added sugar or other sweetening matter; white or red currants
08.11.2013	Fruit and nuts, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter; containing added sugar or other sweetening matter; gooseberries
08.11.2092	Fruit and nuts, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter; Other; Blackberries, mulberries or loganberries
08.11.2094	Fruit and nuts, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter; Other; White or red currants
08.11.2095	Fruit and nuts, uncooked or cooked by steaming or boiling in water, frozen, whether or not containing added sugar or other sweetening matter; Other; Gooseberries
08.12.1000	Fruit and nuts, provisionally preserved (for example, by sulphur dioxide gas, in brine, in sulphur water or in other preservative solutions), but unsuitable in that state for immediate consumption; Cherries
10.08.5000	Buckwheat, millet and canary seeds; other cereals; quinoa ( <i>Chenopodium quinoa</i> )
11.09.0010	Wheat gluten, whether or not dried; for feed purpose
12.12.2910	Locust beans, seaweeds and other algae, sugar beet and sugar cane, fresh, chilled, frozen or dried, whether or not ground; fruit stones and kernels and other vegetable products (including unroasted chicory roots of the variety <i>Chicorium intybus sativum</i> ) of a kind used primarily for human consumption, not elsewhere specified or included; Seaweeds and other algae; Other; for feed purpose
17.02.2010	Other sugars, including chemically pure lactose, maltose, glucose and fructose, in solid form; sugar syrups not containing added flavouring or colouring matter; artificial honey, whether or not mixed with natural honey; caramel; maple sugar and maple syrup; for feed purpose
20.08.9300	Fruit, nuts and other edible parts of plants, otherwise prepared or preserved, whether or not containing added sugar or other sweetening matter or spirit, not elsewhere specified or included; other, including mixtures other than those of subheading 2008.1900; cranberries ( <i>Vaccinium macrocarpon</i> , <i>Vaccinium oxycoccus</i> , <i>Vaccinium vitis-idaea</i> )
20.09.8100	Fruit juices (including grape must) and vegetable juices, unfermented and not containing added spirit, whether or not containing added sugar or other sweetening matter; juice of any other single fruit or vegetable; cranberry ( <i>Vaccinium macrocarpon</i> , <i>Vaccinium oxycoccus</i> , <i>Vaccinium vitis-idaea</i> )
ex 20.09.8999	Fruit juices (including grape must) and vegetable juices, unfermented and not containing added spirit, whether or not containing added sugar or other sweetening matter; juice of any other single fruit or vegetable; Other, other, other, bilberry juice or concentrate
22.06	Other fermented beverages (for example, cider, perry, mead, saké); mixtures of fermented beverages and mixtures of fermented beverages and non-alcoholic beverages, not elsewhere specified or included
23.03.1012	Residues of starch manufacture and similar residues, beet-pulp, bagasse and other waste of sugar manufacture, brewing or distilling dregs and waste, whether or not in the form of pellets; residues of starch manufacture and similar residues; for feed purpose; of potatoes.

(<sup>1</sup>) These products are imported duty free. Nevertheless, Norway reserves its right to introduce a duty if the products are imported for feed purposes.

## ANNEX II

## TARIFF QUOTAS FOR IMPORTS INTO NORWAY OF PRODUCTS ORIGINATING IN THE EUROPEAN UNION

Norwegian customs tariff code	Description of products	Consolidated TRQs (annual quantity in tons)	Of which additional quotas <sup>(1)</sup>	Duty within the quota (NOK/kg)
	Meat of bovine animals, fresh or chilled	2 500	1 600	0
02.01.1000	Carcasses and half-carcasses			
02.01.2001	'Compensated' quarters, i.e. forequarters and hindquarters of the same animal presented at the same time			
02.01.2002	Other forequarters			
02.01.2003	Other hindquarters			
02.01.2004	So-called 'Pistola cuts'			
	Meat of bovine animals, frozen			
02.02.1000	Carcasses and half-carcasses			
02.02.2001	'Compensated' quarters, i.e. forequarters and hindquarters of the same animal presented at the same time			
02.02.2002	Other forequarters			
02.02.2003	Other hindquarters			
02.02.2004	So-called 'Pistola cuts'			
	Meat of swine, fresh, chilled or frozen	300 <sup>(2)</sup>	300 <sup>(2)</sup>	15
02.03.1904	Bellies (streaky) and cuts thereof; With bone in.			
	Meat and edible offal, of the poultry of heading 01.05, fresh, chilled or frozen Of fowls of the species <i>Gallus domesticus</i> ;	950	150	0
02.07.1100	Not cut in pieces, fresh or chilled			
02.07.1200	Not cut in pieces, frozen			
02.07.2400	Of turkeys; Not cut in pieces, fresh or chilled			
02.07.2500	Not cut in pieces, frozen			

Norwegian customs tariff code	Description of products	Consolidated TRQs (annual quantity in tons)	Of which additional quotas <sup>(1)</sup>	Duty within the quota (NOK/kg)
02.07.4401	Of ducks, fresh or chilled; breasts and cuts thereof	200	100	30
	Meat and edible meat offal, salted, in brine, dried or smoked; edible flours and meals of meat or meat offal Meat of swine; Hams, shoulders and cuts thereof, with bone in;			
02.10.1101	Containing 15 % or more by weight of bones	600 <sup>(3)</sup>	200 <sup>(3)</sup>	0
02.10.1109	Other (less than 15 % bone in)			
02.10.1900	Other (than Hams, shoulders and cuts thereof or Bellies and cuts thereof, with bone in)			
04.06	Cheese and curd	8 400	1 200	0
ex 06.02.9043 <sup>(4)</sup> 06.02.9044	Other live plants (including their roots), cuttings and slips; mushroom spawn Other; Pot plants or bedding plants, in flower;	20 million NOK	12 million NOK	0
06.02.9031	Green pot plants from 1 May to 14 December <sup>(5)</sup>	7 million NOK	3 million NOK	0
	Lettuce ( <i>Lactuca sativa</i> ) and chicory ( <i>Cichorium</i> spp.), fresh or chilled Iceberg lettuce; From 1 March to 31 May;	500 <sup>(6)</sup>	100 <sup>(6)</sup>	0
07.05.1112	Whole			
07.05.1119	Other			
10.05.9010	Maize (corn) For feed purpose	15 000	5 000	0
16.01.0000	Sausages and similar products, of meat, meat offal or blood; food preparations based on these products	600	200	0

<sup>(1)</sup> For the period 1.1-31.12, and during the first year of the application of the agreement *pro rata*, if necessary. Additional quotas to be added to existing quotas negotiated under previous EU-Norway agreements.

<sup>(2)</sup> In the period 1.12-31.12.

<sup>(3)</sup> Quantity is given for imports of hams with bone in. A conversion factor of 1.15 is used for imports of hams without bone in.

<sup>(4)</sup> Exception for the following plants: *Argyranthemum frutescens*, *Chrysanthemum frutescens*, *Begonia x hiemalis*, *Begonia elatior*, *Campanula*, *Dendranthema x grandiflora*, *Chrysanthemum x morifolium*, *Euphorbia pulcherrima*, *Poinsettia pulcherrima*, *Hibiscus*, *Kalanchoe*, *Pelargonium*, *Primula* and *Saintpaulia*.

<sup>(5)</sup> The following plants are included: *Condiaeum*, *Croton*, *Dieffenbachia*, *Epipremnum*, *Scindapsus aureum*, *Hedera*, *Nephrolepis*, *Peperomia obtusifolia*, *Peperomia rotundifolia*, *Schefflera*, *Soleirolia* and *Helxine*, also when imported as part of mixed groups of plants.

<sup>(6)</sup> End user criteria: Processing industry.

## ANNEX III

## DUTY FREE ACCESS FOR IMPORTS INTO THE EUROPEAN UNION OF PRODUCTS ORIGINATING IN NORWAY

CN code	Combined nomenclature description
0101 21 00	Live horses, pure-bred breeding animals
0101 29 10	Live horses, other than pure-bred breeding animals for slaughter
0101 29 90	Live horses, other than pure-bred breeding animals, other than for slaughter
0207 43 00	Fatty livers of ducks, fresh or chilled
0207 53 00	Fatty livers of geese, fresh or chilled
ex 0506 90 00	Bones and horn-cores and their powder and waste, unworked, defatted, degelatinised or simply prepared (excl. ossein and bones treated with acid and cut to shape), for animal feeding
ex 0511 99 85	Blood powder for animal feeding, unfit for human consumption
ex 0511 99 85	Meat and blood for animal feeding, unfit for human consumption
ex 0511 99 85	Other animal products for animal feeding, not elsewhere specified or included, unfit for human consumption (other than products of fish or crustaceans, molluscs or other aquatic invertebrates; dead animals of Chapter 3; blood; meat; natural sponges of animal origin; bovine semen)
ex 0602 10 90	Unrooted cuttings of all sorts of <i>Begonia</i> , <i>Campanula isophylla</i> , <i>Euphorbia pulcherrima</i> , <i>Poinsettia pulcherrima</i> , <i>Fuchsia</i> , <i>Hibiscus</i> , <i>Kalanchoe</i> and <i>Petunia</i> -hanging ( <i>Petunia hybrida</i> , <i>Petunia atkinsiana</i> ) for nursery or horticultural purposes [, except of green plants from 15 December to 30 April]
ex 0602 10 90	Unrooted cuttings of <i>Pelargonium</i> for nursery or horticultural purposes [, except of green plants from 15 December to 30 April]
ex 0602 90 99	<i>Asplenium</i> , <i>Begonia x rex-cultorum</i> , <i>Chlorophytum</i> , <i>Euonymus japonicus</i> , <i>Fatsia japonica</i> , <i>Aralia sieboldii</i> , <i>Ficus elastica</i> , <i>Monstera</i> , <i>Philodendron scandens</i> , <i>Radermachera</i> , <i>Stereospermum</i> , <i>Syngonium</i> and <i>X-Fatshedera</i> , presented as green pot plants from 1 May to 14 December
ex 0708 20 00	Beans ( <i>Vigna</i> spp., <i>Phaseolus</i> spp.) shelled or unshelled, fresh or chilled except green beans, asparagus beans, wax beans and string beans
ex 0709 99 60	Sweetcorn for animal feeding, fresh or chilled
ex 0710 22 00	Beans ( <i>Vigna</i> spp., <i>Phaseolus</i> spp.) uncooked or cooked by steaming or boiling in water, frozen except green beans, asparagus beans, wax beans and string beans
0711 51 00	Mushrooms of the genus <i>Agaricus</i> provisionally preserved, but unsuitable in that state for immediate consumptions
0711 59 00	Mushrooms (other than of the genus <i>Agaricus</i> ) and truffles provisionally preserved, but unsuitable in that state for immediate consumptions
ex 0714 30 00	Yams ( <i>Dioscorea</i> spp.) not for animal feeding, fresh, chilled, frozen or dried, whether or not sliced or in the form of pellets
ex 0714 40 00	Taro ( <i>Colocasia</i> spp.) not for animal feeding, fresh, chilled, frozen or dried, whether or not sliced or in the form of pellets

CN code	Combined nomenclature description
ex 0714 50 00	Yautia ( <i>Xanthosoma</i> spp.) not for animal feeding, fresh, chilled, frozen or dried, whether or not sliced or in the form of pellets
ex 0811 20 11	Blackberries, mulberries or loganberries, white- or redcurrants and gooseberries, uncooked or cooked by steaming or boiling in water, frozen, containing added sugar or other sweetening matter, with a sugar content exceeding 13 % by weight
ex 0811 20 19	Blackberries, mulberries or loganberries, white- or redcurrants and gooseberries, uncooked or cooked by steaming or boiling in water, frozen, containing added sugar or other sweetening matter, with a sugar content not exceeding 13 % by weight
0811 20 51	Redcurrants, uncooked or cooked by steaming or boiling in water, frozen, not containing added sugar or other sweetening matter
0811 20 59	Blackberries and mulberries, uncooked or cooked by steaming or boiling in water, frozen, not containing added sugar or other sweetening matter
ex 0811 20 90	Loganberries, whitecurrants and gooseberries, uncooked or cooked by steaming or boiling in water, frozen, not containing added sugar or other sweetening matter
0812 10 00	Cherries, provisionally preserved, but unsuitable in that state for immediate consumption
1008 50 00	Quinoa ( <i>Chenopodium quinoa</i> )
ex 1109 00 00	Wheat gluten for animal feeding, whether or not dried
ex 1212 29 00	Seaweeds and other algae for animal feeding, fresh, chilled, frozen or dried, whether or not ground
ex 1702 20 10	Maple sugar in solid form, containing added flavouring or colouring matter, for animal feeding
ex 1702 20 90	Maple sugar (other than in solid form, containing added flavouring or colouring matter) and maple syrup, for animal feeding
2008 93	Cranberries ( <i>Vaccinium macrocarpon</i> , <i>Vaccinium oxycoccos</i> , <i>Vaccinium vitis-idaea</i> ), otherwise prepared or preserved, whether or not containing added sugar or other sweetening matter or spirit
2009 81	Cranberry ( <i>Vaccinium macrocarpon</i> , <i>Vaccinium oxycoccos</i> , <i>Vaccinium vitis-idaea</i> ) juice, unfermented and not containing added spirit, whether or not containing added sugar or other sweetening matter
ex 2009 89	Bilberry juice or concentrate, unfermented and not containing added spirit, whether or not containing added sugar or other sweetening matter
2206	Other fermented beverages (for example, cider, perry, mead, saké); mixtures of fermented beverages and mixtures of fermented beverages and non-alcoholic beverages, not elsewhere specified or included
ex 2303 10 90	Residues of starch manufacture and similar residues from potatoes, for animal feeding
2302 50	Bran, sharps and other residues, whether or not in the form of pellets, derived from the sifting, milling or other working of cereals or of leguminous plants: — Of leguminous plants
ex 2309 90 31	Preparations of a kind used in animal feeding, containing no starch or containing 10 % or less by weight of starch, containing no milk products or containing less than 10 % by weight of such products, other than dog or cat food put up for retail sale and other than fish feed

## ANNEX IV

## TARIFF QUOTAS FOR IMPORTS INTO THE EUROPEAN UNION OF PRODUCTS ORIGINATING IN NORWAY

CN code	Combined nomenclature description	Consolidated TRQs (annual quantity in tons)	Of which addi- tional quotas (!)	Duty within the quota (EUR/kg)
0207 14 30	Meat and edible offal, of the poultry of heading 0105, fresh, chilled or frozen: Of fowls of the species <i>Gallus domesticus</i> Cuts with bone in, frozen Whole wings, with or without tips	550	550	0
0207 14 70	Meat and edible offal, of the poultry of heading 0105, fresh, chilled or frozen: Of fowls of the species <i>Gallus domesticus</i> Other cuts with bone in, frozen	150	150	0
0204	Meat of sheep or goats, fresh, chilled or frozen	500	0	0
0210	Meat and edible meat offal, salted, in brine, dried or smoked; edible flours and meals of meat or meat offal			
0404 10	Whey and modified whey, whether or not concentrated or containing added sugar or other sweetening matter	1 250	1 250	0
0404 10 02	Whey and modified whey, in powder, granules or other solid forms, without added sugar or other sweetening matter, of a protein content 'nitrogen content × 6,38' of ≤ 15 % by weight and a fat content, by weight, of ≤ 1,5 %	3 150	3 150	0
0603 19 70	Cut flowers and flower buds of a kind suitable for bouquets or for ornamental purposes, fresh, other than Roses, Carnations, Orchids, Chrysantemums, Lilies ( <i>Lilium</i> spp.), Gladioli and Ranunculi	500 000 EUR	500 000 EUR	0
1602	Other prepared or preserved meat, meat offal or blood	300	300	0
2005 20 20	Thin slices of potatoes, fried or baked, whether or not salted or flavoured, in airtight packings, suitable for immediate consumption	350	150	0
2309 90 96	Preparations of a kind used in animal feeding; Other	200	200	0

CN code	Combined nomenclature description	Consolidated TRQs (annual quantity in tons)	Of which addi- tional quotas <sup>(1)</sup>	Duty within the quota (EUR/kg)
3502 20	Albumins (including concentrates of two or more whey proteins, containing by weight more than 80 % whey proteins, calculated on the dry matter), albuminates and other albumin derivatives: — Milk albumin, including concentrates of two or more whey proteins	500	500	0

(1) For the period 1.1-31.12, and during the first year of the application of the agreement pro rata, if necessary. Additional quotas to be added to existing quotas negotiated under previous EU-Norway agreements.

## B. Letter from the Kingdom of Norway

Madam,

I have the honour to acknowledge receipt of your letter of today's date, which reads as follows:

I have the honour to refer to the negotiations between the European Union and the Kingdom of Norway ('the Parties') on bilateral trade in agricultural products, concluded on 5 April 2017.

A new round of agricultural trade negotiations between the European Commission and the Norwegian Government was undertaken on the basis of Article 19 of the Agreement on the European Economic Area ('the EEA Agreement') with a view to furthering the progressive liberalisation of agricultural trade between the Parties on a preferential, reciprocal and mutually beneficial basis. The negotiations were carried out on an orderly basis, with due consideration given to developments in the Parties' respective agricultural policies and circumstances, including developments in bilateral trade and trade conditions with other trading partners.

I hereby confirm that the results of the negotiations were as follows:

1. Norway undertakes to grant duty free access to products originating in the European Union, listed in Annex I to this Agreement.
2. Norway undertakes to establish tariff quotas for products originating in the European Union, listed in Annex II to this Agreement.
3. The European Union undertakes to grant duty free access to products originating in Norway, listed in Annex III to this Agreement.
4. The European Union undertakes to establish tariff quotas for products originating in Norway, listed in Annex IV to this Agreement.
5. The tariff codes set out in Annexes I to IV to this Agreement are the tariff codes that apply to the Parties as of 1 January 2017.
6. The existing tariff quotas for imports into Norway of 600 tons of swine meat, 800 tons of poultry meat and 900 tons of bovine meat, as listed in Annex II to the Agreement in the form of an exchange of letters between the European Union and the Kingdom of Norway signed on 15 April 2011 ('the 2011 Agreement'), will not be affected by the implementation of a possible future WTO agreement on agriculture. Point 7 of the 2011 Agreement is therefore deleted.
7. As regards the additional tariff quota for imports into Norway of 1 200 tons of cheese and curd, the Parties agree that 700 tons will be administered by auction and 500 tons by the licensing system.
8. The Parties will continue efforts to consolidate all bilateral concessions (those already in force and those set out in this Agreement) in a new exchange of letters, which should replace their existing bilateral agricultural agreements.

9. The rules of origin for the purpose of implementing the concessions referred to in Annexes I to IV to this Agreement are set out in Annex IV to the Agreement in the form of an exchange of letters of 2 May 1992 ('the 1992 Agreement'). However, Annex II to Protocol 4 to the EEA Agreement shall be applied instead of the Appendix to Annex IV to the 1992 Agreement.
10. The Parties will ensure that the concessions that they grant to each other will not be undermined.
11. The Parties agree to ensure that tariff quotas will be managed in such a way that imports can take place regularly and that the agreed quantities can actually be imported.
12. The Parties agree to exchange at regular intervals information on traded products, tariff quota management, price quotations and any useful information concerning their respective domestic markets and the implementation of the results of these negotiations.
13. Consultations will be held at the request of either Party on any question relating to the implementation of the results of these negotiations. If difficulties with implementation arise, such consultations will be held as promptly as possible, with a view to adopting appropriate corrective measures.
14. The Parties reaffirm their commitment, in accordance with Article 19 of the EEA Agreement, to continue their efforts with a view to achieving progressive liberalisation of agricultural trade. To this end, the Parties agree to carry out, in two years' time, a new review of the conditions of trade in agricultural products, with a view to exploring possible concessions.
15. In the event of the further enlargement of the European Union, the Parties will assess the impact on bilateral trade, with a view to adapting bilateral preferences so that pre-existing preferential trade flows between Norway and acceding countries can continue.

This Agreement shall enter into force on the first day of the third month following the date of the deposit of the last instrument of approval.'

I have the honour to confirm that the Kingdom of Norway is in agreement with the contents of this letter.

Please accept, Madam, the assurance of my highest consideration.

Utfærdiget i Brussel,

Съставено в Брюксел на

Hecho en Bruselas, el

V Bruselu dne

Udfærdiget i Bruxelles, den

Geschehen zu Brüssel am

Brüssel,

Έγινε στις Βρυξέλλες, στις

Done at Brussels,

Fait à Bruxelles, le

Sastavljeno u Bruxellesu

Fatto a Bruxelles, addì

Briselē,

Priimta Briuselyje,

Kelt Brüsszelben,

Magħmul fi Brussell,

Gedaan te Brussel,

Sporządzono w Brukseli, dnia

Feito em Bruxelas,

Întocmit la Bruxelles,

V Bruseli

V Bruslju,

Tehty Brysselissä

Utfärdat i Bryssel den

04 -12- 2017



For Kongeriket Norge  
За Кралство Норвегия  
Por el Reino de Noruega  
Za Norské království  
For Kongeriget Norge  
Für das Königreich Norwegen  
Norra Kuningriigi nimel  
Για το Βασίλειο της Νορβηγίας  
For the Kingdom of Norway  
Pour le Royaume de Norvège  
Za Kraljevinu Norvešku  
Per il Regno di Norvegia  
Norvēģijas Karalistes vārdā –  
Norvegijos Karalystės vardu  
A Norvég Királyság részéről  
Ghar-Renju tan-Norveġja  
Voor het Koninkrijk Noorwegen  
W imieniu Królestwa Norwegii  
Pelo Reino da Noruega  
Pentru Regatul Norvegiei  
Za Nórske kráľovstvo  
Za Kraljevino Norveško  
Norjan kuningaskunnan puolesta  
För Konungariket Norge

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# REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2018/761

of 16 February 2018

**establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 1077/2012**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety <sup>(1)</sup>, and in particular Article 6(6) thereof,

Having regard to Recommendation ERA-REC-115-REC from the European Union Agency for Railways delivered to the Commission on 9 March 2017, on the revision of the common safety methods on conformity assessment and the common safety method on supervision,

Whereas:

- (1) The common safety methods ('CSMs') describe how the safety levels and the achievement of safety targets and compliance with other safety requirements are assessed.
- (2) In accordance with Article 6(5) of Directive (EU) 2016/798, the CSMs are to be revised at regular intervals, taking into account the experience gained from their application and the global development of railway safety and with the objective of generally maintaining and, where reasonably practicable, continuously improving safety.
- (3) By its Implementing Decision of 1 September 2016 <sup>(2)</sup>, the Commission gave a mandate to the European Union Agency for Railways ('the Agency') in accordance with Article 6(2) of Directive (EU) 2016/798 to revise Commission Regulations (EU) No 1158/2010 <sup>(3)</sup>, (EU) No 1169/2010 <sup>(4)</sup> and (EU) No 1077/2012 <sup>(5)</sup>. On 9 March 2017, the Agency issued its recommendation, enclosing a report on the results of the consultation of national safety authorities, social partners and users and a report assessing the impact of the amended CSMs to be adopted, to address the mandate of the Commission. The Commission examined the recommendation issued by the Agency to verify that the mandate was fulfilled as referred to in Article 6(4) of Directive (EU) 2016/798.
- (4) After a single safety certificate or a safety authorisation is issued, the national safety authority should conduct supervision activities to check whether the safety management system arrangements are effectively used during operation and that all the necessary requirements are complied with on a continuous basis.
- (5) In accordance with Article 17(1) and (8) of Directive (EU) 2016/798, in cases where railway undertakings and infrastructure managers are also entities in charge of maintenance that are not certified in accordance with Article 14(4) of Directive (EU) 2016/798, supervision activities carried out by national safety authorities with the

<sup>(1)</sup> OJ L 138, 26.5.2016, p. 102.

