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EN

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II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2016/1120

of 11 July 2016

amending Annex IV to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products ⁽¹⁾, and in particular Article 31(2) thereof,

Whereas:

- (1) Carbon Black is authorized as a colorant in cosmetics under entry 126 of Annex IV to Regulation (EC) No 1223/2009. The Scientific Committee on Consumer Safety ('SCCS') carried out a risk assessment of Carbon Black (nano) and adopted an opinion on 12 December 2013 ⁽²⁾, in which it concluded that the use of Carbon Black in its nano-structured form (with a primary particle size of 20 nm or larger) at a concentration up to 10 % w/w as a colorant in cosmetic products does not pose any risk of adverse effects in humans after application on healthy, intact skin.
- (2) Moreover, the SCCS indicated, in a further opinion of 23 September 2014 for clarification of the meaning of the term 'sprayable applications/products' for the nano forms of Carbon Black CI 77266, Titanium Dioxide and Zinc Oxide ⁽³⁾, that the opinion on Carbon Black (nano) does not apply to applications that might lead to exposure of the consumer's lungs to Carbon Black nanoparticles by inhalation.
- (3) The SCCS conclusions apply to Carbon Black (nano) with a defined purity and impurity profile. Furthermore, the purity criteria set out for non-nano Carbon Black are no longer up-to-date and should be removed, as Commission Directive 95/45/EC ⁽⁴⁾ was repealed by Directive 2008/128/EC ⁽⁵⁾. Those criteria should be replaced by the criteria applicable to Carbon Black (nano).
- (4) In light of the SCCS opinions mentioned above, the Commission considers that Carbon Black (nano) (according to the SCCS's specifications) should be authorized for use as a colorant in cosmetic products at a maximum concentration of 10 % w/w, except in applications that may lead to exposure of the end user's lungs by inhalation.
- (5) The Commission considers that Annex IV to Regulation (EC) No 1223/2009 should be amended for the purpose of adapting it to technical and scientific progress.

⁽¹⁾ OJ L 342, 22.12.2009, p. 59.

⁽²⁾ SCCS/1515/13 Revision of 15 December 2015, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_144.pdf

⁽³⁾ SCCS/1539/14 Revision of 25 June 2015, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_163.pdf

⁽⁴⁾ Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs (OJ L 226, 22.9.1995, p. 1).

⁽⁵⁾ Commission Directive 2008/128/EC of 22 December 2008 laying down specific purity criteria concerning colours for use in foodstuffs (OJ L 6, 10.1.2009, p. 20).

- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annex IV to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 11 July 2016.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Annex IV to Regulation (EC) No 1223/2009 is amended as follows:

Reference number	Substance identification					Conditions			Wording of conditions of use and warnings
	Chemical Name	Colour index Number/Name of Common Ingredients Glossary	CAS number	EC number	Colour	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i	j
'126	Carbon black	77266	1333-86-4, 7440-44-0	215-609-9, 231-153-3, 931-328-0, 931-334-3	Black			Purity > 97 %, with the following impurity profile: Ash content ≤ 0,15 %, total sulphur ≤ 0,65 %, total PAH ≤ 500 ppb and benzo(a)pyrene ≤ 5 ppb, dibenz(a,h)anthracene ≤ 5 ppb, total As ≤ 3 ppm, total Pb ≤ 10 ppm, total Hg ≤ 1 ppm.	
126a	Carbon black	77266 (nano) Carbon Black (nano)	1333-86-4, 7440-44-0	215-609-9, 231-153-3, 931-328-0, 931-334-3	Black		10 %	Not to be used in applications that may lead to exposure of the end user's lungs by inhalation. Only nanomaterials having the following characteristics are allowed: — Purity > 97 %, with the following impurity profile: Ash content ≤ 0,15 %, total sulphur ≤ 0,65 %, total PAH ≤ 500 ppb and benzo(a)pyrene ≤ 5 ppb, dibenz(a,h)anthracene ≤ 5 ppb, total As ≤ 3 ppm, total Pb ≤ 10 ppm, and total Hg ≤ 1 ppm; — Primary particle size ≥ 20 nm.'	