<sup>(2)</sup> Commission Implementing Decision of 1 September 2016 on a mandate to the European Union Agency for Railways for the revision of the common safety methods for conformity assessment and the common safety method for supervision and repealing Implementing Decision C(2014) 1649 final (C(2016) 5504 final).

<sup>(3)</sup> Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates (OJ L 326, 10.12.2010, p. 11).

<sup>(4)</sup> Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation (OJ L 327, 11.12.2010, p. 13).

<sup>(5)</sup> Commission Regulation (EU) No 1077/2012 of 16 November 2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation (OJ L 320, 17.11.2012, p. 3).

aim of checking the application of the relevant CSMS referred to in Article 6 of Directive (EU) 2016/798 by entities in charge of the maintenance are justified means for supervising the effectiveness of the safety management systems of these railway undertakings and infrastructure managers.

- (6) A supervision process should be set out for the national safety authorities with the aim of improving mutual trust in their approaches to, and decision-making during, supervision activities.
- (7) National safety authorities should be accountable for their decisions and therefore, should have internal arrangements or procedures against which they can be held to account.
- (8) Supervision should be targeted primarily at those activities which a national safety authority believes give rise to the most serious risks or where the risks are least well-controlled. For that purpose, the national safety authority should develop and implement a risk-based supervision strategy and plan(s) outlining how it targets its activities and sets its priorities for supervision.
- (9) Enforcement actions taken by national safety authorities to ensure that railway undertakings and infrastructure managers achieve legal compliance as referred to in Article 17(1) of Directive (EU) 2016/798 should be proportionate to any risks to safety or to the potential seriousness of any non-compliance with their legal obligations.
- (10) To be able to perform its tasks under point (i) of Article 16(2) of Directive (EU) 2016/798, the national safety authority should form a judgement, based on the outcomes of its supervision activities, on the effectiveness of the safety regulatory framework.
- (11) The audit and inspection techniques for supervision should commonly include interviews with people at various levels in an organisation, reviewing documents and records related to the safety management system and examining the safety outcomes of the management system revealed by inspections or related activities.
- (12) In accordance with Article 17(13) of Directive (EU) 2016/798, the Agency, acting as safety certification body, and the national safety authorities should coordinate when and where appropriate to ensure the full exchange of information between assessment and supervision activities, including any notices addressed to railway undertakings. Similarly, the relevant national safety authorities should coordinate in the case of cross-border infrastructures.
- (13) In order to ensure that supervision is carried out effectively by national safety authorities and to reinforce mutual trust between them, those authorities should ensure that staff involved in supervision have the necessary competencies. To that end, those competencies should be identified.
- (14) National safety authorities involved in the supervision of an infrastructure manager with cross-border infrastructure or of a railway undertaking operating in more than one Member State should cooperate with each other to avoid any duplication of supervision and coordinate their approach to supervision to ensure that any key information on the infrastructure manager or railway undertaking, particularly on known risks and its safety performance, is shared and used to target supervision activities on the areas of greatest risk for the whole operation.
- (15) National safety authorities should cooperate, where necessary, with other competent authorities or bodies that interact in the railway sector, such as the regulatory bodies and the licensing authorities within the meaning of Directive 2012/34/EU of the European Parliament and of the Council<sup>(1)</sup>, or the competent authorities for monitoring compliance with applicable working, driving and rest-time rules for train drivers, to deliver their respective mandates, share information, resolve any conflicts in approach, prevent related adverse effects in the railway system and coordinate their response to any failure to comply with the safety regulatory framework.
- (16) According to Article 31(3) of Directive (EU) 2016/798, the new safety certification regime will start from 16 June 2019. However, Member States have the possibility to notify the Agency and the Commission pursuant to Article 33(2) of Directive (EU) 2016/798 that they have extended the transposition period and may in

<sup>(1)</sup> Directive 2012/34/EU of the European Parliament and of the Council of 21 November 2012 establishing a single European railway area (OJ L 343, 14.12.2012, p. 32).

consequence continue to issue certificates in accordance with Directive 2004/49/EC of the European Parliament and of the Council <sup>(1)</sup> until 16 June 2020. It is therefore necessary to align the application dates of this Regulation with the dates set out in Directive (EU) 2016/798 in order to allow smooth transition to the new certification regime.

(17) Regulation (EU) No 1077/2012 has become obsolete and should be replaced by this Regulation,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

##### **Subject matter**

This Regulation establishes common safety methods ('CSMs'), referred to in point (c) of Article 6(1) of Directive (EU) 2016/798, for the supervision of the management of safety by national safety authorities after the railway undertakings have been granted a single safety certificate and infrastructure managers after they have been granted a safety authorisation.

#### *Article 2*

##### **Definition**

For the purposes of this Regulation, the following definitions shall apply:

- (a) 'safety certification body' means the body responsible for issuing a single safety certificate, either the Agency or a national safety authority;
- (b) 'residual concern' means a minor issue identified during the assessment of an application for a single safety certificate or for a safety authorisation which does not prevent their issuing and can be deferred for later supervision.

#### *Article 3*

##### **Supervision process**

1. National safety authorities shall apply the supervision process set out in Annex I.
2. National safety authorities shall establish internal arrangements or procedures for managing the supervision process.
3. For the purposes of supervision, the national safety authorities shall accept the authorisations, recognitions or certificates of products or services provided by railway undertakings and infrastructure managers, or their contractors, partners or suppliers, granted in accordance with relevant Union law, as proof of the ability of railway undertakings and infrastructure managers to fulfil the corresponding requirements defined in Commission Delegated Regulation (EU) 2018/762 <sup>(2)</sup>.

#### *Article 4*

##### **Techniques for supervision**

National safety authorities shall adopt suitable techniques, such as audits and inspections, and select the most appropriate ones when planning their supervision activities.

<sup>(1)</sup> Directive 2004/49/EC of 29 April 2004 of the European Parliament and of the Council on safety of 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).

<sup>(2)</sup> Commission Delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010 (See page 26 of this Official Journal).

*Article 5***Links between supervision and assessment**

1. The national safety authority carrying out supervision shall use and, where relevant, share information gathered on the performance of the safety management system during its supervision activities for the purpose of renewing or updating single safety certificates or safety authorisations.
2. In cases where the national safety authority referred to in paragraph 1 is not responsible for issuing the single safety certificate or safety authorisation, it shall coordinate promptly with the Agency acting as safety certification body or the relevant national safety authority, in the case of cross-border infrastructure, on its request, after the receipt of an application for renewal or update.

Based on the outcome of the coordination referred to in the first subparagraph, the national safety authority shall identify and target the information which is relevant to assessing whether the railway undertaking's or infrastructure manager's safety management system is effectively working, including at least:

- (a) a description of major non-compliances, which may affect safety performance or create serious safety risks, and any other area of concern identified during supervision activities since the previous assessment;
- (b) the status of the action plan (or plans) established by the railway undertaking or infrastructure manager to resolve major non-compliances and any other area of concern referred to in point (a) and relevant actions that have been taken by the national safety authority to supervise resolution of these issues;
- (c) an overview of the safety performance of the railway undertaking or infrastructure manager operating in its Member State;
- (d) the status of the action plan (or plans) established by the railway undertaking or infrastructure manager to resolve residual concerns from previous assessment.

*Article 6***Competence of the staff involved in supervision**

1. The national safety authorities shall ensure that staff involved in supervision have the following competencies:
  - (a) knowledge of the relevant regulatory framework as it applies to supervision;
  - (b) knowledge of the functioning of the railway system;
  - (c) appropriate level of critical analysis;
  - (d) experience in the supervision of a safety or similar management system in the railway sector, or a safety management system in a sector with equivalent operational and technical challenges;
  - (e) knowledge of and experience in interviewing skills;
  - (f) problem solving, communication and teamworking.
2. In the case of teamwork, the competencies may be shared amongst the team members.
3. With a view to ensuring the correct application of paragraph 1, the national safety authorities shall put in place a competence management system which shall include:
  - (a) the development of competence profiles for each job, position or role;
  - (b) the recruitment of staff in accordance with the established competence profiles;
  - (c) the maintenance, development and assessment of staff competence in accordance with the established competence profiles.

*Article 7***Decision-making criteria**

1. The national safety authority shall establish and publish decision-making criteria on how it evaluates the correct application of a safety management system by a railway undertaking or an infrastructure manager and the effectiveness of the safety management system in controlling safety risks associated with the activities of the railway undertaking or infrastructure manager.

These criteria shall include information on how the national safety authority manages and deals with non-compliances identified in the safety management system of the railway undertaking and infrastructure manager.

2. The national safety authority shall adopt and publish a procedure detailing how railway undertakings, infrastructure managers and any other interested party may submit a complaint on decisions taken during supervision activities.

*Article 8***Coordination among national safety authorities and cooperation with other authorities or bodies**

1. National safety authorities involved in the supervision of an infrastructure manager with cross-border infrastructure(s) or of a railway undertaking operating in more than one Member State shall coordinate their approach to supervision in accordance with Article 17(7) and (9) of Directive (EU) 2016/798.

After the granting of the safety authorisation or single safety certificate, national safety authorities shall promptly decide which of them is to have a leading role for coordinating the supervision of the correct application and effectiveness of the safety management system, without prejudice to the obligations of the national safety authorities under points (d) and (j) of Article 16(2) and Article 17 of Directive (EU) 2016/798.

2. For the purposes of paragraph 1, the national safety authorities shall develop arrangements based on the framework for coordinated and joint supervision set out in Annex II.

3. National safety authorities shall also develop cooperation arrangements with the national investigation bodies, certification bodies for entities in charge of maintenance and other competent authorities or bodies.

*Article 9***Repeal**

Regulation (EU) No 1077/2012 is repealed with effect from 16 June 2019.

*Article 10***Entry into force and application**

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

It shall apply from 16 June 2019. However, Article 5(2) and Article 8(1) and (2) shall apply from 16 June 2020 in the Member States that have notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798 that they have extended the period for transposition of that Directive.

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

Done at Brussels, 16 February 2018.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX I

**Supervision process as referred to in Article 3**

## 1. GENERAL

The national safety authority shall develop a structured and auditable process for the complete activity which takes into account the elements below. This ensures that the supervision process is iterative and takes into account the need to continually improve, as shown in the diagram below in the Appendix.

## 2. SETTING UP THE SUPERVISION STRATEGY AND PLAN(S)

The national safety authority shall:

- (a) collect and analyse data/information from a variety of sources as an input to the strategy and the plan or plans. Sources could include information gathered during the assessment of safety management systems, outcomes of previous supervision activities, information from authorisations of subsystems or vehicles, national investigation bodies accident reports/recommendations, other accident/incident reports or data, railway undertakings' or infrastructure managers' annual safety reports to the national safety authority, annual maintenance reports from entities in charge of maintenance, complaints from members of the public and other relevant sources;
- (b) identify in the supervision strategy risk areas for targeted supervision activities, including those emerging from the integration and management of human and organisational factors, where relevant;
- (c) develop a supervision plan or plans showing how it will give effect to the supervision strategy during the lifecycle of valid single safety certificates and safety authorisations;
- (d) produce an initial estimate of resources required to give effect to the plan or plans, based on the target areas identified;
- (e) allocate resources to give effect to the plan or plans;
- (f) address in the supervision strategy and plan(s) any matters relating to cross-border operations or infrastructure(s) through coordination with other national safety authority (or authorities).

## 3. COMMUNICATING THE SUPERVISION STRATEGY AND PLAN(S)

The national safety authority shall:

- (a) communicate the overall objectives of the supervision strategy and overall explanation of the plan or plans to relevant railway undertakings or infrastructure managers and, where appropriate, more widely to other stakeholders;
- (b) provide relevant railway undertakings or infrastructure managers with an overall explanation on how the supervision plan or plans will be undertaken.

## 4. DELIVERING THE SUPERVISION ACTIVITIES

The national safety authority shall:

- (a) give effect to the plan or plans;
- (b) take proportionate action(s) to deal with failure of a railway undertaking or an infrastructure manager to comply with its legal obligations, including issuing any urgent safety alerts and applying temporary safety measures when necessary;
- (c) evaluate how adequately a railway undertaking or an infrastructure manager has developed and implemented an action plan or plans to remedy any non-compliance or residual concern within a specified time period;
- (d) document the results of its supervision activities.



#### 5. OUTCOMES OF SUPERVISION ACTIVITIES

The national safety authority shall:

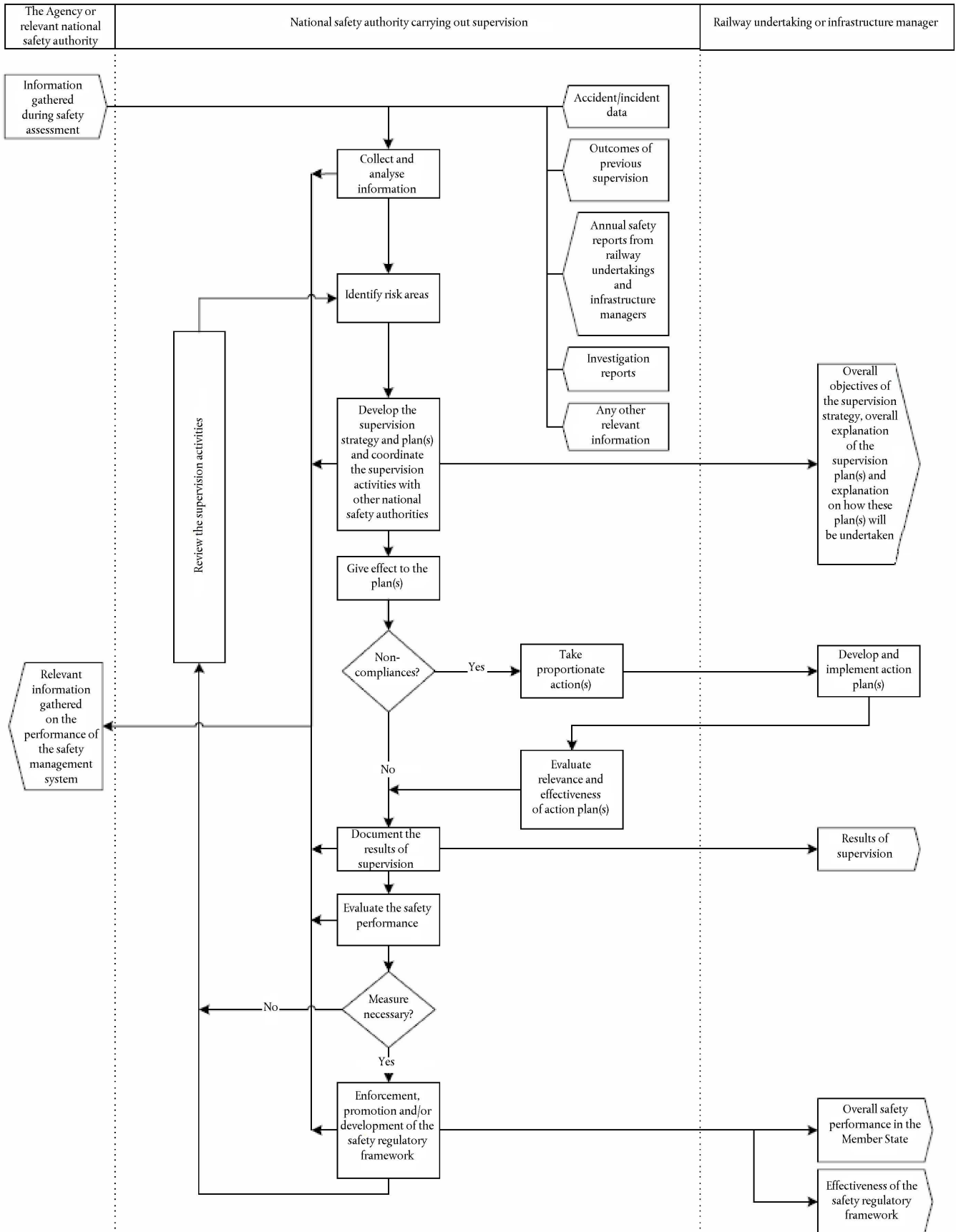
- (a) share results of its supervision activities with the relevant railway undertaking or infrastructure manager, including identifying areas of non-compliance on the part of the railway undertaking or infrastructure manager and any areas of good practice to support safety improvement;
- (b) have an overview of the safety performance of the individual railway undertakings or infrastructure managers operating in its Member State;
- (c) publish and communicate to relevant stakeholders its views on the overall safety performance in the Member State;
- (d) publish and communicate to relevant stakeholders its views on the effectiveness of the safety regulatory framework;
- (e) use and when relevant, share information on the performance of the safety management system gathered during the supervision of railway undertakings or infrastructure managers, prior to reassessing the application for a renewal or an update of the single safety certificate or the safety authorisation, with the Agency acting as safety certification body or the relevant national safety authority, in the case of cross-border infrastructure;
- (f) where appropriate, take any enforcement actions, identify whether there is a case for restricting or revoking the single safety certificate or safety authorisation and in cases where it is not responsible for issuing the single safety certificate or safety authorisation, inform the competent authority accordingly.

#### 6. REVIEWING SUPERVISION ACTIVITIES

On the basis of information gathered and experience gained during supervision activities and the safety performance both at individual level and at Member State level, the national safety authority shall at regular intervals:

- (a) conduct a review of the supervision strategy and plan(s) to check that the original targeted activity, use of data/information from a variety of sources, supervision outcomes and resource allocation are appropriate, changing priorities as necessary;
  - (b) revise the plan or plans if needed and consider the impact of the changes on the supervision strategy;
  - (c) contribute when necessary with its views and any proposals to its Member State to overcome any deficiencies in the safety regulatory framework.
-

Appendix



## ANNEX II

**Framework for coordinated and joint supervision as referred to in Article 8(2)**

The relevant national safety authorities shall develop arrangements based on the following principles and specific elements:

1. Agree which railway undertakings and infrastructure managers are operating in such a manner as to require coordinated or joint supervision.
  2. Agree on common language(s) and the level of confidentiality of the information to be used for the purposes of their coordination arrangements.
  3. Agree what information to exchange and a timetable for the exchange:
    - (a) exchange relevant information on railway undertakings and infrastructure managers identified under point 1 and share results from their assessment activities;
    - (b) provide copies of safety authorisations where appropriate;
    - (c) share results from related supervision activities, including enforcement decisions and actions, where relevant;
    - (d) share information on the safety performance of railway undertakings and infrastructure managers identified under point 1 in each Member State.
  4. Share decision-making criteria:
    - (a) share information on how each national safety authority targets its activities for each railway undertaking and infrastructure manager concerned as part of the supervision plan;
    - (b) establish a dialogue between relevant national safety authorities on the proposed response to dealing with major compliance gaps.
  5. Manage coordination:
    - (a) share existing supervision strategies and plans;
    - (b) establish common points of interest and/or common issues;
    - (c) plan efficiently individual, coordinated or joint initiatives without causing unnecessary inconvenience to the railway undertakings and infrastructure managers and by avoiding overlaps in the scope of these initiatives.
  6. Agree on which national safety authority (or authorities) should follow up actions aimed to address residual concerns which have been deferred for supervision where appropriate.
  7. Agree what areas to target in a coordinated or joint manner:
    - (a) identify key risks for the relevant railway undertakings and infrastructure managers to be addressed in a coordinated or joint manner by national safety authorities;
    - (b) agree which national safety authority will lead activities on what issues, where relevant, on the basis of well-established criteria;
    - (c) agree what types of joint supervision activities to undertake, where relevant;
    - (d) agree how railway undertakings and infrastructure managers should be made aware of the arrangements and agreements national safety authorities are reaching.
  8. Share good practice:
    - (a) develop arrangements to review and coordinate on a regular basis the supervision activities for the relevant railway undertakings and infrastructure managers;
    - (b) develop arrangements to evaluate the effectiveness of the coordination and cooperation between national safety authorities, including the Agency as appropriate.
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**COMMISSION DELEGATED REGULATION (EU) 2018/762****of 8 March 2018****establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety <sup>(1)</sup>, and in particular Article 6(6) thereof,

Having regard to Recommendation ERA-REC-115-REC from the European Union Agency for Railways delivered to the Commission on 9 March 2017, on the revision of the common safety methods for conformity assessment and the common safety methods for supervision,

Whereas:

- (1) The common safety methods (CSMs) describe how the safety levels and the achievement of safety targets and compliance with other safety requirements are assessed.
- (2) In accordance with Article 6(5) of Directive (EU) 2016/798, the CSMs are to be revised at regular intervals, taking into account the experience gained from their application and the global development of railway safety and with the objective of generally maintaining and, where reasonably practicable, continuously improving safety.
- (3) By its Implementing Decision of 1 September 2016 <sup>(2)</sup>, the Commission issued a mandate to the European Union Agency for Railways (the 'Agency') in accordance with Article 6(2) of Directive (EU) 2016/798 to revise Commission Regulations (EU) No 1158/2010 <sup>(3)</sup>, (EU) No 1169/2010 <sup>(4)</sup> and (EU) No 1077/2012 <sup>(5)</sup>. On 9 March 2017, the Agency issued its recommendation, enclosing a report on the results of the consultation of national safety authorities, social partners and users and a report assessing the impact of the amended CSMs to be adopted, to address the mandate of the Commission. The Commission examined the recommendation issued by the Agency to verify that the mandate was fulfilled as referred to in Article 6(4) of Directive (EU) 2016/798.
- (4) The purpose of the safety management system is to ensure that the railway undertakings and infrastructure managers achieve their business objectives in a safe manner. The safety management system is often integrated with other management systems to increase the overall performance of the organisation and reduce costs while mutualising the efforts at all levels of the organisation. To this end, the common framework of the ISO High Level Structure <sup>(6)</sup> is used to functionally cluster the requirements of the safety management system, as referred to in Article 9 of Directive (EU) 2016/798. This framework also facilitates the understanding and application of a process approach by the railway undertakings and infrastructure managers when developing, implementing, maintaining and continually improving their safety management system.
- (5) Once issued with a single safety certificate or with a safety authorisation, the applicant should continue to use its safety management system as referred to in Article 9 of Directive (EU) 2016/798.
- (6) The human behaviour plays a central role in the safe and efficient operation of the railway. Where that behaviour is considered to have contributed to an accident or incident, it may be that organisational factors, such as

<sup>(1)</sup> OJ L 138, 26.5.2016, p. 102.

<sup>(2)</sup> Commission Implementing Decision of 1 September 2016 on a mandate to the European Union Agency for Railways for the revision of the common safety methods for conformity assessment and the common safety method for supervision and repealing Implementing Decision C(2014) 1649 final (C(2016) 5504 final).

<sup>(3)</sup> Commission Regulation (EU) No 1158/2010 of 9 December 2010 on a common safety method for assessing conformity with the requirements for obtaining railway safety certificates (OJ L 326, 10.12.2010, p. 11).

<sup>(4)</sup> Commission Regulation (EU) No 1169/2010 of 10 December 2010 on a common safety method for assessing conformity with the requirements for obtaining a railway safety authorisation (OJ L 327, 11.12.2010, p. 13).

<sup>(5)</sup> Commission Regulation (EU) No 1077/2012 of 16 November 2012 on a common safety method for supervision by national safety authorities after issuing a safety certificate or safety authorisation (OJ L 320, 17.11.2012, p. 3).

<sup>(6)</sup> ISO/IEC Directives, Part 1, consolidated supplement 2016, Annex SL Appendix 2.

workload or job design, had an influence on that behaviour, and thus led to a lesser performance and aggravation of the consequences of that accident or incident. Therefore, it is essential that the railway undertakings and infrastructure managers take a systematic approach to supporting human performance and managing human and organisational factors within the safety management system.

- (7) The way safety is perceived, valued and prioritised in an organisation reflects the real commitment to safety at all levels in the organisation. Therefore, it is also important for railway undertakings and infrastructure managers to identify the actions and behaviours that can shape a positive safety culture and to promote through their safety management system this culture of mutual trust, confidence and learning in which staff are encouraged to contribute to the development of safety by reporting dangerous occurrences and providing safety-related information.
- (8) The safety management system should take into account the fact that Council Directive 89/391/EEC <sup>(1)</sup> and its relevant individual directives are fully applicable to the protection of the health and safety of workers engaged in railway construction, operation and maintenance. It does not create any additional responsibilities or tasks for the issuing authority other than to check if health and safety risks have been taken into account by the applicant for a single safety certificate or for a safety authorisation. Responsibility for checking the compliance with Directive 89/391/EEC may still be allocated on other competent authorities appointed by the Member States.
- (9) The safety management system should where relevant take into consideration the potential additional risks generated by transporting dangerous goods by rail and thereby, should also take account of Directive 2008/68/EC of the European Parliament and of the Council <sup>(2)</sup>.
- (10) Regulations (EU) No 1158/2010 and (EU) No 1169/2010 will become obsolete and should therefore be replaced by this Regulation.
- (11) As regards safety certificates, it follows from Article 10(15) of Directive (EU) 2016/798 that the national safety authority may require that the safety certificates be revised following substantial changes to the safety regulatory framework. The changes brought about by Article 9 of Directive (EU) 2016/798 and by this Regulation, even though relevant and important, are not substantial. Therefore, Regulation (EU) No 1158/2010 should apply to safety certificates issued in accordance with Directive 2004/49/EC of the European Parliament and of the Council <sup>(3)</sup>, until their expiry date. For the same reason, it is also necessary to postpone the repeal of Regulation (EU) No 1158/2010 until the end of the last day of the period during which it may still be applied by national safety authorities for the purposes of supervision. Moreover, in accordance with Directive (EU) 2016/798, existing safety certificates continue to be subject to Directive 2004/49/EC, on which Regulation (EU) No 1158/2010 was based.
- (12) As regards safety authorisations, it follows from Article 12(2), second subparagraph of Directive (EU) 2016/798 that the national safety authority may require that the safety authorisations be revised following substantial changes to the safety regulatory framework. The changes brought about by Article 9 of Directive 2016/798/EC and by this Regulation, even though relevant and important, are not substantial. Therefore, Regulation (EU) No 1169/2010 should apply to safety authorisations issued in accordance with Directive 2004/49/EC, until their expiry date. For the same reason, it is also necessary to postpone the repeal of Regulation (EU) No 1169/2010 until the end of the last day of the period during which it may still be applied by national safety authorities for the purposes of supervision,

HAS ADOPTED THIS REGULATION:

#### Article 1

#### Subject matter and scope

1. This Regulation establishes common safety methods ('CSMs') on safety management system requirements related to railway undertakings and infrastructure managers, as referred to in point (f) of Article 6(1) of Directive (EU) 2016/798.
2. This Regulation shall apply in respect of single safety certificates and safety authorisations issued pursuant to Directive (EU) 2016/798.

<sup>(1)</sup> Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

<sup>(2)</sup> Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

<sup>(3)</sup> 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).

*Article 2***Definition**

For the purposes of this Regulation, 'safety certification body' means the body responsible for issuing a single safety certificate, either the Agency or a national safety authority.

*Article 3***Safety management system requirements related to railway undertakings**

Railway undertakings shall establish their safety management systems in accordance with the requirements set out in Annex I.

Those safety management system requirements shall apply to the single safety certificates referred to in Article 10 of Directive (EU) 2016/798, for the purposes of the assessment of applications and of supervision.

*Article 4***Safety management system requirements related to infrastructure managers**

Infrastructure managers shall establish their safety management systems in accordance with the requirements set out in Annex II.

Those safety management system requirements shall apply to the safety authorisations referred to in Article 12 of Directive (EU) 2016/798, for the purposes of the assessment of applications and of supervision.

*Article 5***Repeal**

Regulations (EU) No 1158/2010 and (EU) No 1169/2010 are repealed with effect from 16 June 2025.

*Article 6***Entry into force and 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 16 June 2019 in the Member States that have not notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798. It shall apply in all Member States from 16 June 2020.

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

Done at Brussels, 8 March 2018.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

## ANNEX I

**Safety management system requirements related to railway undertakings**

## 1. CONTEXT OF THE ORGANISATION

1.1. **The organisation shall:**

- (a) describe the type, extent and area of its operations;
- (b) identify the serious risks for safety posed by its railway operations whether they are carried out by the organisation itself, or by contractors, partners or suppliers under its control;
- (c) identify interested parties (e.g. regulatory bodies, authorities, infrastructure managers, contractors, suppliers, partners), including those parties external to the railway system, that are relevant to the safety management system;
- (d) identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);
- (e) ensure that the requirements referred to in point (d) are taken into account in developing, implementing and maintaining the safety management system;
- (f) describe the scope of the safety management system, indicating which part of the business is included or not in its scope and taking into account the requirements referred to in point (d).

## 2. LEADERSHIP

2.1. **Leadership and commitment**

## 2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:

- (a) taking overall accountability and responsibility for safety;
- (b) ensuring commitment to safety by management at different levels within the organisation through their activities and in their relationships with staff and contractors;
- (c) ensuring that the safety policy and safety objectives are established, understood and are compatible with the strategic direction of the organisation;
- (d) ensuring the integration of the safety management system requirements into the organisation's business processes;
- (e) ensuring that the resources needed for the safety management system are available;
- (f) ensuring that the safety management system is effective in controlling the safety risks posed by the organisation;
- (g) encouraging staff to support compliance with the safety management system requirements;
- (h) promoting continual improvement of the safety management system;
- (i) ensuring that safety is considered when identifying and managing the organisation's business risks and explaining how conflict between safety and other business goals will be recognised and resolved;
- (j) promoting a positive safety culture.

2.2. **Safety policy**

## 2.2.1. A document describing the organisation's safety policy is established by the top management and is:

- (a) appropriate to the organisation's type and extent of railway operations;
- (b) approved by the organisation's chief executive (or a representative(s) of the top-management);
- (c) actively implemented, communicated and made available to all staff.

2.2.2. The safety policy shall:

- (a) include a commitment to conform with all legal and other requirements related to safety;
- (b) provide a framework for setting safety objectives and evaluating the organisation's safety performance against these objectives;
- (c) include a commitment to control safety risks which arise both from its own activities and those caused by others;
- (d) include a commitment to continual improvement of the safety management system;
- (e) be maintained in accordance with the business strategy and the evaluation of the safety performance of the organisation.

### 2.3. **Organisational roles, responsibilities, accountabilities and authorities**

2.3.1. The responsibilities, accountabilities and authorities of staff having a role that affects safety (including management and other staff involved in safety-related tasks) shall be defined at all levels within the organisation, documented, assigned and communicated to them.

2.3.2. The organisation shall ensure that staff with delegated responsibilities for safety-related tasks shall have the authority, competence and appropriate resources to perform their tasks without being adversely affected by the activities of other business functions.

2.3.3. Delegation of responsibility for safety-related tasks shall be documented and communicated to the relevant staff, accepted and understood.

2.3.4. The organisation shall describe the allocation of roles referred to in paragraph 2.3.1. to business functions within and where relevant, outside the organisation (see 5.3. Contractors, partners and suppliers).

### 2.4. **Consultation of staff and other parties**

2.4.1. Staff, their representatives and external interested parties, as appropriate and where relevant, shall be consulted in developing, maintaining and improving the safety management system in the relevant parts they are responsible for, including the safety aspects of operational procedures.

2.4.2. The organisation shall facilitate the consultation of staff by providing the methods and means for involving staff, recording staff's opinion and providing feedback on staff's opinion.

## 3. PLANNING

### 3.1. **Actions to address risks**

3.1.1. Risk assessment

3.1.1.1. The organisation shall:

- (a) identify and analyse all operational, organisational and technical risks relevant to the type, extent and area of operations carried out by the organisation. Such risks shall include those arising from human and organisational factors such as workload, job design, fatigue or suitability of procedures, and the activities of other interested parties (see 1. Context of the organisation);
- (b) evaluate the risks referred to in point (a) by applying appropriate risk assessment methods;
- (c) develop and put in place safety measures, with identification of associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);
- (d) develop a system to monitor the effectiveness of safety measures (see 6.1. Monitoring);
- (e) recognise the need to collaborate with other interested parties (such as railway undertakings, infrastructure managers, manufacturer, maintenance supplier, entity in charge of maintenance, railway vehicle keeper, service provider and procurement entity), where appropriate, on shared risks and the putting in place of adequate safety measures;
- (f) communicate risks to staff and involved external parties (see 4.4. Information and communication).



3.1.1.2. When assessing risk, an organisation shall take into account the need to determine, provide and sustain a safe working environment which conforms to applicable legislation, in particular Directive 89/391/EEC.

3.1.2. Planning for change

3.1.2.1. The organisation shall identify potential safety risks and appropriate safety measures (see 3.1.1. Risk assessment) before the implementation of a change (see 5.4. Management of change) in accordance with the risk management process set out in the Regulation (EU) No 402/2013 <sup>(1)</sup>, including consideration of the safety risks from the change process itself.

## 3.2. Safety objectives and planning

3.2.1. The organisation shall establish safety objectives for relevant functions at relevant levels to maintain and, where reasonably practicable, improve its safety performance.

3.2.2. The safety objectives shall:

- (a) be consistent with the safety policy and the organisation's strategic objectives (where applicable);
- (b) be linked to the priority risks that influence the safety performance of the organisation;
- (c) be measurable;
- (d) take into account applicable legal and other requirements;
- (e) be reviewed as regards their achievements and revised as appropriate;
- (f) be communicated.

3.2.3. The organisation shall have plan(s) to describe how it will achieve its safety objectives.

3.2.4. The organisation shall describe the strategy and plan(s) used to monitor the achievement of the safety objectives (see 6.1. Monitoring).

4. SUPPORT

## 4.1. Resources

4.1.1. The organisation shall provide the resources, including competent staff and effective and useable equipment, needed for the establishment, implementation, maintenance and continual improvement of the safety management system.

## 4.2. Competence

4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:

- (a) identification of the competencies (including knowledge, skills, non-technical behaviours and attitudes) required for safety-related tasks;
- (b) selection principles (basic educational level, psychological and physical fitness required);
- (c) initial training, experience and qualification;
- (d) ongoing training and periodic update of existing competencies;
- (e) periodic assessment of competence and checks of psychological and physical fitness to ensure that qualifications and skills are maintained over time;
- (f) specific training in relevant parts of the safety management system in order to deliver their safety-related tasks.

<sup>(1)</sup> Commission Implementing Regulation (EU) No 402/2013 of 30 April 2013 on the common safety method for risk evaluation and assessment and repealing Regulation (EC) No 352/2009 (OJ L 121, 3.5.2013, p. 8).

- 4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:
- (a) the training programme is delivered according to the identified competency requirements and individual needs of the staff;
  - (b) where applicable, the training ensures that staff can operate under all operating conditions (normal, degraded and emergency);
  - (c) the duration of the training and the frequency of the refresher training are appropriate for the training objectives;
  - (d) records are kept for all staff (see 4.5.3. Control of documented information);
  - (e) the training programme is regularly reviewed and audited (see 6.2. Internal auditing) and changes made when necessary (see 5.4. Management of change).
- 4.2.3. Back to work arrangements shall be in place for staff following accidents/incidents or long absences from work, including providing additional training where such a need is identified.

#### 4.3. **Awareness**

- 4.3.1. Top management shall ensure that they and their staff having a role that affects safety are aware of the relevance, importance and consequences of their activities and how they contribute to the correct application and the effectiveness of the safety management system, including the achievement of safety objectives (see 3.2. Safety objectives and planning).

#### 4.4. **Information and communication**

- 4.4.1. The organisation shall define adequate communication channels to ensure that safety-related information is exchanged among the different levels of the organisation and with external interested parties including contractors, partners and suppliers.
- 4.4.2. To ensure that safety-related information reaches those making judgements and decisions, the organisation shall manage the identification, receipt, processing, generation and dissemination of safety-related information.
- 4.4.3. The organisation shall ensure that safety-related information is:
- (a) relevant, complete and understandable for the intended users;
  - (b) valid;
  - (c) accurate;
  - (d) consistent;
  - (e) controlled (see 4.5.3. Control of documented information);
  - (f) communicated before it takes effect;
  - (g) received and understood.

#### 4.5. **Documented information**

##### 4.5.1. Safety management system documentation

###### 4.5.1.1. There is a description of the safety management system including:

- (a) the identification and description of the processes and activities related to safety of rail operations, including safety-related tasks and associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);
- (b) the interaction of these processes;
- (c) the procedures or other documents describing how these processes are implemented;
- (d) the identification of contractors, partners and suppliers with a description of the type and extent of services delivered;

- (e) the identification of contractual arrangements and other business agreements, concluded between the organisation and other parties identified under (d), necessary to control the safety risks of the organisation and those related to the use of contractors;
  - (f) reference to documented information required by this Regulation.
- 4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:
- (a) a synthesis of the decisions on the level of significance of the safety-related changes, including an overview of significant changes, in accordance with Article 18(1) of Regulation (EU) No 402/2013;
  - (b) the organisation's safety objectives for the following year(s) and how serious risks for safety influence the setting of these safety objectives;
  - (c) the results of internal accident/incident investigation (see 7.1. Learning from accidents and incidents) and other monitoring activities (see 6.1. Monitoring, 6.2. Internal auditing and 6.3. Management review), in accordance with Article 5(1) of Regulation (EU) No 1078/2012 <sup>(1)</sup>;
  - (d) details of progress on addressing outstanding recommendations from the national investigation bodies (see 7.1. Learning from accidents and incidents);
  - (e) the organisation's safety indicators set out to evaluate the organisation's safety performance (see 6.1. Monitoring);
  - (f) where applicable, the conclusions of the annual report of the safety advisor, as referred to in RID <sup>(2)</sup>, on the activities of the organisation relating to the transport of dangerous goods <sup>(3)</sup>.
- 4.5.2. Creating and updating
- 4.5.2.1. The organisation shall ensure that when creating and updating documented information related to the safety management system adequate formats and media are used.
- 4.5.3. Control of documented information
- 4.5.3.1. The organisation shall control documented information related to the safety management system, in particular its storage, distribution and the control of changes, to ensure its availability, suitability and protection where appropriate.
- 4.6. Integration of human and organisational factors**
- 4.6.1. The organisation shall demonstrate a systematic approach to integrating human and organisational factors within the safety management system. This approach shall:
- (a) include the development of a strategy and the use of expertise and recognised methods from the field of human and organisational factors;
  - (b) address risks associated with the design and use of equipment, tasks, working conditions and organisational arrangements, taking into account human capabilities as well as limitations, and the influences on human performance.
5. OPERATION
- 5.1. Operational planning and control**
- 5.1.1. When planning, developing, implementing and reviewing its operational processes, the organisation shall ensure that during operation:
- (a) risk acceptance criteria and safety measures are applied (see 3.1.1. Risk assessment);

<sup>(1)</sup> 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).

<sup>(2)</sup> Point 2.1. of the Appendix to Annex I to Directive (EU) 2016/798.

<sup>(3)</sup> Point 2.2. of the Appendix to Annex I to Directive (EU) 2016/798.

- (b) plan(s) to achieve the safety objectives are delivered (see 3.2. Safety objectives and planning);
  - (c) information is collected to measure the correct application and effectiveness of the operational arrangements (see 6.1. Monitoring).
- 5.1.2. The organisation shall ensure that its operational arrangements conform to the safety-related requirements of applicable Technical Specifications for Interoperability and relevant national rules and any other relevant requirements (see 1. Context of the organisation).
- 5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:
- (a) planning of existing or new train routes and new train services, including the introduction of new types of vehicles, the need to lease vehicles and/or to hire staff from external parties and the exchange of information on the maintenance for operational purposes with entities in charge of maintenance;
  - (b) development and implementation of train timetables;
  - (c) preparation of trains or vehicles before movement, including pre-departure checks and train composition;
  - (d) running trains or movement of vehicles in the different operating conditions (normal, degraded and emergency);
  - (e) adaptation of the operation to requests for removal from operation and notification of return to operation issued by entities in charge of maintenance;
  - (f) authorisations for movements of vehicles;
  - (g) usability of interfaces in train driving cabs and train control centres and with equipment used by maintenance staff.
- 5.1.4. To control the allocation of responsibilities where relevant for the safety of operational activities, the organisation shall identify responsibilities for coordinating and managing the safe running of trains and movements of vehicles and define how relevant tasks affecting the safe delivery of all services are allocated to competent staff within the organisation (see 2.3. Organisational roles, responsibilities, accountabilities and authorities) and to other external qualified parties when appropriate (see 5.3. Contractors, partners and suppliers).
- 5.1.5. To control information and communication where relevant for the safety of operational activities (see 4.4. Information and communication), relevant staff (e.g. train crews) shall be advised of the details of any specified conditions of travel, including relevant changes which may result in a hazard, temporary or permanent operational restrictions (e.g. due to specific type of vehicles or to specific routes) and conditions for exceptional consignments, where applicable.
- 5.1.6. To control competence where relevant for the safety of operational activities (see 4.2. Competence), the organisation shall ensure, in accordance with applicable legislation (see 1. Context of the organisation), for its staff:
- (a) compliance with their training and work instructions, and corrective actions are taken where required;
  - (b) specific training in case of anticipated changes affecting the running of operations or their task assignment;
  - (c) adoption of adequate measures following accidents and incidents.