COMMISSION REGULATION (EU) 2016/1121
of 11 July 2016
amending Annex V to Regulation (EC) No 1223/2009 of the European Parliament and of the
Council on cosmetic products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products ⁽¹⁾, and in particular Article 31(2) thereof,

Whereas:

- (1) The substance Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride, which has been assigned the name Ethyl Lauroyl Arginate HCl under the International Nomenclature of Cosmetic Ingredients (INCI), is currently regulated in entry 197 of Annex III and in entry 58 of Annex V to Regulation (EC) No 1223/2009. Under entry 58 of Annex V, Ethyl Lauroyl Arginate HCl is allowed as a preservative in cosmetic products, except lip products, oral products and spray products, at a maximum concentration of 0,4 % w/w.
- (2) The Scientific Committee on Consumer Safety (SCCS) adopted a scientific opinion on the safety of Ethyl Lauroyl Arginate HCl in oral products on 19 September 2013 (revised on 12 December 2013) ⁽²⁾ and an addendum to that opinion on 16 December 2014 (revised on 25 March 2015) ⁽³⁾.
- (3) The SCCS concluded that Ethyl Lauroyl Arginate HCl is safe for use as a preservative in mouthwashes at a maximum concentration of 0,15 % w/w, but not in oral products in general. The SCCS also considered that the exposure estimations suggested that the acceptable daily intake for children aged 3 to 9 may be exceeded, when adding food exposure and cosmetic exposure. The SCCS thus concluded that the continuous use of Ethyl Lauroyl Arginate HCl as a preservative in mouthwashes at that concentration for children is not safe.
- (4) In light of that SCCS opinion, the Commission considers that Ethyl Lauroyl Arginate HCl should be allowed for use as a preservative up to a concentration of 0,15 % w/w in mouthwashes, except for children under the age of 10.
- (5) Regulation (EC) No 1223/2009 should therefore be amended accordingly.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Cosmetic Products,

HAS ADOPTED THIS REGULATION:

Article 1

Annex V to Regulation (EC) No 1223/2009 is amended in accordance with the Annex to this Regulation.

Article 2

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

⁽¹⁾ OJ L 342, 22.12.2009, p. 59.

⁽²⁾ SCCS/1519/13, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_138.pdf.

⁽³⁾ SCCS/1543/14, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_166.pdf.

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

Done at Brussels, 11 July 2016.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Entry 58 of Annex V to Regulation (EC) No 1223/2009 is replaced by the following:

Ref No	Substance identification				Conditions			Wording of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, Body parts	Maximum concentration in ready for use preparation	Other	
a	b	c	d	e	f	g	h	i
'58	Ethyl-N-alpha-dodecanoyl-L-arginate hydrochloride (*)	Ethyl Lauroyl Arginate HCl	60372-77-2	434-630-6	(a) Mouthwashes (b) Other products	(a) 0,15 % (b) 0,4 %	(a) Not to be used in preparations for children under 10 years of age (b) Not to be used in lip products, oral products (other than mouthwashes), and spray products	(a) Not to be used for children under 10 years of age

(*) For other uses than preservatives, see Annex III, entry No 197.'

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1122**of 11 July 2016****establishing the standard import values for determining the entry price of certain fruit and vegetables**

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 11 July 2016.

*For the Commission,
On behalf of the President,
Jerzy PLEWA*

Director-General for Agriculture and Rural Development

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ L 157, 15.6.2011, p. 1.

ANNEX

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

(EUR/100 kg)			
CN code	Third country code ⁽¹⁾	Standard import value	
0702 00 00	MA	168,9	
	ZZ	168,9	
0709 93 10	TR	136,8	
	ZZ	136,8	
0805 50 10	AR	179,4	
	BO	217,8	
	CL	185,5	
	TR	134,0	
	UY	192,8	
	ZA	148,0	
	ZZ	176,3	
	0808 10 80	AR	154,8
		BR	97,4
CL		126,7	
CN		102,6	
NZ		145,5	
ZA		316,8	
ZZ		157,3	
0808 30 90		AR	129,1
		CL	128,1
	CN	91,9	
	NZ	154,1	
	ZA	118,2	
	ZZ	124,3	
	0809 10 00	TR	206,7
ZZ		206,7	
0809 29 00	TR	321,0	
	ZZ	321,0	