## 5.2. **Asset management**

- 5.2.1. The organisation shall manage the safety risks associated with physical assets throughout their life cycle (see 3.1.1. Risk assessment), from design to disposal, and fulfil the human factors requirements in all phases of the life cycle.
- 5.2.2. The organisation shall:
- (a) ensure that the assets are used for the purpose intended while maintaining their safe operational state, in accordance with Article 14(2) of Directive (EU) 2016/798 where relevant, and their expected level of performance;

- (b) manage the assets in normal and degraded operations;
  - (c) detect as soon as reasonably practicable instances of non-compliance with operating requirements before or during the operation of the asset, including the application of restrictions of use as appropriate to ensure a safe operational state of the asset (see 6.1. Monitoring).
- 5.2.3. The organisation shall ensure that its asset management arrangements, where applicable, conform to all essential requirements as set out in the relevant Technical Specifications for Interoperability and any other relevant requirements (see 1. Context of the organisation).
- 5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:
- (a) the identification of the need for maintenance to keep the asset in a safe operational state, based on the planned and real use of the asset and its design characteristics;
  - (b) the management of the removal of the asset from operation for maintenance, when defects have been identified or when asset condition degrades outside the limits of a safe operational state as referred to in point (a);
  - (c) the management of the return to operation of the asset with eventual restrictions of use after maintenance has been delivered to ensure it is in a safe operational state;
  - (d) the management of monitoring and measurement equipment to ensure that it is fit for its intended purpose.
- 5.2.5. To control information and communication where relevant for the safe management of assets (see 4.4. Information and communication), the organisation shall take into account:
- (a) the exchange of relevant information within the organisation or with external entities responsible for maintenance (see 5.3. Contractors, partners and suppliers), in particular on safety-related malfunctions, accidents, incidents as well as on eventual restrictions of use of the asset;
  - (b) the traceability of all necessary information including the information related to point (a) (see 4.4. Information and communication and 4.5.3. Control of documented information);
  - (c) the establishment and maintenance of records including the management of changes affecting the safety of assets (see 5.4. Management of change).
- 5.3. **Contractors, partners and suppliers**
- 5.3.1. The organisation shall identify and control safety risks arising from outsourced activities, including operations or cooperation with contractors, partners and suppliers.
- 5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:
- (a) the legal and other requirements related to safety (see 1. Context of the organisation);
  - (b) the level of competence required to deliver the tasks set out in the contract (see 4.2. Competence);
  - (c) the responsibilities for the tasks to be performed;
  - (d) the expected safety performance to be maintained during the contract;
  - (e) the obligations relating to the exchange of safety-related information (see 4.4. Information and communication);
  - (f) the traceability of safety-related documents (see 4.5. Documented information).
- 5.3.3. In accordance with the process set out in Article 3 of Regulation (EU) No 1078/2012, the organisation shall monitor:
- (a) the safety performance of all activities and operations of contractors, partners and suppliers to ensure that they comply with the requirements set out in the contract;
  - (b) the awareness of contractors, partners and suppliers of safety risks they entail to the organisation's operations.

#### 5.4. Management of change

- 5.4.1. The organisation shall implement and control changes to the safety management system to maintain or improve the safety performance. This shall include decisions at the different stages of the change management and the subsequent review of safety risks (see 3.1.1. Risk assessment).

#### 5.5. Emergency management

- 5.5.1. The organisation shall identify the emergency situations and associated timely measures to be taken to manage them (see 3.1.1. Risk assessment) and to re-establish normal operating conditions in accordance with Regulation (EU) 2015/995 <sup>(1)</sup>.

- 5.5.2. The organisation shall ensure that, for each identified type of emergency:

- (a) the emergency services can be promptly contacted;
- (b) the emergency services are provided with all relevant information both in advance, to prepare their emergency response, and at the time of an emergency;
- (c) first aid is provided internally.

- 5.5.3. The organisation shall identify and document the roles and responsibilities of all parties in accordance with Regulation (EU) 2015/995.

- 5.5.4. The organisation shall have plans for action, alerts and information in case of emergency including arrangements to:

- (a) alert all staff with responsibility for emergency management;
- (b) communicate information to all parties (e.g. infrastructure manager, contractors, authorities, emergency services), including emergency instructions for passengers;
- (c) take any decisions required in accordance with the type of emergency.

- 5.5.5. The organisation shall describe how resources and means for emergency management have been allocated (see 4.1. Resources) and how training requirements have been identified (see 4.2. Competence).

- 5.5.6. The emergency arrangements are regularly tested in cooperation with other interested parties and updated when appropriate.

- 5.5.7. The organisation shall ensure that competent staff in charge, with adequate language skills, can be contacted easily and without delay by the infrastructure manager and provide the latter with the right level of information.

- 5.5.8. The organisation shall have a procedure to contact the entity in charge of maintenance or the railway vehicle keeper in the event of an emergency.

#### 6. PERFORMANCE EVALUATION

##### 6.1. Monitoring

- 6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU) No 1078/2012:

- (a) to check the correct application and the effectiveness of all the processes and procedures in the safety management system, including the operational, organisational and technical safety measures;
- (b) to check the correct application of the safety management system as a whole, and if it achieves the expected outcomes;

<sup>(1)</sup> Commission Regulation (EU) 2015/995 of 8 June 2015 amending Decision 2012/757/EU concerning the technical specification for interoperability relating to the 'operation and traffic management' subsystem of the rail system in the European Union (OJ L 165, 30.6.2015, p. 1).

- (c) to investigate whether the safety management system conforms to the requirements in this Regulation;
- (d) to identify, implement and evaluate the effectiveness of the corrective measures (see 7.2. Continual improvement), as appropriate, if any relevant instance of non-compliance to points (a), (b) and (c) is detected.

6.1.2. The organisation shall regularly monitor at all levels within the organisation the performance of safety-related tasks and intervene if these tasks are not being properly performed.

## 6.2. Internal auditing

6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:

- (a) A schedule of planned internal audits which can be revised depending on the results of previous audits and monitoring of performance;
- (b) The identification and selection of competent auditors (see 4.2. Competence);
- (c) The analysis and evaluation of the results of the audits;
- (d) The identification of the need for corrective or improvement measures;
- (e) The verification of the completion and effectiveness of these measures;
- (f) The documentation pertaining to the execution and results of audits;
- (g) The communication of the results of audits to the top management.

## 6.3. Management review

6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:

- (a) details of progress on addressing outstanding actions from previous management reviews;
- (b) changing internal and external circumstances (see 1. Context of the organisation);
- (c) the organisation's safety performance related to:
  - (i) the achievement of its safety objectives;
  - (ii) the results from its monitoring activities, including the internal audit findings, and internal accident/incident investigations and status of their respective actions;
  - (iii) the relevant outputs from supervisory activities conducted by the national safety authority;
- (d) recommendations for improvement.

6.3.2. Based on the outputs of its management review, the top management shall take overall responsibility for the planning and implementation of needed changes to the safety management system.

## 7. IMPROVEMENT

### 7.1. Learning from accidents and incidents

7.1.1. Accidents and incidents related to the organisation's railway operations shall be:

- (a) reported, logged, investigated and analysed to determine their causes;
- (b) reported to national bodies as appropriate.

7.1.2. The organisation shall ensure that:

- (a) recommendations from the national safety authority, the national investigating body and industry/internal investigations are evaluated and implemented if appropriate or mandated;
- (b) relevant reports/information from other interested parties such as railway undertakings, infrastructure managers, entities in charge of maintenance and railway vehicle keepers are considered and taken into account.

7.1.3. The organisation shall use information relating to the investigation to review the risk assessment (see 3.1.1. Risk assessment), to learn with the aim of improving safety and, where applicable, to adopt corrective and/or improvement measures (see 5.4. Management of change).

## 7.2. **Continual improvement**

7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in Regulation (EU) No 1078/2012 and at least the outputs of the following activities:

(a) monitoring (see 6.1. Monitoring);

(b) internal auditing (see 6.2. Internal auditing);

(c) management review (see 6.3. Management review);

(d) learning from accidents and incidents (see 7.1. Learning from accidents and incidents).

7.2.2. The organisation shall provide means to motivating staff and other interested parties to be active in improving safety as part of its organisational learning.

7.2.3. The organisation shall provide a strategy to continually improve its safety culture, relying on the use of expertise and recognised methods to identify behavioural issues affecting the different parts of the safety management system and to put in place measures to address these.

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## ANNEX II

**Safety management system requirements related to infrastructure managers**

## 1. CONTEXT OF THE ORGANISATION

1.1. **The organisation shall:**

- (a) describe the character and extent of its operations;
- (b) identify the serious risks for safety posed by its railway operations whether they are carried out by the organisation itself, or by contractors, partners or suppliers under its control;
- (c) identify interested parties (e.g. regulatory bodies, authorities, railway undertakings, infrastructure managers, contractors, suppliers, partners), including those parties external to the railway system, that are relevant to the safety management system;
- (d) identify and maintain legal and other requirements related to safety from the interested parties referred to in point (c);
- (e) ensure that the requirements referred to in point (d) are taken into account in developing, implementing and maintaining the safety management system;
- (f) describe the scope of the safety management system, indicating which part of the business is included or not in its scope and taking into account the requirements referred to in point (d).

1.2. **For the purpose of this Annex the following definitions are applied:**

- (a) 'character' in relation to railway operations carried out by infrastructure managers means the characterisation of operation by its scope, including infrastructure design and construction, infrastructure maintenance, traffic planning, traffic management and control, and by the use of the railway infrastructure, including conventional and/or high speed lines, transport of passengers and/or goods;
- (b) 'extent' in relation to railway operations carried out by infrastructure managers means the extent characterised by the length of railway track and the estimated size of the infrastructure manager in terms of number of employees working in the railway sector.

## 2. LEADERSHIP

2.1. **Leadership and commitment**

## 2.1.1. Top management shall demonstrate leadership and commitment to the development, implementation, maintenance and continual improvement of the safety management system by:

- (a) taking overall accountability and responsibility for safety;
- (b) ensuring commitment to safety by management at different levels within the organisation through their activities and in their relationships with staff and contractors;
- (c) ensuring that the safety policy and safety objectives are established, understood and are compatible with the strategic direction of the organisation;
- (d) ensuring the integration of the safety management system requirements into the organisation's business processes;
- (e) ensuring that the resources needed for the safety management system are available;
- (f) ensuring that the safety management system is effective in controlling the safety risks posed by the organisation;
- (g) encouraging staff to support compliance with the safety management system requirements;
- (h) promoting continual improvement of the safety management system;
- (i) ensuring that safety is considered when identifying and managing the organisation's business risks and explaining how conflict between safety and other business goals will be recognised and resolved;
- (j) promoting a positive safety culture.

## 2.2. **Safety policy**

2.2.1. A document describing the organisation's safety policy is established by the top management and is:

- (a) appropriate to the organisation's character and extent of railway operations;
- (b) approved by the organisation's chief executive (or a representative(s) of the top-management);
- (c) actively implemented, communicated and made available to all staff.

2.2.2. The safety policy shall:

- (a) include a commitment to conform with all legal and other requirements related to safety;
- (b) provide a framework for setting safety objectives and evaluating the organisation's safety performance against these objectives;
- (c) include a commitment to control safety risks which arise both from its own activities and those caused by others;
- (d) include a commitment to continual improvement of the safety management system;
- (e) be maintained in accordance with the business strategy and the evaluation of the safety performance of the organisation.

## 2.3. **Organisational roles, responsibilities, accountabilities and authorities**

2.3.1. The responsibilities, accountabilities and authorities of staff having a role that affects safety (including management and other staff involved in safety-related tasks) shall be defined at all levels within the organisation, documented, assigned and communicated to them.

2.3.2. The organisation shall ensure that staff with delegated responsibilities for safety-related tasks shall have the authority, competence and appropriate resources to perform their tasks without being adversely affected by the activities of other business functions.

2.3.3. Delegation of responsibility for safety-related tasks shall be documented and communicated to the relevant staff, accepted and understood.

2.3.4. The organisation shall describe the allocation of roles referred to in paragraph 2.3.1. to business functions within and where relevant, outside the organisation (see 5.3. Contractors, partners and suppliers).

## 2.4. **Consultation of staff and other parties**

2.4.1. Staff, their representatives and external interested parties, as appropriate and where relevant, shall be consulted in developing, maintaining and improving the safety management system in the relevant parts they are responsible for, including the safety aspects of operational procedures.

2.4.2. The organisation shall facilitate the consultation of staff by providing the methods and means for involving staff, recording staff's opinion and providing feedback on staff's opinion.

## 3. **PLANNING**

### 3.1. **Actions to address risks**

3.1.1. Risk assessment

3.1.1.1. The organisation shall:

- (a) identify and analyse all operational, organisational and technical risks relevant to the character and extent of operations carried out by the organisation. Such risks shall include those arising from human and organisational factors such as workload, job design, fatigue or suitability of procedures, and the activities of other interested parties (see 1. Context of the organisation);
- (b) evaluate the risks referred to in point (a) by applying appropriate risk assessment methods;

- (c) develop and put in place safety measures, with identification of associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);
  - (d) develop a system to monitor the effectiveness of safety measures (see 6.1. Monitoring);
  - (e) recognise the need to collaborate with other interested parties (such as railway undertakings, infrastructure managers, manufacturer, maintenance supplier, entity in charge of maintenance, railway vehicle keeper, service provider and procurement entity), where appropriate, on shared risks and the putting in place of adequate safety measures;
  - (f) communicate risks to staff and involved external parties (see 4.4. Information and communication).
- 3.1.1.2. When assessing risk, an organisation shall take into account the need to determine, provide and sustain a safe working environment which conforms to applicable legislation, in particular Directive 89/391/EEC.
- 3.1.2. Planning for change
- 3.1.2.1. The organisation shall identify potential safety risks and appropriate safety measures (see 3.1.1. Risk assessment) before the implementation of a change (see 5.4. Management of change) in accordance with the risk management process set out in Regulation (EU) No 402/2013, including consideration of the safety risks from the change process itself.
- 3.2. Safety objectives and planning**
- 3.2.1. The organisation shall establish safety objectives for relevant functions at relevant levels to maintain and, where reasonably practicable, improve its safety performance.
- 3.2.2. The safety objectives shall:
- (a) be consistent with the safety policy and the organisation's strategic objectives (where applicable);
  - (b) be linked to the priority risks that influence the safety performance of the organisation;
  - (c) be measurable;
  - (d) take into account applicable legal and other requirements;
  - (e) be reviewed as regards their achievements and revised as appropriate;
  - (f) be communicated.
- 3.2.3. The organisation shall have plan(s) to describe how it will achieve its safety objectives.
- 3.2.4. The organisation shall describe the strategy and plan(s) used to monitor the achievement of the safety objectives (see 6.1. Monitoring).
- 4. SUPPORT**
- 4.1. Resources**
- 4.1.1. The organisation shall provide the resources, including competent staff and effective and useable equipment, needed for the establishment, implementation, maintenance and continual improvement of the safety management system.
- 4.2. Competence**
- 4.2.1. The organisation's competence management system shall ensure that staff having a role that affects safety are competent in the safety-related tasks for which they are responsible (see 2.3. Organisational roles, responsibilities, accountabilities and authorities), including at least:
- (a) identification of the competencies (including knowledge, skills, non-technical behaviours and attitudes) required for safety-related tasks;
  - (b) selection principles (basic educational level, psychological and physical fitness required);
  - (c) initial training, experience and qualification;
  - (d) ongoing training and periodic update of existing competencies;

- (e) periodic assessment of competence and checks of psychological and physical fitness to ensure that qualifications and skills are maintained over time;
  - (f) specific training in relevant parts of the safety management system in order to deliver their safety-related tasks.
- 4.2.2. The organisation shall provide a training programme, as referred to in points (c), (d) and (f) of paragraph 4.2.1, for staff performing safety-related tasks which ensures that:
- (a) the training programme is delivered according to the identified competency requirements and individual needs of the staff;
  - (b) where applicable, the training ensures that staff can operate under all operating conditions (normal, degraded and emergency);
  - (c) the duration of the training and the frequency of the refresher training are appropriate for the training objectives;
  - (d) records are kept for all staff (see 4.5.3. Control of documented information);
  - (e) the training programme is regularly reviewed and audited (see 6.2. Internal auditing) and changes made when necessary (see 5.4. Management of change).
- 4.2.3. Back to work arrangements shall be in place for staff following accidents/incidents or long absences from work, including providing additional training where such a need is identified.

#### 4.3. **Awareness**

- 4.3.1. Top management shall ensure that they and their staff having a role that affects safety are aware of the relevance, importance and consequences of their activities and how they contribute to the correct application and the effectiveness of the safety management system, including the achievement of safety objectives (see 3.2. Safety objectives and planning).

#### 4.4. **Information and communication**

- 4.4.1. The organisation shall define adequate communication channels to ensure that safety-related information is exchanged among the different levels of the organisation and with external interested parties including contractors, partners and suppliers.
- 4.4.2. To ensure that safety-related information reaches those making judgements and decisions, the organisation shall manage the identification, receipt, processing, generation and dissemination of safety-related information.
- 4.4.3. The organisation shall ensure that safety-related information is:
- (a) relevant, complete and understandable for the intended users;
  - (b) valid;
  - (c) accurate;
  - (d) consistent;
  - (e) controlled (see 4.5.3. Control of documented information);
  - (f) communicated before it takes effect;
  - (g) received and understood.

#### 4.5. **Documented information**

##### 4.5.1. Safety management system documentation

###### 4.5.1.1. There is a description of the safety management system including:

- (a) the identification and description of the processes and activities related to safety of rail operations, including safety-related tasks and associated responsibilities (see 2.3. Organisational roles, responsibilities, accountabilities and authorities);
- (b) the interaction of these processes;

- (c) the procedures or other documents describing how these processes are implemented;
  - (d) the identification of contractors, partners and suppliers with a description of the type and extent of services delivered;
  - (e) the identification of contractual arrangements and other business agreements, concluded between the organisation and other parties identified under (d), necessary to control the safety risks of the organisation and those related to the use of contractors;
  - (f) reference to documented information required by this Regulation.
- 4.5.1.2. The organisation shall ensure that an annual safety report is submitted to the relevant national safety authority (or authorities) in accordance with Article 9(6) of Directive (EU) 2016/798, including:
- (a) a synthesis of the decisions on the level of significance of the safety-related changes, including an overview of significant changes, in accordance with Article 18(1) of Regulation (EU) No 402/2013;
  - (b) the organisation's safety objectives for the following year(s) and how serious risks for safety influence the setting of these safety objectives;
  - (c) the results of internal accident/incident investigation (see 7.1. Learning from accidents and incidents) and other monitoring activities (see 6.1. Monitoring, 6.2. Internal auditing and 6.3. Management review), in accordance with Article 5(1) of Regulation (EU) No 1078/2012;
  - (d) details of progress on addressing outstanding recommendations from the national investigation bodies (see 7.1. Learning from accidents and incidents);
  - (e) the organisation's safety indicators set out to evaluate the organisation's safety performance (see 6.1. Monitoring);
  - (f) where applicable, the conclusions of the annual report of the safety advisor, as referred to in RID <sup>(1)</sup>, on the activities of the organisation relating to the transport of dangerous goods <sup>(2)</sup>.
- 4.5.2. Creating and updating
- 4.5.2.1. The organisation shall ensure that when creating and updating documented information related to the safety management system adequate formats and media are used.
- 4.5.3. Control of documented information
- 4.5.3.1. The organisation shall control documented information related to the safety management system, in particular its storage, distribution and the control of changes, to ensure its availability, suitability and protection where appropriate.
- 4.6. **Integration of human and organisational factors**
- 4.6.1. The organisation shall demonstrate a systematic approach to integrating human and organisational factors within the safety management system. This approach shall:
- (a) include the development of a strategy and the use of expertise and recognised methods from the field of human and organisational factors;
  - (b) address risks associated with the design and use of equipment, tasks, working conditions and organisational arrangements, taking into account human capabilities as well as limitations, and the influences on human performance.
5. OPERATION
- 5.1. **Operational planning and control**
- 5.1.1. When planning, developing, implementing and reviewing its operational processes, the organisation shall ensure that during operation:
- (a) risk acceptance criteria and safety measures are applied (see 3.1.1. Risk assessment);

<sup>(1)</sup> Point 2.1. of the Appendix to Annex I to Directive (EU) 2016/798.

<sup>(2)</sup> Point 2.2. of the Appendix to Annex I to Directive (EU) 2016/798.

- (b) plan(s) to achieve the safety objectives are delivered (see 3.2. Safety objectives and planning);
  - (c) information is collected to measure the correct application and effectiveness of the operational arrangements (see 6.1. Monitoring).
- 5.1.2. The organisation shall ensure that its operational arrangements conform to the safety-related requirements of applicable Technical Specifications for Interoperability and relevant national rules and any other relevant requirements (see 1. Context of the organisation).
- 5.1.3. To control risks where relevant for the safety of operational activities (see 3.1.1. Risk assessment), at least the following shall be taken into account:
- (a) identification of the safe boundaries of transport for traffic planning and control based on the design characteristics of the infrastructure;
  - (b) traffic planning, including timetable and train path allocation;
  - (c) real-time traffic management in normal mode and in degraded modes with the application of traffic restrictions of use and the management of traffic disruptions;
  - (d) setting of conditions for running exceptional consignments.
- 5.1.4. To control the allocation of responsibilities where relevant for the safety of operational activities, the organisation shall identify responsibilities for planning and operating the rail network and define how relevant tasks affecting the safe delivery of all services are allocated to competent staff within the organisation (see 2.3. Organisational roles, responsibilities, accountabilities and authorities) and to other external qualified parties when appropriate (see 5.3. Contractors, partners and suppliers).
- 5.1.5. To control information and communication where relevant for the safety of operational activities (see 4.4. Information and communication), relevant staff (e.g. signallers) shall be informed about specific routing requirements for trains and movements of vehicles including relevant changes which may result in a hazard, temporary or permanent operational restrictions (e.g. due to track maintenance) and conditions for exceptional consignments where applicable.
- 5.1.6. To control competence where relevant for the safety of operational activities (see 4.2. Competence), the organisation shall ensure, in accordance with applicable legislation (see 1. Context of the organisation), for its staff:
- (a) compliance with their training and work instructions, and corrective actions are taken where required;
  - (b) specific training in case of anticipated changes affecting the running of operations or their task assignment;
  - (c) adoption of adequate measures following accidents and incidents.
- 5.2. **Asset management**
- 5.2.1. The organisation shall manage the safety risks associated with physical assets throughout their lifecycle (see 3.1.1. Risk assessment), from design to disposal, and fulfil the human factors requirements in all phases of the life cycle.
- 5.2.2. The organisation shall:
- (a) ensure that the assets are used for the purpose intended while maintaining their safe operational state and their expected level of performance;
  - (b) manage the assets in normal and degraded operations;
  - (c) detect as soon as reasonably practicable instances of non-compliance with operating requirements before or during the operation of the asset, including the application of restrictions of use as appropriate to ensure a safe operational state of the asset (see 6.1. Monitoring).
- 5.2.3. The organisation shall ensure that its asset management arrangements, where applicable, conform to all essential requirements as set out in the relevant Technical Specifications for Interoperability and any other relevant requirements (see 1. Context of the organisation).

- 5.2.4. To control risks where relevant for the supply of maintenance (see 3.1.1. Risk assessment), at least the following shall be taken into account:
- (a) the identification of the need for maintenance to keep the infrastructure in a safe operational state, based on the planned and real use of the infrastructure and its design characteristics;
  - (b) the management of the removal of the asset from operation for maintenance, when defects have been identified or when asset condition degrades outside the limits of a safe operational state as referred to in point (a);
  - (c) the management of the return to operation of the asset with eventual restrictions of use after maintenance has been delivered to ensure it is in a safe operational state;
  - (d) the management of monitoring and measurement equipment to ensure that it is fit for its intended purpose.
- 5.2.5. To control information and communication where relevant for the safe management of assets (see 4.4. Information and communication), the organisation shall take into account:
- (a) the exchange of relevant information within the organisation or with external entities responsible for maintenance (see 5.3. Contractors, partners and suppliers), in particular on safety-related malfunctions, accidents, incidents as well as on eventual restrictions of use of the asset;
  - (b) the traceability of all necessary information including the information related to point (a) (see 4.4. Information and communication and 4.5.3. Control of documented information);
  - (c) the establishment and maintenance of records including the management of changes affecting the safety of assets (see 5.4. Management of change).
- 5.3. **Contractors, partners and suppliers**
- 5.3.1. The organisation shall identify and control safety risks arising from outsourced activities, including operations or cooperation with contractors, partners and suppliers.
- 5.3.2. To control the safety risks referred to in paragraph 5.3.1, the organisation shall define the criteria for the selection of the contractors, partners and suppliers and the contract requirements they have to meet, including:
- (a) the legal and other requirements related to safety (see 1. Context of the organisation);
  - (b) the level of competence required to deliver the tasks set out in the contract (see 4.2. Competence);
  - (c) the responsibilities for the tasks to be performed;
  - (d) the expected safety performance to be maintained during the contract;
  - (e) the obligations relating to the exchange of safety-related information (see 4.4. Information and communication);
  - (f) the traceability of safety-related documents (see 4.5. Documented information).
- 5.3.3. In accordance with the process set out in Article 3 of Regulation (EU) No 1078/2012, the organisation shall monitor:
- (a) the safety performance of all activities and operations of contractors, partners and suppliers to ensure that they comply with the requirements set out in the contract;
  - (b) the awareness of contractors, partners and suppliers of safety risks they entail to the organisation's operations.
- 5.4. **Management of change**
- 5.4.1. The organisation shall implement and control changes to the safety management system to maintain or improve the safety performance. This shall include decisions at the different stages of the change management and the subsequent review of safety risks (see 3.1.1. Risk assessment).

## 5.5. **Emergency management**

- 5.5.1. The organisation shall identify the emergency situations and associated timely measures to be taken to manage them (see 3.1.1. Risk assessment) and to re-establish normal operating conditions in accordance with Regulation (EU) 2015/995.
- 5.5.2. The organisation shall ensure that, for each identified type of emergency:
- (a) the emergency services can be promptly contacted;
  - (b) the emergency services are provided with all relevant information both in advance, to prepare their emergency response, and at the time of an emergency;
  - (c) first aid is provided internally.
- 5.5.3. The organisation shall identify and document the roles and responsibilities of all parties in accordance with Regulation (EU) 2015/995.
- 5.5.4. The organisation shall have plans for action, alerts and information in case of emergency, including arrangements to:
- (a) alert all staff with responsibility for emergency management;
  - (b) communicate information to all parties (e.g. railway undertakings, contractors, authorities, emergency services), including emergency instructions for passengers;
  - (c) take any decisions required in accordance with the type of emergency.
- 5.5.5. The organisation shall describe how resources and means for emergency management have been allocated (see 4.1. Resources) and how training requirements have been identified (see 4.2. Competence).
- 5.5.6. The emergency arrangements are regularly tested in cooperation with other interested parties and updated when appropriate.
- 5.5.7. The organisation shall coordinate emergency plans with all railway undertakings that operate on the organisation's infrastructure, with the emergency services, so as to facilitate their rapid intervention, and with any other party that could be involved in an emergency situation.
- 5.5.8. The organisation shall have arrangements to halt operations and railway traffic promptly, if necessary, and to inform all interested parties of the action taken.
- 5.5.9. For cross-border infrastructure, the cooperation between the relevant infrastructure managers shall facilitate the necessary coordination and preparedness of the competent emergency services on both sides of the border.

## 6. **PERFORMANCE EVALUATION**

### 6.1. **Monitoring**

- 6.1.1. The organisation shall perform monitoring in accordance with Regulation (EU) No 1078/2012:
- (a) to check the correct application and the effectiveness of all the processes and procedures in the safety management system, including the operational, organisational and technical safety measures;
  - (b) to check the correct application of the safety management system as a whole, and if it achieves the expected outcomes;
  - (c) to investigate whether the safety management system conforms to the requirements in this Regulation;
  - (d) to identify, implement and evaluate the effectiveness of the corrective measures (see 7.2. Continual improvement), as appropriate, if any relevant instance of non-compliance to points (a), (b) and (c) is detected.
- 6.1.2. The organisation shall regularly monitor at all levels within the organisation the performance of safety-related tasks and intervene if these tasks are not being properly performed.



## 6.2. Internal auditing

- 6.2.1. The organisation shall conduct internal audits in an independent, impartial and transparent way to collect and analyse information for the purposes of its monitoring activities (see 6.1. Monitoring), including:
- (a) A schedule of planned internal audits which can be revised depending on the results of previous audits and monitoring of performance;
  - (b) The identification and selection of competent auditors (see 4.2. Competence);
  - (c) The analysis and evaluation of the results of the audits;
  - (d) The identification of the need for corrective or improvement measures;
  - (e) The verification of the completion and effectiveness of these measures;
  - (f) The documentation pertaining to the execution and results of audits;
  - (g) The communication of the results of audits to the top management.

## 6.3. Management review

- 6.3.1. Top management shall regularly review the continuing adequacy and effectiveness of the safety management system including at least consideration of:
- (a) details of progress on addressing outstanding actions from previous management reviews;
  - (b) changing internal and external circumstances (see 1. Context of the organisation);
  - (c) the organisation's safety performance related to:
    - (i) the achievement of its safety objectives;
    - (ii) the results from its monitoring activities, including the internal audit findings, and internal accident/incident investigations and status of their respective actions;
    - (iii) the relevant outputs from supervisory activities conducted by the national safety authority;
  - (d) recommendations for improvement.
- 6.3.2. Based on the outputs of its management review, the top management shall take overall responsibility for the planning and implementation of needed changes to the safety management system.

## 7. IMPROVEMENT

### 7.1. Learning from accidents and incidents

- 7.1.1. Accidents and incidents related to the organisation's railway operations shall be:
- (a) reported, logged, investigated and analysed to determine their causes;
  - (b) reported to national bodies as appropriate.
- 7.1.2. The organisation shall ensure that:
- (a) recommendations from the national safety authority, the national investigating body and industry/internal investigations are evaluated and implemented if appropriate or mandated;
  - (b) relevant reports/information from other interested parties such as railway undertakings, infrastructure managers, entities in charge of maintenance and railway vehicle keepers are considered and taken into account.
- 7.1.3. The organisation shall use information relating to the investigation to review the risk assessment (see 3.1.1. Risk assessment), to learn with the aim of improving safety and, where applicable, to adopt corrective and/or improvement measures (see 5.4. Management of change).

## 7.2. **Continual improvement**

- 7.2.1. The organisation shall continually improve the adequacy and effectiveness of its safety management system, taking into account the framework set out in Regulation (EU) No 1078/2012 and at least the outputs of the following activities:
- (a) monitoring (see 6.1. Monitoring);
  - (b) internal auditing (see 6.2. Internal auditing);
  - (c) management review (see 6.3. Management review);
  - (d) learning from accidents and incidents (see 7.1. Learning from accidents and incidents).
- 7.2.2. The organisation shall provide means to motivating staff and other interested parties to be active in improving safety as part of its organisational learning.
- 7.2.3. The organisation shall provide a strategy to continually improve its safety culture, relying on the use of expertise and recognised methods to identify behavioural issues affecting the different parts of the safety management system and to put in place measures to address these.
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**COMMISSION IMPLEMENTING REGULATION (EU) 2018/763****of 9 April 2018****establishing practical arrangements for issuing single safety certificates to railway undertakings pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council, and repealing Commission Regulation (EC) No 653/2007****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety <sup>(1)</sup>, and in particular Article 10(10) thereof,

Whereas:

- (1) Provisions harmonising the approach to safety certification at Union level and fostering collaboration among all the parties involved in the safety assessment process are necessary, in order to reduce the complexity, length and cost of the certification procedure.
- (2) Taking into account the experience gained in the preparation of the cooperation agreements referred to in Article 11(1) of Directive (EU) 2016/798, early contact with the applicant in the form of coordination ('pre-engagement') is recognised as good practice to facilitate the development of the relationship between the parties involved in the safety assessment process. Such pre-engagement should be offered before an application for a single safety certificate is submitted, with the aim of enabling the certification body to become familiar with the applicant's safety management system, clarifying how the safety assessment process will be conducted and how decisions will be made and verifying that the applicant has received sufficient information to know what is expected of it. Clarifications given in the context of pre-engagement should not affect the outcome of the assessment.
- (3) The Agency should monitor the expiry dates of all valid single safety certificates with an area of operation in more than one Member State and should share that information with the relevant national safety authorities in order to facilitate the planning of their respective safety assessment activities.
- (4) The Agency should publish and keep up to date an application guide, free of charge, describing and where necessary explaining the requirements set out in this Regulation. With the aim of harmonising the approach to the exchange and recording of information through the one-stop shop, the application guide should also include model templates developed by the Agency in cooperation with the national safety authorities.
- (5) The Agency and the national safety authorities should implement internal arrangements or procedures to ensure the requirements of the safety assessment are fulfilled.
- (6) To avoid any duplication of assessment and to reduce the administrative burden and cost for the applicant, the Agency and the national safety authorities should take into account the cooperation agreements and multilateral agreements concluded pursuant to Article 11 of Directive (EU) 2016/798, where relevant.
- (7) Where the intended area of operation is limited to one Member State, and the applicant intends to operate to one or more stations close to the border in neighbouring Member States with similar network characteristics and similar operating rules, it should be able to do so without an extension of its area of operation to those neighbouring Member States. When submitting its application for a single safety certificate, the applicant should select the safety certification body in accordance with Article 10(5) and (8) of Directive (EU) 2016/798. Where the Agency acts as the safety certification body it should consult the relevant national safety authorities and should take into account the relevant cross-border agreements.

<sup>(1)</sup> OJ L 138, 26.5.2016, p. 102.

- (8) Where the Agency acts as the safety certification body, the applicant should have the right to submit its application file to the Agency in one of the official languages of the Union, without any obligation to translate it. This principle applies without prejudice to the possibility for the national safety authority to define a language policy concerning the part of the application referred to in point (b) of Article 10(3) of Directive (EU) 2016/798. During the course of the assessment, the national safety authority should have the right to address documents pertaining to the assessment to the Agency in a language of its Member State, without any obligation to translate them.
- (9) Certification should be based on an assessment of the ability of the applicant to meet the safety management system requirements applicable to railway undertakings, including the relevant national rules and requirements of the applicable technical specification for interoperability relating to the operation and traffic management subsystem, and to apply them consistently. Once issued with a single safety certificate, the applicant should continue to use its safety management system as referred to in Article 9 of Directive (EU) 2016/798.
- (10) The Agency and the national safety authorities should register all relevant information and the outcome of the assessment in the one-stop shop, to support and justify the decisions at each stage of the safety assessment process. If the Agency and the national safety authorities have their own information management systems for the purposes of safety assessment, they should ensure that all relevant information is transferred to the one-stop shop for the same reasons.
- (11) The Agency and the national safety authorities should develop internal arrangements or procedures for managing the issuing of single safety certificates with a view to reducing administrative burdens and costs for the applicant. In that respect, the applicant should have the possibility to submit copies of documents in the application file. The original documents should be available for verification by the Agency and the national safety authorities following the issuing of the single safety certificate.
- (12) It is necessary to harmonise the categorisation of issues in the assessment process to ensure that the applicant understands the severity of any issues raised by the Agency or by a national safety authority. That categorisation is particularly important when several national safety authorities are involved in the process.
- (13) In order to ensure that assessments are carried out effectively by the Agency and the national safety authorities and to reinforce mutual trust between them, the Agency and the national safety authorities should ensure that staff involved in assessments have the necessary competencies. To that end, those competencies should be identified.
- (14) According to Article 31(3) of Directive (EU) 2016/798, the new safety certification regime will start from 16 June 2019. However, Member States have the possibility notifying the Agency and the Commission pursuant to Article 33(2) of that Directive that they have extended the transposition period and may in consequence continue to issue certificates in accordance with Directive 2004/49/EC of the European Parliament and of the Council <sup>(1)</sup> until 16 June 2020. It is therefore necessary to clarify how the new regime should apply in addition to the old one where the intended area of operation includes one or more of those Member States.
- (15) Where a national safety authority recognises that it will not be able to issue a safety certificate in accordance with Directive 2004/49/EC before either 16 June 2019, or 16 June 2020 in respect of those Member States that have notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798, the Agency, when acting as safety certification body, should take into account the results of the assessment of the national safety authority concerning the assessment of the corresponding elements set out in point (a) of Article 10(2) of Directive 2004/49/EC to avoid any duplication of assessment.
- (16) A single safety certificate issued by the Agency should be recognised as equivalent to the part of the safety certificate referred to in point (a) of Article 10(2) of Directive 2004/49/EC. That certification is valid throughout the Union for equivalent rail transport operations. Therefore, Member States which have notified the Agency and the Commission pursuant to Article 33(2) of Directive (EU) 2016/798 should accept a single safety certificate issued by the Agency as equivalent to the part issued in accordance with point (a) of Article 10(2) of Directive 2004/49/EC.

<sup>(1)</sup> Directive 2004/49/EC of the European Parliament and of the Council of 29 April 2004 on safety of 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).

- (17) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 21 of Council Directive 96/48/EC <sup>(1)</sup>,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

### **Subject matter and scope**

This Regulation sets out the practical arrangements to be applied by railway undertakings when submitting applications for single safety certificates or for the renewal or update of such certificates through the one-stop shop facility referred to in Article 12 of Regulation (EU) 2016/796 of the European Parliament and of the Council <sup>(2)</sup> ('one-stop shop').

It also sets out the practical arrangements to be applied by safety certification bodies when assessing applications for single safety certificates, or for the renewal or update of such certificates as well as for coordinating with the national safety authorities concerned with the intended area of operation.

#### *Article 2*

### **Definitions**

For the purposes of this Regulation, the following definitions shall apply:

- (1) 'safety certification body' means the body responsible for issuing a single safety certificate, either the Agency or a national safety authority;
- (2) 'date of receipt of the application' means:
  - (a) where the Agency acts as the safety certification body, the first working day common to the Agency and to the national safety authorities concerned with the intended area of operation following the acknowledgement of receipt of the application file;
  - (b) where a national safety authority acts as the safety certification body, the first working day in the Member State concerned following the acknowledgement of receipt of the application file;
- (3) 'pre-engagement' means a procedural stage preceding the submission of an application, in the course of which the applicant may request additional information on the following stages of the safety assessment process from the safety certification body and the national safety authorities concerned with the intended area of operation;
- (4) 'residual concern' means a minor issue identified during the assessment of an application for a single safety certificate which does not prevent its issuing and can be deferred for later supervision;
- (5) 'relevant date' means 16 June 2019, except as regards those Member States that have notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798 that they have extended the transposition period of that Directive, in which case the relevant date is 16 June 2020.

#### *Article 3*

### **Responsibilities of the Agency and the national safety authorities**

1. In addition to the issuing of single safety certificates, the safety certification body shall be responsible for the following tasks:
  - (a) the planning, implementation and monitoring of the assessment work it carries out;
  - (b) the setting up of coordination arrangements between the relevant parties.
2. The safety certification body and the national safety authorities concerned with the intended area of operation shall accept pre-engagement at the request of the applicant and shall provide any clarifications requested by the applicant in the context of the pre-engagement.

<sup>(1)</sup> Council Directive 96/48/EC of 23 July 1996 on the interoperability of the trans-European high-speed rail system (OJ L 235, 17.9.1996, p. 6).

<sup>(2)</sup> Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 (OJ L 138, 26.5.2016, p. 1).

3. For the purposes of issuing single safety certificates, the safety certification body and the national safety authorities concerned with the intended area of operation shall, each for their own part, compile the following information:
  - (a) all relevant information concerning the different stages of the assessment, including the reasons for the decisions taken during the assessment and the identification of any restriction or condition of use to be included in the single safety certificate;
  - (b) the outcome of the assessment, including summary conclusions and where appropriate, an opinion concerning the issuing of the single safety certificate.
4. Where the Agency acts as the safety certification body, it shall compile the information referred to in point (b) of paragraph 3 in the final outcome of the assessment.
5. The Agency shall monitor the expiry dates of all valid single safety certificates with an area of operation in more than one Member State and share that information with the relevant national safety authorities.
6. National safety authorities shall share with the Agency and other national safety authorities concerned with the intended area of operation all relevant information that may have an impact on the safety assessment process.
7. The Agency shall publish and keep up to date an application guide, free of charge, in all the official languages of the Union, describing and where necessary explaining the requirements set out in this Regulation. The application guide shall also include model templates developed by the Agency in cooperation with the national safety authorities.
8. The national safety authorities shall publish and keep up to date an application guide, free of charge, describing and where necessary explaining the national rules that apply in respect of the intended area of operation and the applicable national procedural rules.
9. The Agency and the national safety authority shall establish internal arrangements or procedures for managing the safety assessment process. Those arrangements or procedures shall take into account the agreements referred to in Article 11 of Directive (EU) 2016/798.
10. Each single safety certificate shall be given a unique European Identification Number (EIN). The Agency shall define the structure and content of EINs and make them available on its website.
11. Where the applicant indicates in its application that it intends to operate to stations in neighbouring Member States with similar network characteristics and similar operating rules, when those stations are close to the border, the single safety certificate shall also be valid to such stations without requesting an extension of the area of operation, following consultation of the national safety authorities of the neighbouring Member States by the safety certification body. The national safety authorities of the Member States concerned shall confirm to the safety certification body that the relevant notified national rules and the obligations pertaining to the relevant cross-border agreements are met before it issues the single safety certificate.
12. For the purposes of the assessment of applications, the safety certification body shall accept the authorisations, recognitions or certificates of products or services provided by railway undertakings or their contractors, partners or suppliers, granted in accordance with relevant Union law, as proof of the ability of railway undertakings to fulfil the corresponding requirements defined in Commission Delegated Regulation (EU) 2018/762 <sup>(1)</sup>.

#### Article 4

### Responsibilities of applicants

1. Without prejudice to the timeframe allowed for the assessment set out in Article 6, the applicant shall submit the application for a single safety certificate, or for the update or renewal of such a certificate, through the one-stop shop before the following dates, as appropriate:
  - (a) the planned start date of any new rail transport operation;
  - (b) the planned start date of a rail transport operation under conditions other than those laid down in the current single safety certificate, following a substantial change made to the type, extent or area of operation;
  - (c) the expiry date of the current single safety certificate.

<sup>(1)</sup> Commission Delegated Regulation (EU) 2018/762 of 8 March 2018 establishing common safety methods on safety management system requirements pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulations (EU) No 1158/2010 and (EU) No 1169/2010 (see page 26 of this Official Journal).

2. When submitting an application for a new single safety certificate, the applicant shall provide the information listed in Annex I.

3. When submitting an application for the update or renewal of a single safety certificate, the applicant shall provide the information listed in Annex I and describe changes made since the current certificate was issued.

If major non-compliances, which may affect safety performance or create serious safety risks, or any other areas of concern are identified during supervision activities since the previous assessment, the safety certification body and the national safety authorities concerned with the intended area of operation shall decide whether the whole application file needs to be re-assessed.

4. The selection of the safety certification body made by the applicant shall be binding until the safety assessment process is completed or terminated.

5. When the applicant requests pre-engagement, it shall submit the information listed in points 1 to 6 of Annex I through the one-stop shop.

6. Where the submitted file contains copies of documents issued by entities other than the safety certification body, the applicant shall keep the originals for at least 5 years after the end of the period of validity of the single safety certificate. In the case of renewal or update, the applicant shall keep the originals of documents submitted for that application and issued by entities other than the safety certification body for at least 5 years after the end of the period of validity of the renewed or updated single safety certificate. The applicant shall make available those original documents at the request of the Agency or the national safety authorities.

#### *Article 5*

#### **Language**

1. Where the Agency acts as the safety certification body, the language to be used for the application shall be as follows:

- (a) for the part of the application file referred to in point (a) of Article 10(3) of Directive (EU) 2016/798, one of the official languages of the Union at the choice of the applicant;
- (b) for the parts of the application file referred to in point (b) of Article 10(3) of Directive (EU) 2016/798, as well as for the parts of the application file referred to in point 8.1 of Annex I, the language determined by the Member State concerned and indicated in the application guide referred to in Article 3(8) of this Regulation.

2. Any decision concerning the issuing of the single safety certificate taken by the Agency, including the reasons for the decision in the final outcome of the assessment and where applicable, the single safety certificate, shall be in the language referred to in point (a) of paragraph 1.

#### *Article 6*

#### **Procedural stages and timeframes**

1. The safety certification body and the national safety authorities concerned with the intended area of operation shall apply the process set out in Annex II.

2. The safety certification body and the national safety authorities concerned with the intended area of operation shall evaluate, each for their own part, whether the application file contains the required documentary evidence listed in Annex I. The safety certification body shall inform the applicant, without undue delay, and in any case no later than one month following the date of receipt of the application, whether the application is complete.

3. The decision on the issuing of the single safety certificate shall be taken no later than four months following the date on which the applicant is informed that the application is complete, subject to paragraphs 5 to 7.

4. If the applicant is informed that its file is not complete, the safety certification body, in coordination with the national safety authorities concerned with the intended area of operation, shall request the necessary supplementary information promptly, including justifications and details of the timeframe for the applicant's response.