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

DECISIONS

COUNCIL DECISION (EU) 2016/1123

of 17 June 2016

establishing the position to be adopted on behalf of the European Union within the relevant Committees of the United Nations Economic Commission for Europe as regards the proposals for amendments to UN Regulations Nos 9, 11, 13, 13-H, 14, 16, 30, 41, 44, 49, 54, 55, 60, 64, 75, 78, 79, 83, 90, 106, 113, 115, 117, 129 and 134, the proposals for amendments to UN Global Technical Regulations Nos 15 and 16, the proposals for new UN Regulations on Brake Assist Systems (BAS), on Electronic Stability Control (ESC), on Tyre Pressure Monitoring Systems (TPMS) and on Tyre Installation, the proposal for a new UN Global Technical Regulation on the measurement procedure for emissions of two- or three-wheeled motor vehicles and the proposal for a new Special Resolution No 2 (S.R.2) for improving the implementation of the 1998 Global Agreement

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114, in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) In accordance with Council Decision 97/836/EC ⁽¹⁾, the Union acceded to the Agreement of the United Nations Economic Commission for Europe (UNECE) concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions (the 'Revised 1958 Agreement').
- (2) In accordance with Council Decision 2000/125/EC ⁽²⁾, the Union acceded to the Agreement concerning the establishing of global technical regulations for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles (the 'Parallel Agreement').
- (3) Directive 2007/46/EC of the European Parliament and of the Council ⁽³⁾ replaced the approval systems of the Member States with a Union approval procedure and established a harmonised framework containing administrative provisions and general technical requirements for all new vehicles, systems, components and separate technical units. That Directive incorporated regulations adopted under the Revised 1958 Agreement (hereinafter referred to as 'UN Regulations') in the EU type-approval system, either as requirements for type-approval or as alternatives to Union legislation. Since the adoption of that Directive, UN Regulations have increasingly been incorporated into Union legislation in the framework of the EU type-approval.
- (4) In the light of experience and technical developments, the requirements relating to certain elements or features covered by UN Regulations Nos. 9, 11, 13, 13-H, 14, 16, 30, 41, 44, 49, 54, 55, 60, 64, 75, 78, 79, 83, 90, 106, 113, 115, 117, 129 and 134, as well as by UN Global Technical Regulations (GTR) Nos. 15 and 16, need to be adapted to technical progress.
- (5) In order to lay down uniform provisions concerning the approval of Brake Assist Systems (BAS), Electronic Stability Control (ESC), Tyre Pressure Monitoring Systems (TPMS) and Tyre Installation, four new UN Regulations should be adopted.

⁽¹⁾ Council Decision 97/836/EC of 27 November 1997 with a view to accession by the European Community to the Agreement of the United Nations Economic Commission for Europe concerning the adoption of uniform technical prescriptions for wheeled vehicles, equipment and parts which can be fitted to and/or be used on wheeled vehicles and the conditions for reciprocal recognition of approvals granted on the basis of these prescriptions ('Revised 1958 Agreement') (OJ L 346, 17.12.1997, p. 78).

⁽²⁾ Council Decision 2000/125/EC of 31 January 2000 concerning the conclusion of the Agreement concerning the establishing of global technical regulations for wheeled vehicles, equipment and parts which can be fitted and/or be used on wheeled vehicles ('Parallel Agreement') (OJ L 35, 10.2.2000, p. 12).

⁽³⁾ Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263, 9.10.2007, p. 1).

- (6) In order to lay down uniform technical provisions concerning the measurement procedure for two- or three-wheeled motor vehicles with regard to certain types of emissions, a new UN Global Technical Regulation (GTR) should be adopted.
- (7) In order to improve the implementation of the 1998 Global Agreement, a new Special Resolution No 2 (S.R.2) should be adopted.
- (8) It is appropriate to establish the position to be adopted on behalf of the Union within the relevant Committees of the UNECE, namely the Administrative Committee of the Revised 1958 Agreement and the Executive Committee of the Parallel Agreement, as regards the adoption of the UN acts referred to above,

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on behalf of the Union within the Administrative Committee of the Revised 1958 Agreement and the Executive Committee of the Parallel Agreement during the period from 20 to 24 June 2016 shall be to vote in favour of the proposals listed in the Annex to this Decision.

Article 2

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

Done at Luxembourg, 17 June 2016.