The timeframe for providing supplementary information shall be reasonable, proportionate to the difficulty of providing the information requested and agreed with the applicant as soon as it is informed that its file is not complete. If the applicant does not provide the required information within the agreed timeframe, the safety certification body may decide to extend the timeframe for the applicant's response or to notify the applicant that its application is rejected.

The decision on the issuing of the single safety certificate shall be taken no later than four months following the date on which the requested supplementary information is submitted by the applicant.

5. Even if the application file is complete, the Agency or any national safety authority concerned with the intended area of operation may request further information at any time prior to taking its decision and shall set a reasonable deadline for the provision thereof. Such a request shall extend the timeframe laid down in paragraph 3 of this Article under the conditions laid down in Annex II.

6. The timeframe in paragraph 3 of this Article may be extended by the Agency for the following periods referred to in Article 10(7) of Directive (EU) 2016/798:

- (a) the period of cooperation with a view to agreeing on a mutually acceptable assessment;
- (b) the period when the matter is referred to the Board of Appeal for arbitration.

7. The timeframe may also be extended for the time necessary for the applicant to arrange a visit or inspection on its sites, or an audit of its organisation.

8. The single safety certificate shall contain the information listed in Annex III.

#### *Article 7*

### **Communication**

1. The safety certification body, the national safety authorities concerned with the intended area of operation and the applicant shall communicate through the one-stop shop as regards any issue referred to in Article 12.

2. The status of all stages of the safety assessment process, the outcome of the assessment and the decision on the application shall be communicated to the applicant through the one-stop shop.

3. Without prejudice to paragraph 1, the application guides of the Agency and of the national safety authorities shall indicate arrangements for communicating between themselves and with the applicant.

4. The one-stop shop shall acknowledge receipt of the application for a single safety certificate.

#### *Article 8*

### **Period of validity of single safety certificates**

Single safety certificates shall be valid for a period of five years.

However, if a shorter period is necessary to ensure the effective control of risks affecting the safety of railway operations, the safety certification body may decide, in coordination with the national safety authorities concerned with the intended area of operation, to grant the single safety certificate for a period of less than five years. In this case, the safety certification body shall include the reasons for its decision in the outcome of the assessment registered in accordance with Article 9.

#### *Article 9*

### **Information management**

The safety certification body and the national safety authorities concerned with the intended area of operation shall register all relevant information and the outcome of the assessment referred to in Article 3(3) in the one-stop shop. The Agency shall also register the final outcome of the assessment referred to in Article 3(4) in the one-stop shop.

Where the national safety authorities use an information management system for processing the applications addressed to them, they shall transfer all relevant information to the one-stop shop.

#### *Article 10*

### **Arrangements for visits and inspections on the sites of railway undertakings and audits**

1. When undertaking visits and inspections on the sites of applicants and audits, as referred to in Article 10(5) of Directive (EU) 2016/798, the objectives and scope of these visits and inspections on the sites of applicants and audits, as well as the role assigned to each authority, shall be coordinated between the Agency and the national safety authorities concerned with the intended area of operation.



2. When undertaking visits and inspections on the sites of applicants and audits, as referred to in Article 10(5) and (8) of Directive (EU) 2016/798, the body responsible for carrying out the visit, inspection or audit shall produce a report, identifying issues identified in the course of the assessment and specifying whether they have been closed by evidence provided during the visit, inspection or audit and, if so, how. That report may also include additional issues referred to in Article 12 to be resolved by the applicant within an agreed timeframe.

3. In the case of visits, inspections on the sites of applicants and audits as referred to in Article 10(5) and (8) of Directive (EU) 2016/798 cases, the applicant shall provide details of who will represent it and the site safety rules and procedures that need to be respected by the body responsible for carrying out the visit, inspection or audit. The timeframe for visits, inspections and audits, including the provision of the information referred above, shall be agreed among the authorities concerned and the applicant.

#### Article 11

### Coordination between the Agency and national safety authorities

1. When acting as the certification body, the Agency shall coordinate with the national safety authorities concerned with the intended area of operation at the different stages of the safety assessment process. The Agency and the national safety authorities shall discuss any issues relating to the safety assessment process, including any deficiency, and any requests for supplementary information which have an impact on the timeframe of the assessment or have the potential to affect the work of the other national safety authorities concerned with the area of operation.

2. Without prejudice to paragraph 1, each body involved in the safety assessment process may take direct contact with the applicant with regard to issues related to its own part of the assessment.

3. Before deciding on the issuing of a single safety certificate, the Agency and the national safety authorities concerned with the intended area of operation shall take the following steps:

- (a) discuss the outcome of their respective assessments;
- (b) agree on any residual concerns to be deferred for consideration during later supervision;
- (c) agree on any restrictions or conditions of use to be included in the single safety certificate.

4. Where the applicant establishes an action plan to address the residual concerns referred to in point (b) of paragraph 3, the national safety authorities shall agree which of them shall follow up its completion. To that end, the national safety authorities shall coordinate where appropriate, in accordance with the arrangements referred to in Article 8(2) of Delegated Regulation (EU) 2018/761 <sup>(1)</sup>, and inform the Agency about their agreement and the outcome of their related supervision activities.

The Agency shall take into account information on the outcome of supervision activities carried out by the national safety authorities concerned with the intended area of operation regarding the follow up of residual concerns to decide whether these can be closed during the assessment of the update or renewal application.

5. The Agency shall keep records of coordination activities and shall register them in the one-stop shop in accordance with Article 9.

#### Article 12

### Categorisation of issues

1. The safety certification body and the national safety authorities concerned with the intended area of operation shall categorise issues identified in the course of their assessment of the application file as follows:

- (a) 'Type 1': issues that require a response from the applicant for the understanding of the application file;
- (b) 'Type 2': issues that may lead to an amendment of the application file or minor action from the applicant; the action to be taken shall be left to the judgement of the applicant and shall not prevent the issuing of the single safety certificate;

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<sup>(1)</sup> Commission Delegated Regulation (EU) 2018/761 of 16 February 2018 establishing common safety methods for supervision by national safety authorities after the issue of a single safety certificate or a safety authorisation pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council and repealing Commission Regulation (EU) No 1077/2012 (see page 16 of this Official Journal).

- (c) 'Type 3': issues that require specific action to be taken by the applicant, completion of which may be postponed until after the single safety certificate is granted; action to resolve an issue shall be proposed by the applicant and shall be agreed with the party that identified the issue;
  - (d) 'Type 4': issues that require an amendment of the application file or specific action to be taken by the applicant; the single safety certificate shall not be granted unless the issue is resolved or restrictions or conditions of use are included in the certificate to address the issue; any action to resolve an issue shall be proposed by the applicant and shall be agreed with the party that identified the issue.
2. Following the response or the action taken by the applicant according to the issue, the safety certification body or the national safety authority concerned shall re-evaluate the issues it identified, re-classify them where relevant and assign one of the following statuses for each of the issues identified:
- (a) 'Issue pending' if the evidence provided by the applicant is not satisfactory and additional information is still required;
  - (b) 'Residual concern for supervision' if a residual concern still exists;
  - (c) 'Issue closed out' if a suitable applicant's response has been provided and no residual concern remains.

#### Article 13

### Competence of the staff involved in assessments

1. The Agency and the national safety authorities shall ensure that staff involved in assessments have the following competencies:
- (a) knowledge of the relevant regulatory framework as it applies to assessment;
  - (b) knowledge of the functioning of the railway system;
  - (c) appropriate level of critical analysis;
  - (d) experience in the assessment of a safety or similar management system in the railway sector, or a safety management system in a sector with equivalent operational and technical challenges;
  - (e) problem solving, communication and team working;
  - (f) any other competency required by a particular assessment.

In the case of team work, the competencies may be shared amongst the team members.

Staff carrying out visits, inspections and audits as referred to in Article 10 shall also demonstrate knowledge of, and experience in interviewing skills.

2. With a view to ensuring the correct application of paragraph 1, the Agency and the national safety authorities shall put in place a competence management system which shall include:
- (a) the development of competence profiles for each job, position or role;
  - (b) the recruitment of staff in accordance with the established competence profiles;
  - (c) the maintenance, development and assessment of staff competence in accordance with the established competence profiles.

#### Article 14

### Review under Article 10(12) of Directive (EU) 2016/798

1. Where the safety certification body issues a negative decision, which includes the refusal of the single safety certificate, the exclusion of part of the network in accordance with a negative assessment as referred to in Article 10(7) of Directive (EU) 2016/798 and the identification of restrictions or conditions of use other than those requested in the application, the applicant may request the review of the decision.
2. The request for review shall be submitted by the applicant through the one-stop shop and include a list of any issues that, in the view of the applicant, have not been properly considered during the safety assessment process.
3. Any supplementary information provided after the adoption of the decision on issuing or refusing a single safety certificate shall not be admissible as evidence.

4. The safety certification body in coordination with the national safety authorities concerned with the intended area of operation shall ensure impartiality of the review process.
5. The review process shall target the issues justifying the deviation of the decision of the safety certification body from the applicant's request.
6. Where the Agency acts as the safety certification body, the review shall be carried out in coordination with the national safety authorities concerned with the intended area of operation.
7. The safety certification body shall communicate its decision to confirm or to adapt the initial decision to all parties involved in the assessment, including the applicant, through the one-stop shop.

#### Article 15

#### Transitional provisions

1. Where a national safety authority recognises that it will not be able to issue a safety certificate in accordance with Directive 2004/49/EC before the relevant date in the Member State concerned, it shall inform the applicant and the Agency immediately.
2. In the case referred to in Article 10(8) of Directive (EU) 2016/798, the applicant shall decide whether the application should continue to be assessed by the national safety authority or transferred to the Agency. The applicant shall inform both and the following shall apply:
  - (a) In cases where the applicant has decided to use the Agency as safety certification body, the national safety authority shall transfer the application file and the results of the assessment referred to in point (a) of Article 10(2) of Directive 2004/49/EC to the Agency. The Agency and the national safety authority shall cooperate and assist the applicant to supplement the application in order to meet the additional requirements of Article 9 of Directive (EU) 2016/798.
  - (b) In cases where the applicant has decided to use the national safety authority as safety certification body, the national safety authority shall continue the assessment of the application and decide on the issue of the single safety certificate in accordance with Article 10 of Directive (EU) 2016/798 and this Regulation. That authority shall assist the applicant to supplement the application in order to meet the additional requirements of Article 9 of Directive (EU) 2016/798.
3. In the case of an applicant intending to operate in more than one Member State, the safety certification body shall be the Agency and the procedure set out in point (a) of paragraph 2 applies.
4. In all cases, the applicant shall submit the revised application after the relevant date in the Member State concerned through the one-stop shop. The safety certification body shall assist the applicant in this task.
5. After the relevant date, any railway undertaking established in the Member State concerned, for which a safety certificate issued in accordance with Directive 2004/49/EC needs renewal or update resulting from changes to type, extent and area of operation, shall submit a new application for a single safety certificate through the one-stop shop, in accordance with this Regulation.
6. Where the area of intended operation is not limited to one Member State, a single safety certificate issued by the Agency between 16 June 2019 and 16 June 2020 shall exclude the network or networks in any of the Member States that have notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798 and that have not yet transposed that Directive and not brought into force its national transposition measures. The national safety authorities of the Member States that have made such a notification shall:
  - (a) treat a single safety certificate issued by the Agency as equivalent to the part of the safety certificate issued in accordance with point (a) of Article 10(2) of Directive 2004/49/EC;
  - (b) issue safety certificates in accordance with point (b) of Article 10(2) of Directive 2004/49/EC from 16 June 2019 with a validity period not extending beyond that of the single safety certificate.
7. In the cases referred to in point (a) of paragraph 2 and in paragraph 6 of this Article, the national safety authority shall cooperate and coordinate with the Agency to undertake the assessment of the elements set out in point (a) of Article 10(3) of Directive (EU) 2016/798. When doing so, the Agency shall accept the assessment referred to in point (a) of Article 10(2) of Directive 2004/49/EC carried out by the national safety authority.

*Article 16***Repeal**

Regulation (EC) No 653/2007 is repealed with effect from 16 June 2019. However, it shall continue to apply until 15 June 2020 in respect of those Member States that have notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798 that they have extended the period for transposition of that Directive.

*Article 17***Entry into force and 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 16 June 2019 in the Member States that have not notified the Agency and the Commission in accordance with Article 33(2) of Directive (EU) 2016/798. It shall apply in all Member States from 16 June 2020. However, Article 15(1), (2), (3) and (7) shall apply from 16 February 2019 and Article 15(6) shall apply from 16 June 2019 in all Member States.

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

Done at Brussels, 9 April 2018.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX I

**Content of the application for a single safety certificate**

*Note: all information is mandatory, including the documents annexed to the application, except where indicated with 'O' (optional). Where the railway undertaking needs to establish a corrective action plan referred to in point 9, the information about it is mandatory.*

**1. Type of application:**

- 1.1. New
- 1.2. Renewal
- 1.3. Update
- 1.4. EIN of the previous certificate (in case of renewal or update application only)

**2. Type of operation requested (select one or more) <sup>(1)</sup>:**

- 2.1. Passenger transport including high-speed services
- 2.2. Passenger transport excluding high-speed services
- 2.3. Freight transport including dangerous goods services <sup>(2)</sup>
- 2.4. Freight transport excluding dangerous goods services
- 2.5. Shunting only
- 2.6. Other (specify)

**3. Rail transport operations:**

- 3.1. Expected date of starting services/operations (O)
- 3.2. Member State(s) concerned with the intended area of operation
- 3.3. Definition of the intended area of operation (for the concerned networks) <sup>(3)</sup>
- 3.4. Station(s) in neighbouring Member State(s) (in the cases referred to in Article 3(11) of Implementing Regulation (EU) 2018/763 and Article 10(8) of Directive (EU) 2016/798)

**4. Safety certification body:**

- 4.1. The Agency
- 4.2. The national safety authority (in the cases referred to in Article 10(8) of Directive (EU) 2016/798)

**5. Applicant's information:**

- 5.1. Legal denomination
- 5.2. Acronym (O)
- 5.3. Complete postal address
- 5.4. Phone
- 5.5. Fax (O)
- 5.6. Email
- 5.7. Website (O)

<sup>(1)</sup> For each Member State concerned with the intended area of operation.

<sup>(2)</sup> 'Dangerous goods' means substances and articles whose carriage is authorised only under the conditions prescribed in Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

<sup>(3)</sup> For each Member State concerned with the intended area of operation.

- 5.8. National registration number
- 5.9. VAT number (O)
- 5.10. Other relevant information (O)
6. **Contact person information:**
  - 6.1. First name
  - 6.2. Surname
  - 6.3. Title or function
  - 6.4. Complete postal address
  - 6.5. Phone
  - 6.6. Fax (O)
  - 6.7. Email
  - 6.8. Language or languages spoken

#### **Documents annexed to the application**

7. **Documents submitted for the safety management system part of the assessment:**
    - 7.1. Description of the safety management system and other documents demonstrating compliance with the requirements set out in point (a) of Article 10(3) of Directive (EU) 2016/798 and showing how those requirements are met.
    - 7.2. Information cross-referencing the safety management system (see point 7.1) against Annex I to Delegated Regulation (EU) 2018/762, including an indication where in the safety management system documentation the relevant requirements of the applicable technical specification for interoperability relating to the operation and traffic management subsystem are met.
  8. **Documents submitted for the national part (for each Member State covered by the intended area of operation) of the assessment:**
    - 8.1. Description or other demonstration of how the safety management arrangements address the relevant national rules notified in accordance with Article 8 of Directive (EU) 2016/798.
    - 8.2. Information cross-referencing the safety management system (see point 7.1) against the requirements laid down in the relevant national rules (see point 8.1).
  9. **Corrective action plan(s)**
    - 9.1. The current status of the action plan or plans established by the railway undertaking to resolve any major non-compliance and any other area of concern identified during supervision activities since the previous assessment.
    - 9.2. The current status of the action plan or plans established by the railway undertaking to resolve residual concerns from the previous assessment.
-

## ANNEX II

**Safety assessment process**

## 1. GENERAL

- 1.1. The safety certification body and the national safety authorities concerned with the intended area of operation shall develop a structured and auditable process for the complete activity which takes into account the elements set out in this Annex. The safety assessment process shall be iterative, as shown in the diagram below (see Figure 1 in the Appendix), that is the safety certification body and the national safety authorities concerned with the intended area of operation shall be entitled to make reasonable requests for further information or re-submission in accordance with this Regulation.

## 2. RECEIPT OF APPLICATION

- 2.1. After receiving the application for a single safety certificate, the safety certification body shall formally and promptly acknowledge receipt of the application.
- 2.2. The safety certification body and the national safety authorities concerned with the intended area of operation shall assign competent resources to deliver the assessment process.

## 3. INITIAL SCREEN

- 3.1. The safety certification body in coordination with the national safety authorities concerned with the intended area of operation shall undertake promptly on receipt of the application an initial screen to check the following elements:
  - (a) the applicant has provided the basic information which is either required by the legislation or needed for it to be processed effectively;
  - (b) the application file contains sufficient evidence and is structured and internally cross-referenced so that it can be properly assessed against the safety management system requirements and relevant notified national rules. The safety certification body in coordination with the national safety authorities concerned with the intended area of operation shall conduct an initial review of the actual content of the evidence contained in the application to make an initial judgement on the quality, sufficiency and appropriateness of the safety management system;
  - (c) if applicable, the current status of the action plan (or plans) established by the railway undertaking to resolve any major non-compliance and any other area of concern identified during supervision activities since the previous assessment is included;
  - (d) if applicable, the current status of the action plan (or plans) established by the railway undertaking to resolve residual concerns from previous assessment is included.
- 3.2. The national safety authorities concerned with the intended area of operation shall also check that the evidence for the type, extent and intended area of operation is clearly identified.
- 3.3. Following the checks referred to in points 3.1 and 3.2, the safety certification body and the national safety authorities concerned with the intended area of operation shall decide if there are any areas in which, for their respective part, further information is necessary. Where further information is necessary, the safety certification body and the national safety authorities concerned with the intended area of operation may promptly seek the information, to the extent that they deem reasonably necessary to support their assessment.
- 3.4. The safety certification body and the national safety authorities concerned with the intended area of operation shall read a sufficient sample of the application, each for their own part, to check that its content is understandable. If it is clearly not, the safety certification body and the national safety authorities concerned with the intended area of operation shall decide, each for their own part, whether it needs to be returned, with a request for an improved version.

## 4. DETAILED ASSESSMENT

- 4.1. After the completion of the initial screen stage, the safety certification body and the national safety authorities concerned with the intended area of operation shall proceed, each for their own part, to the detailed assessment of the application file (see Figure 2 in the Appendix), using the safety management system requirements and relevant notified national rules.

- 4.2. In undertaking the detailed assessment referred to in point 4.1, in accordance with Article 18(1) of Directive (EU) 2016/798, the safety certification body and the national safety authorities concerned with the intended area of operation shall exercise professional judgment, be impartial and proportionate, and provide documented reasons for conclusions reached.
- 4.3. The assessment shall determine whether the safety management system requirements and relevant notified national rules are met or whether further information shall be requested. During the assessment, the safety certification body and the national safety authorities concerned with the intended area of operation shall also seek evidence that the safety management system requirements and relevant notified national rules have been met from the outputs of the safety management system processes, using sampling methods where appropriate, to ensure that the applicant has understood and can meet the requirements according to the type and extent of the railway operations and the intended area of operation in order to ensure safe operation of the railway.
- 4.4. Any type 4 issue shall be resolved to the satisfaction of the safety certification body and lead to an update of the application file where appropriate before the single safety certificate can be issued.
- 4.5. Residual concerns may be deferred for consideration to supervision, or actions may be agreed upon with the applicant, based on its proposal for updating the application file, or both. In such a case formal resolution of the issue shall take place after the issue of the single safety certificate.
- 4.6. The safety certification body and the national safety authorities concerned with the intended area of operation shall be transparent on how they judge the severity of each identified issue referred to in Article 12(1).
- 4.7. When identifying an issue referred to in Article 12(1), the safety certification body and the national safety authorities concerned with the intended area of operation shall be specific and help the applicant understand the level of detail expected in the response. To that end, the safety certification body and the national safety authorities concerned with the intended area of operation shall take the following steps:
  - (a) refer accurately to the relevant safety management system requirements and notified national rules and help the applicant to understand the identified issues;
  - (b) identify the relevant part of related regulations and rules;
  - (c) state why the individual safety management system requirement or notified national rule, including any related legislation, is not met;
  - (d) agree with the applicant on further commitments, documents and any other supporting information to be provided, as required by the level of detail of the safety management system requirement or the notified national rule;
  - (e) specify and agree with the applicant on a timeframe for compliance, reasonable and proportionate to the difficulty of providing the information requested.
- 4.8. If the applicant significantly delays providing the requested information, the safety certification body may decide to extend the timeframe for the applicant's response or to reject the application after notice.
- 4.9. The timeframe for taking the decision on the issuing of the single safety certificate may only be extended, until the requested information has been submitted, upon decision of the safety certification body in coordination with the national safety authorities concerned with the intended area of operation and with the agreement of the applicant in one of the following cases:
  - (a) type 1 issues referred to in Article 12(1) that, considered individually or collectively, prevent the assessment or parts of it from continuing;
  - (b) type 4 issues or multiple type 3 issues referred to in Article 12(1) that, considered collectively, may raise the category to a type 4 issue, preventing the issuing of the single safety certificate.
- 4.10. To be satisfactory, the applicant's written responses shall be sufficient to allay the concerns expressed and to demonstrate that its proposed arrangements will meet the relevant criteria or notified national rules.
- 4.11. Where a response is considered unsatisfactory, it shall be explained precisely why, identifying the further information or demonstration required of the applicant to make it satisfactory.