For the Council
The President
J.R.V.A. DIJSSELBLOEM

ANNEX

Agenda item title	Document reference
Proposal for Supplement 2 to the 07 series of amendments to UN Regulation No 9 (Noise of three-wheeled vehicles)	ECE/TRANS/WP.29/2016/45
Proposal for Supplement 4 to the 03 series of amendments to UN Regulation No 11 (Door latches and hinges)	ECE/TRANS/WP.29/2016/33
Proposal for Supplement 1 to the 04 series of amendments to UN Regulation No 11 (Door latches and hinges)	ECE/TRANS/WP.29/2016/34
Proposal for Supplement 14 to the 11 series of amendments to UN Regulation No 13 (Heavy vehicle braking)	ECE/TRANS/WP.29/2016/49
Proposal for the 01 series of amendments to UN Regulation No 13-H (Brakes of M1 and N1 vehicles)	ECE/TRANS/WP.29/2016/50
Proposal for Supplement 7 to the 07 series of amendments to UN Regulation No 14 (Safety-belt, ISOFIX and i-Size anchorages)	ECE/TRANS/WP.29/2016/35
Proposal for Supplement 7 to the 06 series of amendments to UN Regulation No 16 (Safety-belts, ISOFIX and i-Size)	ECE/TRANS/WP.29/2016/36
Proposal for Supplement 18 to the 02 series of amendments to UN Regulation No 30 (Tyres for passenger cars and their trailers)	ECE/TRANS/WP.29/2016/51
Proposal for Supplement 5 to the 04 series of amendments to UN Regulation No 41 (Noise emissions of motorcycles)	ECE/TRANS/WP.29/2016/46
Proposal for Supplement 11 to the 04 series of amendments to UN Regulation No 44 (Child restraint systems)	ECE/TRANS/WP.29/2016/37
Proposal for Supplement 8 to the 05 series of amendments to UN Regulation No 49 (Emissions of compression ignition and positive ignition (LPG and CNG) engines)	ECE/TRANS/WP.29/2016/40
Proposal for Supplement 4 to the 06 series of amendments to UN Regulation No 49 (Emissions of compression ignition and positive ignition (LPG and CNG) engines)	ECE/TRANS/WP.29/2016/41
Proposal for Supplement 21 to the 01 series of amendments to UN Regulation No 54 (Tyres for commercial vehicles and their trailers)	ECE/TRANS/WP.29/2016/52
Proposal for Supplement 6 to the 01 series of amendments to UN Regulation No 55 (Mechanical couplings)	ECE/TRANS/WP.29/2016/53
Proposal for Supplement 5 to UN Regulation No 60 (Driver operated controls (mopeds/motorcycles))	ECE/TRANS/WP.29/2016/27
Proposal for a new 03 series of amendments to UN Regulation No 64 (Temporary use spare unit, run flat tyres, run flat-system and tyre pressure monitoring system)	ECE/TRANS/WP.29/2016/54
Proposal for Supplement 16 to UN Regulation No 75 (Tyres for L-category vehicles)	ECE/TRANS/WP.29/2016/55

Agenda item title	Document reference
Proposal for Supplement 3 to the 03 series of amendments to UN Regulation No 78 (Braking (category L vehicles))	ECE/TRANS/WP.29/2016/56 and WP.29-169-03
Proposal for Supplement 5 to the 01 series of amendments to UN Regulation No 79 (Steering equipment)	ECE/TRANS/WP.29/2016/57
Proposal for Supplement 7 to the 06 series of amendments to UN Regulation No 83 (Emissions of M1 and N1 vehicles)	ECE/TRANS/WP.29/2016/42
Proposal for Supplement 3 to the 07 series of amendments to UN Regulation No 83 (Emissions of M1 and N1 vehicles)	ECE/TRANS/WP.29/2016/43
Proposal for Supplement 3 to the 02 series of amendments to UN Regulation No 90 (Replacement braking parts)	ECE/TRANS/WP.29/2016/58
Proposal for Supplement 14 to UN Regulation No 106 (Tyres for agricultural vehicles)	ECE/TRANS/WP.29/2016/59
Proposal for Supplement 6 to the 01 series of amendments to UN Regulation No 113 (Headlamps emitting a symmetrical passing-beam)	ECE/TRANS/WP.29/2016/74
Proposal for Supplement 7 to the original version of UN Regulation No 115 (LPG and CNG retrofit systems)	ECE/TRANS/WP.29/2016/44
Proposal for Supplement 9 to the 02 series of amendments to UN Regulation No 117 (Tyres, rolling resistance, rolling noise and wet grip)	ECE/TRANS/WP.29/2016/60
Proposal for 01 series of amendments to UN Regulation No 129 (Enhanced Child Restraint Systems (ECRS))	ECE/TRANS/WP.29/2016/38
Proposal for Supplement 2 to Supplement 2 to UN Regulation No 134 (Hydrogen and fuel cells vehicles (HFCV))	ECE/TRANS/WP.29/2016/39
Proposal for a new UN Regulation on Brake Assist Systems (BAS)	ECE/TRANS/WP.29/2016/61
Proposal for a new UN Regulation on Electronic Stability Control (ESC)	ECE/TRANS/WP.29/2016/62
Proposal for a new UN Regulation on Tyre Pressure Monitoring Systems (TPMS)	ECE/TRANS/WP.29/2016/63
Proposal for a new UN Regulation on Tyre Installation	ECE/TRANS/WP.29/2016/64
Proposal for Amendment 1 to global technical regulation (UN GTR) No 15 (World-wide harmonized Light vehicles Test Procedures (WLTP))	ECE/TRANS/WP.29/2016/68
Proposal for Amendment 1 to global technical regulation (UN GTR) No 16 (Tyres)	ECE/TRANS/WP.29/2016/70
Proposal for new Special Resolution No 2 (S.R.2) — Improvement in the implementation of the 1998 Global Agreement	ECE/TRANS/WP.29/2016/65
Proposal for a Global Technical Regulation (UN GTR) on the measurement procedure for two- or three-wheeled motor vehicles equipped with a combustion engine with regard to the crankcase and evaporative emissions	ECE/TRANS/WP.29/2016/66