- 4.12. If concerns emerge that the application could be rejected, or that it will take a longer time to reach a decision than the timeframe allowed for the assessment, the safety certification body may consider possible contingency measures.
- 4.13. When it is concluded that either the application meets all requirements or that further progress is unlikely in securing satisfactory responses to outstanding matters, the safety certification body and the national safety authorities concerned with the intended area of operation shall, each for their own part, complete the assessment by the following steps:
- (a) stating whether all criteria have been met or whether there are still matters outstanding;
  - (b) identifying any residual concern;
  - (c) identifying any restriction or condition of use to be included in the single safety certificate;
  - (d) reporting on the follow-up of major non-compliances identified during supervision activities, as referred to in Article 5 of Delegated Regulation (EU) 2018/761, where appropriate;
  - (e) ensuring that the safety assessment process has been correctly applied;
  - (f) compiling the outcome of the assessment, including summary conclusions and where appropriate, an opinion concerning the issuing of the single safety certificate.
- 4.14. The safety certification body and the national safety authorities concerned with the intended area of operation shall record and justify in writing all findings and judgments in order to facilitate both the assurance process and the decision-making process, as well as to assist with any appeal against the decision to issue or not the single safety certificate.

## 5. DECISION-MAKING

- 5.1. Based on the conclusions of the completed assessment, a decision shall be made on whether to issue a single safety certificate or to reject the application. Where a single safety certificate is to be issued, some residual concerns may be identified. A single safety certificate shall not be issued where any type 4 issue referred to in Article 12(1) is identified and not resolved during the assessment.
- 5.2. The safety certification body may decide to restrict the scope of the single safety certificate, by identifying restrictions or conditions of use, if it is concluded in coordination with the national safety authorities concerned with the intended area of operation that such restrictions or conditions of use address any type 4 issue that would prevent the issue of the single safety certificate. The single safety certificate shall be updated on request of the applicant after all residual concerns have been addressed in its application file.
- 5.3. The applicant shall be informed about the decision of the safety certification body, including the outcome of the assessment, and a single safety certificate shall be issued as appropriate.
- 5.4. If the issuing of the single safety certificate is refused or if the single safety certificate contains restrictions or conditions of use other than those defined in the application, the safety certification body shall inform the applicant, giving the reasons for the decision, and notify it of the procedure to request a review of or to appeal against the decision.

## 6. CLOSING ASSESSMENT

- 6.1. The safety certification body shall complete the administrative closure by ensuring that all documents and records are reviewed, organised and archived. To continually improve its process, the safety certification body shall identify historic information and lessons learned for use by future assessments.

## 7. SPECIFIC PROVISIONS FOR THE RENEWAL OF A SINGLE SAFETY CERTIFICATE

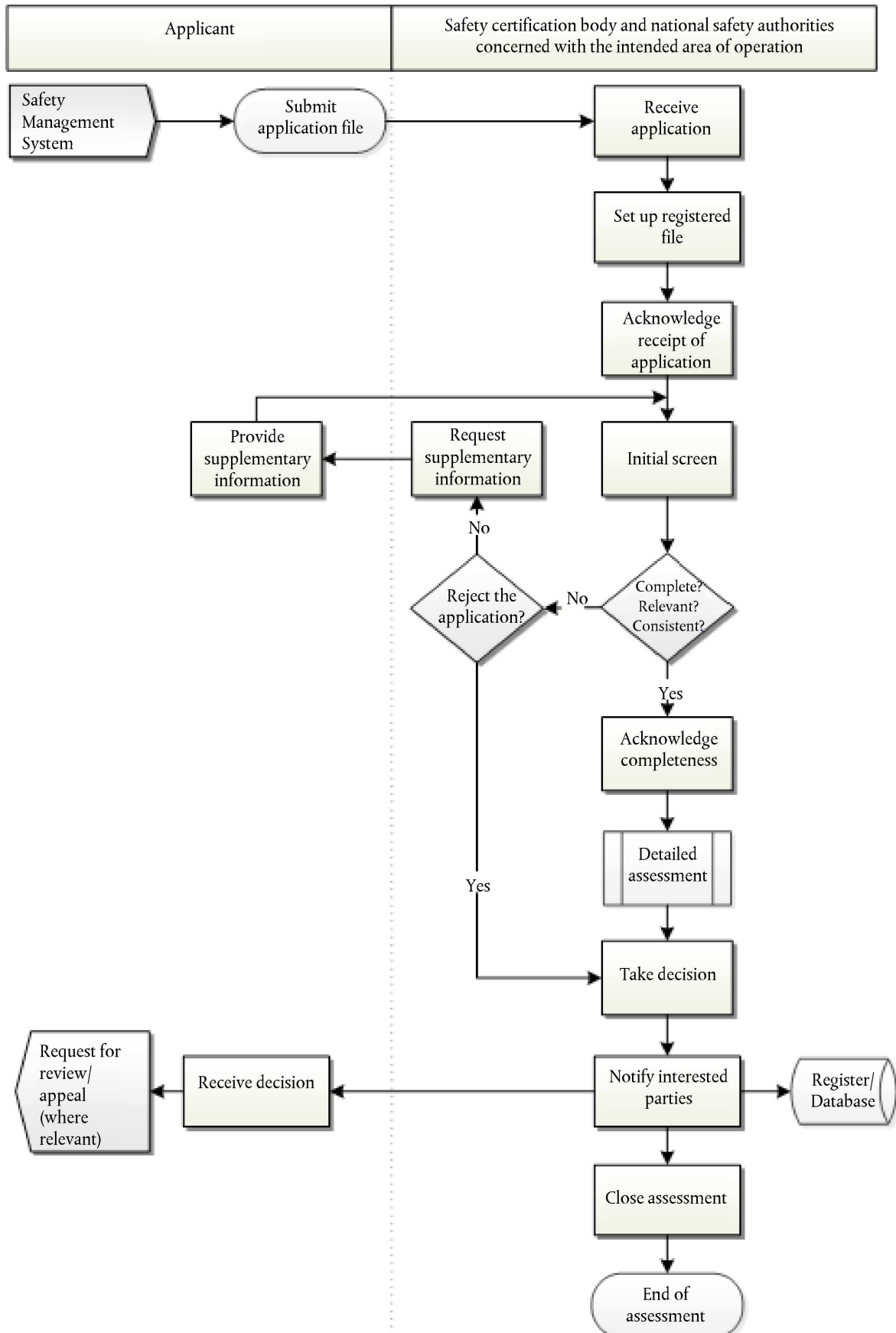
- 7.1. A single safety certificate may be renewed upon request of the applicant before the expiry of its validity to ensure continuity of certification.
- 7.2. In the case of a renewal application, the safety certification body and the national safety authorities concerned with the intended area of operation shall check details of changes to the evidence submitted in the previous application and consider the results of past supervision activities as referred to in Article 5 of Delegated Regulation (EU) 2018/761 to prioritise or target the relevant safety management system requirements and notified national rules upon which to assess the renewal application.

- 7.3. The safety certification body and the national safety authorities concerned with the intended area of operation shall take a proportionate approach to re-assessment, based on the degree of changes proposed.
8. SPECIFIC PROVISIONS FOR THE UPDATE OF A SINGLE SAFETY CERTIFICATE
- 8.1. A single safety certificate shall be updated whenever there is a substantial change proposed to the type or extent of operation in accordance with Article 10(13) of Directive (EU) 2016/798, or in case of extension of the area of operation in accordance with Article 10(14) of that Directive.
- 8.2. Where it intends to make any change referred to in point 8.1, the railway undertaking holding the single safety certificate shall notify the safety certification body without delay.
- 8.3. Following the notification by the railway undertaking as referred to in point 8.2, the safety certification body shall:
- (a) check that the change relating to any potential application is clearly described and that potential safety risks are assessed;
  - (b) discuss with the railway undertaking and the national safety authorities concerned with the intended area of operation the need for an update of the single safety certificate.
- 8.4. The safety certification body in coordination with the national safety authorities concerned with the intended area of operation may make further enquiries with the applicant. Where the safety certification body agrees that the proposed change is not substantial, it shall inform the applicant in writing that an update is not required, keeping a record of the decision for the registered file.
- 8.5. In the case of an update application, the safety certification body and the national safety authorities concerned with the intended area of operation shall:
- (a) check details of changes to the evidence submitted in the previous application upon which the current certificate was issued;
  - (b) consider the results of past supervision activities as referred to in Article 5 of Delegated Regulation (EU) 2018/761, and in particular, issues relating to the ability of the applicant to effectively implement and monitor its change management process;
  - (c) prioritise or target the relevant safety management system requirements and notified national rules in order to assess the update application.
- 8.6. The safety certification body and the national safety authorities concerned with the intended area of operation shall take a proportionate approach to re-assessment, based on the degree of changes proposed.
- 8.7. An application to the safety certification body to update a single safety certificate shall not lead to the extension of its validity period.
- 8.8. The safety certification body shall decide at the request of the applicant whether the single safety certificate needs to be updated where the conditions under which the single safety certificate was issued are to be changed without any impact on the type, extent or area of operation.
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Appendix

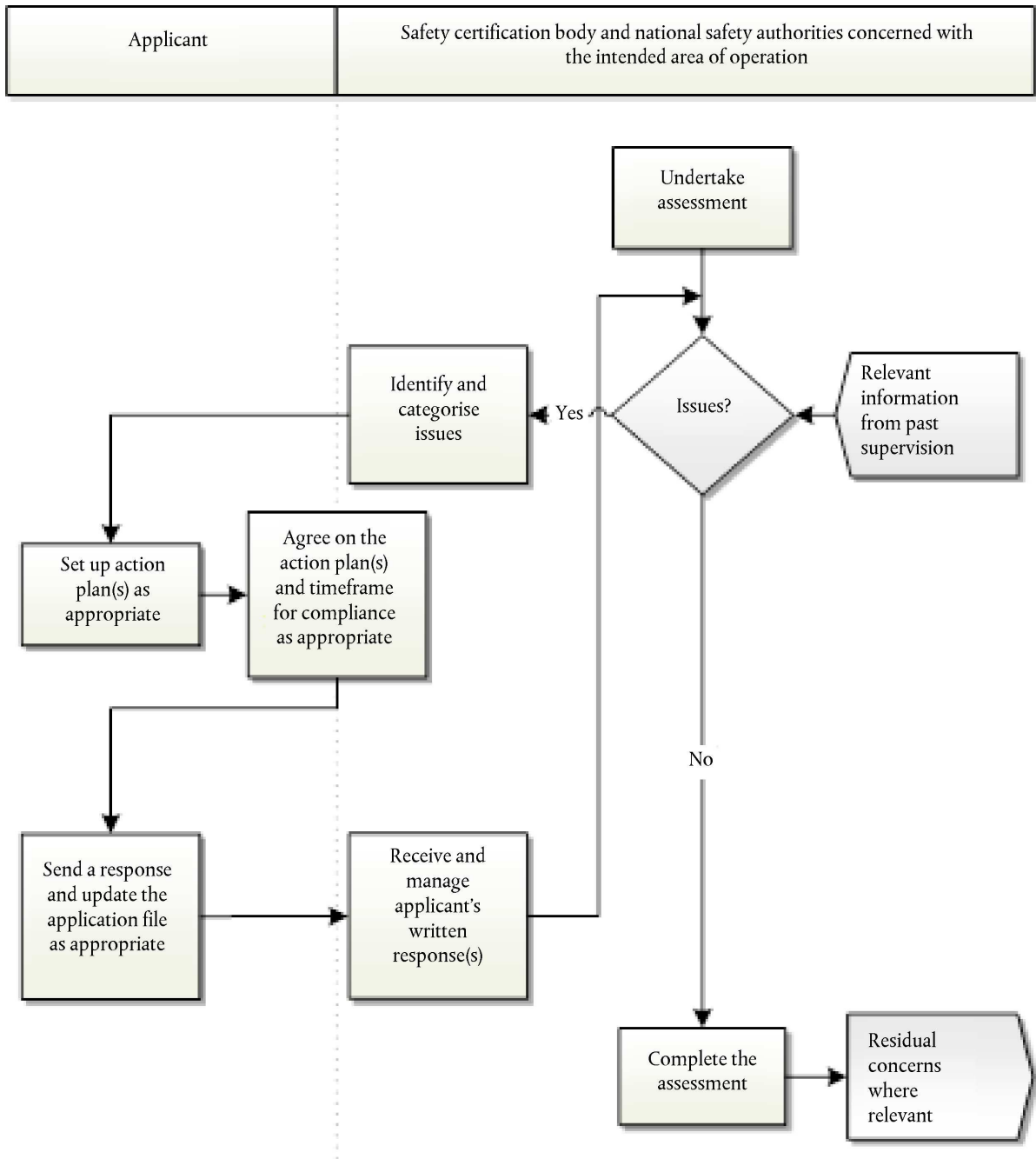
**Safety assessment process**

Figure 1: Safety assessment process.



**Detailed assessment process**

Figure 2: Detailed assessment process.



## ANNEX III

**Content of the single safety certificate**

The single safety certificate confirming acceptance of the railway undertaking's safety management system including the provisions adopted by the railway undertaking to meet specific requirements necessary for safe operation on the relevant network in conformity with Directive (EU) 2016/798 and applicable national legislation shall contain the following information:

1. **European Identification Number (EIN) of the single safety certificate**
2. **Identification of the railway undertaking:**
  - 2.1. Legal denomination
  - 2.2. National registration number
  - 2.3. VAT number
3. **Identification of the safety certification body:**
  - 3.1. Organisation
  - 3.2. Member State (where applicable)
4. **Certificate information:**
  - 4.1. New
  - 4.2. Renewal
  - 4.3. Update
  - 4.4. EIN of the previous certificate (in case of renewal or update only)
  - 4.5. Validity start and end dates
  - 4.6. Type of operation <sup>(1)</sup>
    - 4.6.1. Passenger transport including high-speed services
    - 4.6.2. Passenger transport excluding high-speed services
    - 4.6.3. Freight transport including dangerous goods services
    - 4.6.4. Freight transport excluding dangerous goods services
    - 4.6.5. Shunting only
    - 4.6.6. Other operations <sup>(1)</sup>
5. **Applicable national legislation <sup>(1)</sup>**
6. **Area of operation <sup>(1)</sup>**
7. **Restrictions and conditions of use**
8. **Additional information**
9. **Issuing date and authorised signatory/stamp of the authority**

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<sup>(1)</sup> For each Member State concerned with the intended area of operation.

**COMMISSION IMPLEMENTING REGULATION (EU) 2018/764**  
**of 2 May 2018**  
**on the fees and charges payable to the European Union Agency for Railways and their conditions**  
**of payment**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/796 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Railways and repealing Regulation (EC) No 881/2004 <sup>(1)</sup>, and in particular Article 80 thereof,

Whereas:

- (1) The revenue of the European Union Agency for Railways ('the Agency') consists of a contribution from the Union and the fees and charges paid by applicants for the processing of applications for certificates, authorisations and decisions for approval, handling of appeals and other services provided by the Agency in accordance with Article 64 of Regulation (EU) 2016/796.
- (2) The fees and charges payable to the Agency should be set in a transparent, fair and uniform manner, in particular with the objective of simplification. They should not result in the imposition of unnecessary financial burden on enterprises and should not jeopardise the competitiveness of the European railway sector.
- (3) The calculation of fees and charges should take account of the cost of staff and external experts involved in the processing of applications, where relevant. Account should equally be taken of the costs of supporting services and activities related to the processing of applications, as well as any other operational costs in order to provide those services. These costs should be related and proportionate to the relevant activities and they should be non-discriminatory.
- (4) The fees and charges levied by the Agency should cover the full costs of the services rendered by the Agency.
- (5) The time spent by the Agency to provide those services should be invoiced at an hourly rate, until the maturity of the system allows for a regime of fixed rates. The fees and charges of the Agency should be set at such a level as to avoid a deficit or a significant accumulation of surplus, in accordance with Regulation (EU) 2016/796.
- (6) The amounts payable should not depend on where the applicant is established, or the language used for the application. Therefore, the travel and translation costs incurred in relation to the part of the application processed by the Agency should be aggregated and divided among all applications.
- (7) Fees and charges should be established to meet the specific needs of small and medium-sized enterprises. Undertakings should have the possibility to split payment into several instalments if needed.
- (8) Applicants have been secured the right to appeal within the Regulation (EU) 2016/796 and should be able to seek relief and exercise this right against decisions of the Agency. The payment of the fees and charges for an appeal against decisions of the Agency should therefore not be a prerequisite for an appeal to be admissible. Fees and charges should only be levied for the processing of appeals in cases where the appeal is dismissed.
- (9) In line with good project management, the applicant should have the possibility to request an estimate. The applicant should be informed, as far as possible, of the likely amount to be paid and the way in which payment should be made. Time limits for the payment of fees and charges should be established.
- (10) Information on the fees and charges established in this Regulation should be publicly available. Any future revisions of the fees levied by the Agency should be based on a transparent evaluation of the costs of the Agency and the relevant costs resulting from the tasks carried out by the NSAs.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Committee in line with Article 81 of Regulation (EU) 2016/796,

<sup>(1)</sup> OJ L 138, 26.5.2016, p. 1.

HAS ADOPTED THIS REGULATION:

### Article 1

#### Subject matter and scope

1. This Regulation lays down the fees and charges payable to the European Union Agency for Railways ('the Agency') for the processing of applications pursuant to Articles 14, 20, 21 and 22 of Regulation (EU) 2016/796 as well as for the provision of other services in accordance with the objectives for which the Agency has been established. It also specifies the method to be used for calculating those fees and charges and conditions for payment.
2. This Regulation also establishes procedures to ensure transparency, non-discrimination and other basic principles of European law in relation to the costs of the national safety authorities ('NSAs') for processing the national part of the applications for which the Agency is responsible pursuant to Articles 14, 20, and 21 of Regulation (EU) 2016/796.
3. This Regulation shall not apply to the fees and charges levied in relation to the following activities of the NSAs:
  - (a) processing of applications for single safety certificates pursuant to Article 10(8) of Directive (EU) 2016/798 <sup>(1)</sup> and the related pre-engagement process provided for in Commission Implementing Regulation (EU) 2018/763 <sup>(2)</sup>,
  - (b) processing of applications for vehicle authorisations for placing on the market or type authorisations of vehicles pursuant to Articles 21(8) and 24(1) of Directive (EU) 2016/797 <sup>(3)</sup> and the related pre-engagement process provided for in Commission Implementing Regulation (EU) 2018/545 <sup>(4)</sup>;
  - (c) issuing an opinion on the request for ERTMS track-side equipment approval in accordance with the last sub paragraph of Article 19(3) of Directive (EU) 2016/797;
  - (d) delivering temporary authorisations for on-site tests pursuant to Article 21(3) and (5) of Directive (EU) 2016/797.

### Article 2

#### Types of fees and charges

1. The Agency shall levy fees for the processing of applications, including for the issuing of estimates and where an application is withdrawn by the applicant, or where the Agency amends a decision. The Agency may also levy fees where it revokes an earlier decision due to non-compliance of the holder of an authorisation or certification.
2. The applications referred to in paragraph 1 shall cover:
  - (a) vehicle authorisations for placing on the market and vehicle type authorisations in accordance with Article 20 and 21 of Regulation (EU) 2016/796;
  - (b) single safety certificates in accordance with Article 14 of Regulation (EU) 2016/796;
  - (c) decisions for approval of the interoperability compliance of an ERTMS track-side equipment solution with the relevant TSI in accordance with Article 22 of Regulation (EU) 2016/796;
  - (d) appeals referred to in Article 58 of Regulation (EU) 2016/796, in accordance with Article 7 of this Regulation.
3. The Agency shall levy charges for the provision of services other than those referred to in paragraph 1, requested by an applicant or any other person. In particular, it shall levy charges for the pre-engagement process provided for in Regulation (EU) 2018/545 and in Implementing Regulation (EU) 2018/763.
4. The Agency shall publish a list of services on its website.

<sup>(1)</sup> Directive (EU) 2016/798 of the European Parliament and of the Council of 11 May 2016 on railway safety (OJ L 138, 26.5.2016, p. 102).

<sup>(2)</sup> Commission Implementing Regulation (EU) 2018/763 of 9 April 2018 establishing practical arrangements for issuing single safety certificates to railway undertakings pursuant to Directive (EU) 2016/798 of the European Parliament and of the Council, and repealing Commission Regulation (EC) No 653/2007 (see page 49 of this Official Journal).

<sup>(3)</sup> Directive (EU) 2016/797 of the European Parliament and of the Council of 11 May 2016 on the interoperability of the rail system within the European Union (OJ L 138, 26.5.2016, p. 44).

<sup>(4)</sup> Commission Implementing Regulation (EU) 2018/545 of 4 April 2018 establishing practical arrangements for the railway vehicle authorisation and railway vehicle type authorisation process pursuant to Directive (EU) 2016/797 of the European Parliament and of the Council (OJ L 90, 6.4.2018, p. 66).

*Article 3***Calculation of fees and charges**

1. The amount of fees and charges shall be the total of the following:
  - (a) the number of hours spent by Agency staff and external experts, on the processing of the application multiplied by the hourly rate of the Agency; and
  - (b) the relevant costs of the NSAs resulting from the processing of the national part of the application.
2. The Agency shall apply an hourly rate of EUR 130 for the purposes of paragraph 1(a).

*Article 4***Estimates of fees and charges**

1. The Agency shall, at the request of the applicant, issue a non-binding estimate of the amount of the fees and charges related to the application or request for services and provide information on when the invoices will be issued.

The NSAs which are involved in the processing of an application shall provide a non-binding estimate of their costs as referred to in Article 3(1)(b) to the Agency to be included in the estimate issued by the Agency.

2. During the processing of an application, the Agency and the NSAs shall monitor their costs. At the request of the applicant, when costs risk exceeding the estimate by more than 15 %, the Agency shall inform the applicant thereof.
3. Where the processing of an application or a service lasts longer than one year, the applicant may request a new estimate.
4. Where the issuing of estimates and any review thereof is requested, the deadlines set by Article 19(4) and Article 21(6) of Directive (EU) 2016/797 and Article 10(6) of Directive (EU) 2016/798 may be suspended for a maximum of 10 working days.

*Article 5***Conditions of payment**

1. The Agency shall issue an invoice for the fees and charges due, within 30 calendar days of the date:
  - (a) of the decision of the Agency or Board of Appeal; or
  - (b) when the service rendered ended; or
  - (c) of withdrawal of an application; or
  - (d) of any other event leading to cessation of processing of an application.
2. The invoice shall detail:
  - (a) the number of hour spent by the Agency; and
  - (b) where relevant, the costs charged per NSA responsible. These shall be specified in relation to task and time spent or in form of fixed rates applied to the processing of the national part of the application.
3. The NSAs shall provide the Agency with a statement of costs for their contribution to be included in the invoice issued by the Agency, at the latest when the Agency requests it. The statement of costs shall detail how these costs have been calculated.
4. Payment of the fees and charges shall be denominated and payable in euro.
5. The Agency shall notify applicants of the decision and issue the invoice via the one-stop shop referred to in Article 12 of Regulation (EU) 2016/796.
6. The Agency may invoice interim amounts every 6 months.
7. Payment of the fees and charges shall be made by means of transfer to the Agency's bank account indicated for that purpose.
8. Applicants shall ensure that the Agency receives payment of the amounts due, including any bank charges related to that payment, within 60 calendar days from the date of notification of the invoice.



9. Where the applicant is a small or medium-sized enterprise, the Agency shall take into account requests for a reasonable extension of the time limit for payment and payment by instalments.

For the purposes of this Regulation, small or medium-sized enterprise means an enterprise which employs fewer than 250 persons and which has an annual turnover not exceeding EUR 50 million or an annual balance sheet total not exceeding EUR 43 million.

10. NSAs shall receive reimbursement of cost incurred for processing the national part of the applications within the deadlines referred to in paragraphs 8 and 9.

#### Article 6

##### Failure to pay

1. Where the Agency has not received the payment within the periods laid down in Article 5(8) and (9), it may charge interest for each additional calendar day until the payment is received and shall apply the recovery rules provided for in Article 80 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council <sup>(1)</sup>.

2. The interest rate shall be the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the *Official Journal of the European Union*, in force on the first calendar day of the month in which the due date falls, increased by eight percentage points.

3. Where the Agency has evidence that the applicant's financial ability is at risk, it may reject an application unless the applicant provides a bank guarantee or secured deposit.

4. The Agency may reject a new application, where the applicant has not fulfilled its payment obligations arising out of previous authorisation, certification and approval tasks or services performed by the Agency, unless the applicant pays for the outstanding amounts due for those authorisation, certification and approval tasks or services provided.

5. The Agency shall take all appropriate legal steps to ensure full payment of invoices issued. To this end, NSAs which have submitted a statement of cost for reimbursement shall support the Agency in this process.

#### Article 7

##### Appeal and fees for appeal

1. The Agency shall levy a fee in respect of any appeal which is dismissed or withdrawn.

2. The appeal fee shall be EUR 10 000 or equal to the amount of the fee charged for the decision appealed against, whichever is lower.

3. The Registrar of the Board of Appeal shall inform the appellant of the conditions of payment. The appellant shall have 30 calendar days for payment from the date of notification of the invoice.

4. An applicant may appeal against the invoiced fees and charges to the Board of Appeal.

#### Article 8

##### Publication and revision of the rates

1. The Agency shall publish its hourly rate, referred to in Article 3, on its website.

2. The NSA shall publish the rates relevant for establishing the costs charged to the Agency referred to in Article 3(1)(b). Where the NSA applies a fixed rate it shall specify to which authorisation and certification case the fixed rate will apply.

3. The website of the Agency shall contain a link to that information.

4. The Agency shall include in the annual report referred to in Article 51(1)(a) of Regulation (EU) 2016/796 information on the elements serving as a basis for the hourly rate, the financial results and the forecasts.

<sup>(1)</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

*Article 9***Procedures of the Agency**

1. In order to distinguish the revenue and expenditure from the activities subject to fees and charges referred to in Article 1(1), the Agency shall:
  - (a) receive and keep the fees and charges generated income in a separate bank account;
  - (b) annually report on the total revenue and expenditure attributable to the activities subject to fees and charges as well as the cost structure and performance.
2. If at the end of a financial year the overall revenue from fees and charges exceeds the overall cost of the activities subject to fees and charges, the excess shall be kept in a budgetary reserve and shall be used to deal with surpluses or deficits in accordance with the Agency's Financial Regulation.
3. The sustainability of income from activities subject to fees and charges shall be ensured.

*Article 10***Evaluation and revision**

1. The regime for fees and charges shall be subject to an assessment once every financial year. This assessment shall be based on the Agency's previous financial results and its estimate of expenditure and revenue. It shall also be related to the Agency's Single Programming Document.
2. The Commission shall on the basis of the assessment of financial results and forecasts of the Agency, revise fees and charges, if necessary.
3. In light of the information provided by the Agency in its annual report referred to in Article 8, this Regulation shall be reviewed at the latest by 16 June 2022 with a view to the progressive introduction of fixed fees.

*Article 11***Transitional provisions**

In the cases referred to in Article 55(4) of Regulation (EU) 2018/545 and in Article 15(4) of Implementing Regulation (EU) 2018/763, the work done before the submission of the application to the Agency shall not be covered by fees and charges in this Regulation and shall be subject to national legislation.

*Article 12***Entry into force**

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

It shall apply from 16 February 2019.

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

Done at Brussels, 2 May 2018.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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**COMMISSION IMPLEMENTING REGULATION (EU) 2018/765****of 23 May 2018****amending Implementing Regulation (EU) 2016/2080 as regards the date of entry into storage of the skimmed milk powder sold by a tendering procedure**

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 <sup>(1)</sup>,Having regard to Commission Implementing Regulation (EU) 2016/1240 of 18 May 2016 laying down rules for the application of Regulation (EU) No 1308/2013 of the European Parliament and of the Council with regard to public intervention and aid for private storage <sup>(2)</sup>, and in particular Article 28 thereof,

Whereas:

- (1) In order to define the quantities of skimmed milk powder covered by the tendering procedure opened by Commission Implementing Regulation (EU) 2016/2080 <sup>(3)</sup>, Article 1 of that Regulation lays down a time limit before which the skimmed milk powder must have entered into public storage.
- (2) Given the current situation on the milk and milk products market in terms of price recovery and the high level of intervention stocks, it is appropriate that an additional volume of skimmed milk powder is made available for sale by changing the date of entry into storage.
- (3) Implementing Regulation (EU) 2016/2080 should therefore be amended accordingly.
- (4) In order to make the skimmed milk powder available for sale without delay, this Regulation should enter into force on the day after its publication in the *Official Journal of the European Union*.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of the Agricultural Markets,

HAS ADOPTED THIS REGULATION:

*Article 1*

In Article 1 of Implementing Regulation (EU) 2016/2080, the date of 1 May 2016 is replaced by '1 June 2016'.

*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, 23 May 2018.

*For the Commission,*  
*On behalf of the President,*  
Phil HOGAN  
*Member of the Commission*

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<sup>(1)</sup> OJ L 347, 20.12.2013, p. 671.

<sup>(2)</sup> OJ L 206, 30.7.2016, p. 71.

<sup>(3)</sup> Commission Implementing Regulation (EU) 2016/2080 of 25 November 2016 opening the sale of skimmed milk powder by a tendering procedure (OJ L 321, 29.11.2016, p. 45).

**COMMISSION IMPLEMENTING REGULATION (EU) 2018/766****of 23 May 2018****amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin**

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 <sup>(1)</sup>, and in particular Article 183(b) thereof,Having regard to Regulation (EU) No 510/2014 of the European Parliament and of the Council of 16 April 2014 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products and repealing Council Regulations (EC) No 1216/2009 and (EC) No 614/2009 <sup>(2)</sup>, and in particular Article 5(6)(a) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1484/95 <sup>(3)</sup> lays down detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.
- (2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin.
- (3) Regulation (EC) No 1484/95 should therefore be amended accordingly.
- (4) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex I to Regulation (EC) No 1484/95 is replaced by the text set out 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, 23 May 2018.

*For the Commission,  
On behalf of the President,  
Jerzy PLEWA  
Director-General*

*Directorate-General for Agriculture and Rural Development*

<sup>(1)</sup> OJ L 347, 20.12.2013, p. 671.

<sup>(2)</sup> OJ L 150, 20.5.2014, p. 1.

<sup>(3)</sup> Commission Regulation (EC) No 1484/95 of 28 June 1995 laying down detailed rules for implementing the system of additional import duties and fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and repealing Regulation No 163/67/EEC (OJ L 145, 29.6.1995, p. 47).

## ANNEX

## 'ANNEX I

CN Code	Description	Representative price (EUR/100 kg)	Security under Article 3 (EUR/100 kg)	Origin <sup>(1)</sup>
0207 12 10	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as '70 % chickens', frozen	105,7	0	AR
0207 12 90	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as '65 % chickens', frozen	127,4	0	AR
		126,2	0	BR
0207 14 10	Fowls of the species <i>Gallus domesticus</i> , boneless cuts, frozen	247,1	16	AR
		242,0	17	BR
		328,9	0	CL
		239,5	18	TH
0207 27 10	Turkeys, boneless cuts, frozen	325,2	0	BR
		310,1	0	CL
0408 91 80	Eggs, not in shell, dried	475,7	0	AR
1602 32 11	Preparations of fowls of the species <i>Gallus domesticus</i> , uncooked	243,7	13	BR

<sup>(1)</sup> 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).'

# DECISIONS

## COUNCIL DECISION (EU, Euratom) 2018/767

of 22 May 2018

### fixing the period for the ninth election of representatives to the European Parliament by direct universal suffrage

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Act of 20 September 1976 concerning the election of the members of the European Parliament by direct universal suffrage <sup>(1)</sup>, and in particular the second subparagraph of Article 11(2) thereof,

Having regard to the opinion of the European Parliament <sup>(2)</sup>,

Whereas:

- (1) By its Decision 78/639/Euratom, ECSC, EEC <sup>(3)</sup>, the Council fixed the period for the first election of representatives of the European Parliament by direct universal suffrage from 7 to 10 June 1979.
- (2) It proves to be impossible to hold the ninth election during the corresponding period of 2019.
- (3) Another electoral period should therefore be determined,

HAS ADOPTED THIS DECISION:

#### *Article 1*

The period referred to in Article 10(1) of the Act of 20 September 1976 concerning the election of the members of the European Parliament by direct universal suffrage shall be from 23 to 26 May 2019 for the ninth election.

#### *Article 2*

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 22 May 2018.

*For the Council*  
*The President*  
K. VALCHEV

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<sup>(1)</sup> OJ L 278, 8.10.1976, p. 5.

<sup>(2)</sup> Opinion of 18 April 2018 (not yet published in the Official Journal).

<sup>(3)</sup> Council Decision 78/639/Euratom, ECSC, EEC of 25 July 1978 fixing the period for the first election of representatives of the European Parliament by direct universal suffrage (OJ L 205, 29.7.1978, p. 75).

**COUNCIL DECISION (EU) 2018/768****of 22 May 2018****establishing the position to be adopted, on behalf of the European Union, at the 55th session of the Committee of Experts for the Carriage of Dangerous Goods of the Intergovernmental Organisation for International Carriage by Rail as regards certain amendments to Appendix C to the Convention concerning International Carriage by Rail**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91, in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Union acceded to the Convention concerning International Carriage by Rail of 9 May 1980, as amended by the Vilnius Protocol of 3 June 1999 (the 'COTIF Convention'), by means of Council Decision 2013/103/EU <sup>(1)</sup>.
- (2) All Member States, with the exception of Cyprus and Malta, are contracting parties to and apply the COTIF Convention.
- (3) Pursuant to point (d) of Article 13(1) and Article 33(5) of the COTIF Convention, the Committee of Experts for the Carriage of Dangerous Goods (the 'RID Expert Committee') of the Intergovernmental Organisation for International Carriage by Rail (OTIF) can amend the Annex to Appendix C of the COTIF Convention, namely the Regulations concerning the International Carriage of Dangerous Goods by Rail (RID).
- (4) Directive 2008/68/EC of the European Parliament and of the Council <sup>(2)</sup> lays down provisions concerning the transport of dangerous goods by road, by rail or by inland waterway within or between Member States, by referring to the RID.
- (5) In order to adapt the Annex to the RID to technical and scientific progress, it is essential for the RID Expert Committee to adopt amendments concerning technical standards or uniform technical prescriptions. The objective of those amendments is to ensure safe and efficient transport of dangerous goods while taking into account scientific and technical progress in the sector and the development of new substances and articles that could pose a danger while being transported.
- (6) The committee on the transport of dangerous goods established by Directive 2008/68/EC has carried out preliminary discussions on proposed amendments.
- (7) The RID Expert Committee, during its 55th session on 30 May 2018, is to adopt a decision on amendments to the RID.
- (8) It is appropriate to establish the position to be adopted on the Union's behalf in the RID Expert Committee, as the decision adopted by that committee will be binding on the Union.
- (9) The position of the Union within the 55th session of the RID Expert Committee should therefore be based on the Attachment to this Decision,

HAS ADOPTED THIS DECISION:

*Article 1*

The position to be adopted on the Union's behalf within the 55th session of the RID Expert Committee in the framework of the Convention concerning International Carriage by Rail of 9 May 1980, as amended by the Vilnius Protocol of 3 June 1999, is set out in the Attachment to this Decision.

<sup>(1)</sup> Council Decision 2013/103/EU of 16 June 2011 on the signing and conclusion of the Agreement between the European Union and the Intergovernmental Organisation for International Carriage by Rail on the Accession of the European Union to the Convention concerning International Carriage by Rail (COTIF) of 9 May 1980, as amended by the Vilnius Protocol of 3 June 1999 (OJ L 51, 23.2.2013, p. 1).

<sup>(2)</sup> Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods (OJ L 260, 30.9.2008, p. 13).

Minor changes to the documents referred to in the Attachment to this Decision may be agreed to by the representatives of the Union in the RID Expert Committee without further decision of the Council.

*Article 2*

The decisions of the RID Expert Committee, once adopted, shall be published in the *Official Journal of the European Union*, indicating the date of their entry into force.

*Article 3*

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

Done at Brussels, 22 May 2018.

*For the Council*  
*The President*  
K. VALCHEV

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## ATTACHMENT

Proposal	Reference document	Issue	Comments	Union position
1	OTIF/RID/CE/GTP/2017/1	Hazard identification number for UN numbers 3166 and 3171	Technical consensus at the OTIF Standing Working Group to adopt the text as amended	Agree with the amendments
2	OTIF/RID/CE/GTP/2017/3	Carriage of dangerous goods as hand luggage or registered luggage	Technical consensus at the OTIF Standing Working Group to adopt the text as amended	Agree with the amendment
3	OTIF/RID/CE/GTP/2017/5	102nd session of WP.15 (Geneva, 8-12 May 2017)	Technical consensus at the OTIF Standing Working Group to adopt the text as amended	Agree with the amendments as revised in the Standing Working Group
4	OTIF/RID/CE/GTP/2017/7/Rev.1	Draft list of corrections 2 to the 2017 edition of RID	Technical consensus at the OTIF Standing Working Group to adopt the text as amended	Agree with the amendments as revised in the Standing Working Group
5	OTIF/RID/CE/GTP/2017/8	Informal working group on checklists for the filling and emptying of liquefied gas tank-wagons (Florence 11-13 July 2017)	Technical consensus at the OTIF Standing Working Group to adopt the text as amended	Agree with the amendments as revised in the Standing Working Group
6	OTIF/RID/CE/GTP/2017/15	Consolidated texts adopted by the Joint Meeting in 2016 and 2017 and by the RID Committee of Experts' standing working group in November 2016	Technical consensus at the OTIF Standing Working Group to adopt the text as amended	Agree with the amendments as revised in the Standing Working Group
7	Idem	Amendments left for further examination by the Standing Working Group	—	—
8	Idem	Those calling for a common view from the UNECE — OTIF Joint Meeting	Efficient multimodal transport needs to be facilitated	Agree with the amendment as recommended by the Joint Meeting
9	OTIF/RID/CE/GTP/2017/INF.8	Duplicated indents in 4.3.3.5.	Technical consensus at the OTIF Standing Working Group to adopt the text as amended	Agree with the amendments as revised in the Standing Working Group
10	OTIF/RID/CE/GTP/2017/INF.10	Transitional provisions	Technical consensus at the OTIF Standing Working Group to adopt the text as amended	Agree with the amendments as revised in the Standing Working Group
11	OTIF/RID/CE/GTP/2017/INF.12	Proposed amendment to 2.1.3.5.5 in document OTIF/RID/CE/GTP/2017/15	Technical consensus at the OTIF Standing Working Group to adopt the text as amended	Agree with the amendments as revised in the Standing Working Group
12	OTIF/RID/CE/GTP/2017/INF.16	103rd session of WP.15 (Geneva, 6-10 November 2017)	Technical consensus at the OTIF Standing Working Group to adopt the text as amended	Agree with the amendments as revised in the Standing Working Group

**COUNCIL DECISION (EU, Euratom) 2018/769****of 22 May 2018****appointing three members, proposed by the Kingdom of the Netherlands, of the European Economic and Social Committee**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 302 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 106a thereof,

Having regard to the proposal of the Government of the Netherlands,

Having regard to the opinion of the European Commission,

Whereas:

- (1) On 18 September 2015 and 1 October 2015, the Council adopted Decisions (EU, Euratom) 2015/1600 <sup>(1)</sup> and (EU, Euratom) 2015/1790 <sup>(2)</sup> appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020.
- (2) Three members' seats on the European Economic and Social Committee have become vacant following the end of the terms of office of Mr Dirk WESTENDORP, Mr Jan SIMONS and Mr Joost VAN IERSEL,

HAS ADOPTED THIS DECISION:

*Article 1*

The following are hereby appointed as members of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2020:

- Mr A.P. August MESKER, *Member Supervisory Council and Member Financial Audit Committee at Hivos*,
- Mr R.A.C. René BLIJLEVENS, *Secretary of the Foundation for Sustainable (Micro) Pensions in Developing Countries*,
- Mr T.J.M. Thom VAN MIERLO, *former senior consumer affairs officer and secretary self-regulation dialogue at the Social Economic Council*.

*Article 2*

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

Done at Brussels, 22 May 2018.

*For the Council*

*The President*

K. VALCHEV

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<sup>(1)</sup> Council Decision (EU, Euratom) 2015/1600 of 18 September 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 248, 24.9.2015, p. 53).

<sup>(2)</sup> Council Decision (EU, Euratom) 2015/1790 of 1 October 2015 appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020 (OJ L 260, 7.10.2015, p. 23).

**COUNCIL DECISION (EU) 2018/770****of 22 May 2018****appointing an alternate member, proposed by the Kingdom of Spain, of the Committee of the Regions**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Spanish Government,

Whereas:

- (1) On 26 January 2015, 5 February 2015 and 23 June 2015, the Council adopted Decisions (EU) 2015/116 <sup>(1)</sup>, (EU) 2015/190 <sup>(2)</sup> and (EU) 2015/994 <sup>(3)</sup> appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020. On 9 October 2015, by Council Decision (EU) 2015/1915 <sup>(4)</sup>, Mr Esteban MAS PORTELL was replaced by Mr Marc PONS i PONS as an alternate member. On 9 June 2016, by Council Decision (EU) 2016/991 <sup>(5)</sup>, Mr Marc PONS i PONS was replaced by Ms Pilar COSTA i SERRA as an alternate member.
- (2) An alternate member's seat on the Committee of the Regions has become vacant following the end of the term of office of Ms Pilar COSTA i SERRA as an alternate member of the Committee of the Regions,

HAS ADOPTED THIS DECISION:

*Article 1*

The following is hereby appointed as an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020:

— Mr Josep Enric CLAVEROL i FLORIT, *Director General de Relaciones Institucionales y Acción Exterior del Gobierno de las Illes Balears*.

*Article 2*

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

Done at Brussels, 22 May 2018.

*For the Council*  
*The President*  
K. VALCHEV

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<sup>(1)</sup> Council Decision (EU) 2015/116 of 26 January 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 20, 27.1.2015, p. 42).

<sup>(2)</sup> Council Decision (EU) 2015/190 of 5 February 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 31, 7.2.2015, p. 25).

<sup>(3)</sup> Council Decision (EU) 2015/994 of 23 June 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 159, 25.6.2015, p. 70).

<sup>(4)</sup> Council Decision (EU) 2015/1915 of 9 October 2015 appointing two Spanish members and three Spanish alternate members of the Committee of the Regions (OJ L 280, 24.10.2015, p. 26).

<sup>(5)</sup> Council Decision (EU) 2016/991 of 9 June 2016 appointing an alternate member, proposed by the Kingdom of Spain of the Committee of the Regions (OJ L 162, 21.6.2016, p. 14).

**COMMISSION DELEGATED DECISION (EU) 2018/771****of 25 January 2018****on the applicable system to assess and verify constancy of performance of anchor devices used for construction works and intended to prevent persons from falling from a height or to arrest falls from a height pursuant to Regulation (EU) No 305/2011 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 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC <sup>(1)</sup>, and in particular Article 28 and Article 60(h) thereof,

Whereas:

- (1) An appropriate decision for assessment and verification of constancy of performance does not exist for anchor devices used for construction works and intended to prevent persons from falling from a height or to arrest falls from a height ('anchor devices'). It is therefore necessary to establish which system of assessment and verification of constancy of performance is applicable to the anchor devices.
- (2) Taking into account that the anchor devices are intended to prevent persons from falling from a height or to arrest falls from a height, it is appropriate to choose a system of assessment and verification of constancy of performance that comprises continuing surveillance, assessment and evaluation of the manufacturer's factory production control and audit testing of samples taken by the notified product certification body at the manufacturing plant or at the manufacturer's storage facilities,

HAS ADOPTED THIS DECISION:

*Article 1*

This Decision applies to anchor devices used for construction works and intended to prevent persons from falling from a height or to arrest falls from a height.

*Article 2*

The anchor devices referred to in Article 1 shall be assessed and verified for constancy of performance in relation to their essential characteristics in accordance with the system specified in the Annex.

*Article 3*This Decision shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 25 January 2018.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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<sup>(1)</sup> OJ L 88, 4.4.2011, p. 5.

## ANNEX

**SYSTEM OF ASSESSMENT AND VERIFICATION OF CONSTANCY OF PERFORMANCE**

Products and intended use	Essential Characteristics	Applicable system
Anchor devices used for construction works and intended to prevent persons from falling from a height or to arrest falls from a height	For all essential characteristics	1+





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