COUNCIL DECISION (EU) 2016/1124**of 24 June 2016****on the position to be taken by the Member States on behalf of the European Union within the Permanent Commission of Eurocontrol as regards the decisions to be adopted on centralised services**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 100(2) in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) Council Decision (EU) 2015/2394 ⁽¹⁾ established a Union position in respect of a decision on centralised services that was planned to be taken by the Permanent Commission of Eurocontrol ('the Permanent Commission') on 9 December 2015. The purpose of that decision on centralised services was to allow Eurocontrol to develop financing, procurement arrangements and technical specifications with a view to timely deploying a new 'European Air/Ground Data Communication Services' ('EAGDCS').
- (2) The position established in Decision (EU) 2015/2394 was that a decision on centralised services by the Permanent Commission had to be postponed because the Union was not in possession of sufficient information to evaluate the substance of such decision on centralised services and because it could have prejudged future activity conducted by Eurocontrol in a manner that would have been detrimental to the Union's activity in that field.
- (3) On 9 December 2015, due to the Union's position established in Decision (EU) 2015/2394, the Permanent Commission did not take a decision on EAGDCS and asked the Eurocontrol Agency to continue working on a revised proposal in close cooperation with the industry stakeholders and to provide an assessment of the economic costs of EAGDCS.
- (4) The Eurocontrol Agency and industry stakeholders presented on 9 February 2016 a revised and commonly supported proposal on EAGDCS, and the Eurocontrol Agency ensured the full availability of the assessment of economic costs through existing feasibility studies.
- (5) The Eurocontrol Agency proposed on 6 April 2016 to the Permanent Commission to adopt the decision based on the proposal on EAGDCS in a written procedure.
- (6) That decision concerns the development of EAGDCS. It has legal effects since it governs areas covered by Union law and, depending on its content, may have concrete effects on those areas. It may affect the benefits flowing from the technical work on data link services performed by the SESAR Joint Undertaking, the risk of mismatches in the area of certification and oversight, given the role of the European Aviation Safety Agency ('EASA') in that area, and thus the risk of ineffective spending of funds stemming from route charges and Union support, as well as the cost-efficiency of relevant deployment activities to be conducted by the Union in the context of the SESAR project.
- (7) Given the advantages that can be expected from the development of technical solutions, such as a demonstrator, the decision favouring the relevant collaboration should be supported in principle. However, the decision should contain conditions safeguarding the Union's interests on the points referred to above.
- (8) It is appropriate to establish the position to be taken by the Member States on the Union's behalf within the Permanent Commission with regard to the decisions on centralised services to be adopted by that Commission,

⁽¹⁾ Council Decision (EU) 2015/2394 of 8 December 2015 on the position to be taken by the Member States on behalf of the European Union, concerning the decisions to be adopted by the Permanent Commission of Eurocontrol, with regard to the roles and tasks of Eurocontrol and on centralised services (OJ L 332, 18.12.2015, p. 136).

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken by the Member States on behalf of the Union within the Permanent Commission of Eurocontrol shall be the following:

as regards the proposal of 6 April 2016 sent out by the Eurocontrol Agency, the Union's position is to support the Eurocontrol Agency's continued collaboration with Air Navigation Service Providers and, where appropriate, with aircraft operators of the Member States of Eurocontrol in the context of the SESAR project, including the development of the necessary Governance, Financing and Procurement arrangements, and to develop technical specifications with a view to timely deploying the European Air/Ground Data Communication Services (EAGDCS). The above arrangements and technical solutions will be submitted to the Provisional Council/Permanent Commission for information and before proceeding to any possible procurement. This should also be based on evidence of the technical and operational feasibility and the development of a comprehensive economic impact assessment.

The decision to be adopted within the Permanent Commission shall ensure that:

- the outcome of the technical work on data link performed by the SESAR Joint Undertaking is fully taken into account,
- the activities covered by that decision are conducted in cooperation with EASA in so far as that decision concerns EASA's preparatory work for future certification and oversight of EAGDCS,
- it remains without prejudice to the deployment and operation of EAGDCS, as well as the procurement thereof, which shall be subject to further decisions by the Member States of the Eurocontrol,
- the activities covered by that decision are based on agreement with Air Navigation Service Providers, and
- financing and procurement arrangements, as well as technical specifications remain without prejudice to any investment and associated costs already incurred by the Union Member State Air Navigation Service Providers and aircraft operators in compliance with the requirements of Commission Regulation (EC) No 29/2009 ⁽¹⁾.

The Member States shall act jointly in the interest of the Union.

Article 2

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

Done at Luxembourg, 24 June 2016.

For the Council
The President
A.G. KOENDERS

⁽¹⁾ Commission Regulation (EC) No 29/2009 of 16 January 2009 laying down requirements on data link services for the single European sky (OJ L 13, 17.1.2009, p. 3).

COUNCIL DECISION (EU, Euratom) 2016/1125**of 8 July 2016****appointing a member, proposed by the Portuguese Republic, 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 Portuguese Government,

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 ⁽¹⁾ and (EU, Euratom) 2015/1790 ⁽²⁾ appointing the members of the European Economic and Social Committee for the period from 21 September 2015 to 20 September 2020.
- (2) A member's seat on the European Economic and Social Committee has become vacant following the end of the term of office of Mr Lino DA SILVA MAIA,

HAS ADOPTED THIS DECISION:

Article 1

Mr José Custódio LEIRIÃO, *Member of the National Confederation of Solidarity Institutions (CNIS)*, is hereby appointed as a member of the European Economic and Social Committee for the remainder of the current term of office, which runs until 20 September 2020.

Article 2

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

Done at Brussels, 8 July 2016.

For the Council
The President
M. LAJČÁK

⁽¹⁾ 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).

⁽²⁾ 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).

COMMISSION DECISION (EU) 2016/1126**of 4 April 2016****on State aid SA. 35484 (2013/C) (ex SA. 35484 (2012/NN)) regarding general healthcare control activities pursuant to the Milk and Fat Law***(notified under document C(2016) 1878)***(Only the German text is authentic)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 108(2) thereof,

Having called on interested parties to submit their observations pursuant to the provision cited above ⁽¹⁾ and having regard to their comments,

Whereas:

1. PROCEDURE

- (1) By letters dated 28 November 2011 and 27 February 2012, the European Commission (hereinafter: 'the Commission') asked Germany for additional information concerning the 2010 Annual Report on State aid in the agricultural sector which Germany had submitted in accordance with Article 26 of Council Regulation (EU) 2015/1589 ⁽²⁾. Germany answered the Commission's questions by letters dated 16 January 2012 and 27 April 2012. In the light of Germany's answers, it emerged that Germany had granted financial support to the German dairy sector pursuant to the 1952 Milk and Fat Law (*Gesetz über den Verkehr mit Milch, Milcherzeugnissen und Fetten*, hereinafter: 'the MFG').
- (2) By letter dated 2 October 2012, the Commission informed Germany that the measures in question had been registered as non-notified aid under the number SA.35484 (2012/NN). By letters dated 16 November 2012, 7, 8, 11, 13, 14, 15 and 19 February, 21 March, 8 April, 28 May, 10 and 25 June and 2 July 2013, Germany submitted further information.
- (3) By letter of 17 July 2013 (C(2013) 4457 final) the Commission informed Germany that it had decided to initiate with regard to certain sub-measures under the MFG the procedure laid down in Article 108(2) of the Treaty of Functioning of the European Union (TFEU) ⁽³⁾ (hereinafter: 'the opening Decision'). In the same letter, the Commission came to the conclusion that other sub-measures were compatible with the internal market, either during the period from 28 November 2001 to 31 December 2006 or in the period starting 1 January 2007 or in both periods, or that further sub-measures did not constitute State aid within the meaning of Article 107(1) TFEU or that they fell outside the scope of State aid rules.
- (4) As regards the sub-measures that are subject to the current Decision, namely the general healthcare control sub-measures referred by the opening Decision as contaminant monitoring sub-measures ⁽⁴⁾, BW 9, BY 5, HE 8, NI 2, NW 1, RP 3, SL 4 and TH 8 (hereinafter 'the sub-measures') the Commission stated that those sub-measures appeared to have all the characteristics of State aid and requested Germany to submit its comments and to provide all information which may be helpful for the assessment of the aid concerning the period from 28 November 2001.

⁽¹⁾ OJ C 7, 10.1.2014, p. 8.

⁽²⁾ Council Regulation (EU) 2015/1589 of 13 July 2015 laying down detailed rules for the application of Article 108 of the Treaty on the Functioning of the European Union (OJ L 248, 24.9.2015, p. 9).

⁽³⁾ With effect from 1 December 2009, Articles 87 and 88 of the EC Treaty have become Articles 107 and 108, respectively, of the Treaty on the Functioning of the European Union ('TFEU'). The two sets of provisions are, in substance, identical. For the purposes of this Decision, references to Articles 87 and 88 of the EC Treaty should be understood as references to Articles 107 and 108 of the TFEU where appropriate. The TFEU also introduced certain changes in terminology, such as the replacement of 'Community' by 'Union' and 'common market' by 'internal market'. The terminology of the TFEU will be used throughout this Decision.

⁽⁴⁾ Although the short description of measures BW9 and RP3 in the annex to the opening Decision also refers to other quality controls, it became clear from the further information submitted by Germany, that these measure only cover contaminants monitoring, subject to the present decision, and not other quality controls.

- (5) By letter dated 20 September 2013, Germany submitted comments concerning the opening Decision.
- (6) The opening Decision was published in the *Official Journal of the European Union* ⁽¹⁾. The Commission invited interested parties to submit their comments within one month. The Commission received 10 comments from interested parties on the sub-measures referred to in recital 4. Those comments received were transmitted to Germany by letters of 27 February, 3 March and 3 October 2014. Germany did not respond to those comments.

2. DESCRIPTION OF THE SCHEME

- (7) The MFG is a German Federal law which entered into force in 1952. It constitutes the legal framework of the sub-measures, and its validity is unlimited in time.
- (8) Section 22(1) of the MFG authorises the German Federal States (hereinafter: '*Länder*') to impose a milk levy on dairies based on the quantities of delivered milk.
- (9) Section 22(2) of the MFG provides that the revenues obtained from the milk levy may be used solely for:
- (a) improving and sustaining quality on the basis of certain implementing provisions;
 - (b) improving hygiene during milking and the delivery, processing and distribution of milk and milk products;
 - (c) milk yield recording;
 - (d) advice to operators on matters relating to the dairy industry and ongoing training of young employees;
 - (e) advertising aimed at increasing the consumption of milk and milk products;
 - (f) performance of the tasks conferred by the MFG.
- (10) Section 22(2a) of the MFG provides that, by derogation from paragraph 2, the revenues obtained from the milk levy may also be used for:
- (a) reducing increased structural collection costs in respect of the supply of milk and cream from the producer to the dairy;
 - (b) reducing increased transport costs in respect of the supply of milk between dairies where such supply is necessary to ensure the supply of drinking milk to the recipient dairy's sales area; and
 - (c) improving quality regarding the central distribution of milk products.
- (11) In the following *Länder*: Baden-Württemberg, Bayern, Hessen, Niedersachsen, Nordrhein-Westfalen, Rheinland-Pfalz, Saarland and Thüringen the milk levy was used to finance the sub-measures referred to in recital 4.
- (12) The sub-measures include controls of different contaminants in milk and milk products such as dioxin, polychlorobiphenyls (PCBs), aflatoxin, detergents, pesticides, polychlorinated hydrogen that can be harmful for human health. The controls were carried out by special control bodies to which these tasks were assigned by the responsible public authorities in the *Länder* where the sub-measures were carried out. The control samples were taken from the milk transportation vehicles at random basis and anonymously. The objective of the controls was to survey the presence of the contaminants in the milk with a view to preventing human health risks and protecting consumers. These activities are referred to in this Decision as 'contaminants monitoring'. Between 2001 and 2011, the total budget of those activities (all *Länder* where the sub-measures were carried out compounded) amounted to around EUR 9 million.

⁽¹⁾ OJ C 7, 10.1.2014, p. 8.

- (13) According to the assessment undertaken by the Commission in the opening Decision Germany failed to present the provisions of national or Union law which would justify the classification of the contaminants monitoring as a non-aid. In addition, the Commission had doubts on whether the sub-measures did not confer an advantage to the dairies as the Commission considered that the controls seek to ensure milk product quality and therefore the costs incurred for carrying out such controls have to be typically borne by the dairy undertakings concerned. Moreover, the Commission raised the concern that the quality controls at stake are carried out on a routine basis.

3. COMMENTS FROM GERMANY

- (14) Germany described the legal basis for the contaminants monitoring. There were two sets of rules. The first set of legal provisions regulated the execution of the controls in the framework of the contaminants monitoring. This included the methodological preparation and the establishment of controls schedule, the way of sampling, the testing method, and the use of the results. These activities were substantially governed by the food safety law.
- (15) The second set of legal provisions concerned the financing of those activities. As already explained in the 'opening Decision' those activities were financed by the milk levy paid by the dairies. The legal basis was Section 22(2) of the MFG. Additional implementing provisions existed at regional level including budgetary rules.
- (16) Germany presented an overview of the applicable food safety law:
- (a) At Union level: The official food safety control was regulated in the following legal acts: Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽¹⁾, Regulation (EC) No 882/2004 of the European Parliament and of the Council ⁽²⁾, Regulation (EC) No 854/2004 of the European Parliament and of the Council ⁽³⁾, in particular Annex IV thereof, Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽⁴⁾, in particular Annex I, part A thereof, Commission Regulation (EC) No 1881/2006 ⁽⁵⁾, Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽⁶⁾. The monitoring of residues or substances was regulated in Council Directive 96/23/EC ⁽⁷⁾ and Commission Decision 97/747/EC ⁽⁸⁾.
- (b) At national level: The official food safety control and monitoring of residues or substances were regulated in the Food and Feed Safety Law (*Lebensmittel- und Futtermittelgesetzbuch*), the Administrative ordinance on the principles of execution of the official food and feed safety controls (*Allgemeine Verwaltungsvorschrift über die Grundsätze zur Durchführung der amtlichen Überwachung der Erhaltung lebensmittelrechtlicher, weinrechtlicher, futtermittelrechtlicher und tabakrechtlicher Vorschriften*) and the Regulation on limitation of contaminants in food (*Verordnung zur Begrenzung von Kontaminanten in Lebensmittel*), the national residues control plan (*Nationaler Rückstandskontrollplan*).
- (c) In addition to those food safety official controls the contaminants monitoring was performed, based on the following provisions of Union and national law: Regulation (EC) No 178/2002, Regulation (EC) No 882/2004 and Commission Recommendation 2011/516/EU ⁽⁹⁾, Section 14 MFG, Sections 50 and 51 of the Food and Feed Safety Law and the annually issued regional (*Länder*) provisions approving the contaminants monitoring exercise and its financing.

⁽¹⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

⁽²⁾ Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (OJ L 165, 30.4.2004, p. 1).

⁽³⁾ Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (OJ L 139, 30.4.2004, p. 206).

⁽⁴⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

⁽⁵⁾ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

⁽⁶⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

⁽⁷⁾ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (OJ L 125, 23.5.1996, p. 10).

⁽⁸⁾ Commission Decision 97/747/EC of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products (OJ L 303, 6.11.1997, p. 12).

⁽⁹⁾ Commission Recommendation 2011/516/EU of 23 August 2011 on the reduction of the presence of dioxins, furans and PCBs in feed and food (OJ L 218, 24.8.2011, p. 23).

- (17) Germany presented statistics on the food safety official controls, the residues controls and the contaminants monitoring as well as a list of the bodies responsible for those controls.

3.1. Comments from Germany concerning the character of the contaminants monitoring as an additional component to the official food safety surveillance system

- (18) The main comment put forward by Germany was that the contaminants monitoring is an additional component to the official food safety surveillance system and does not confer any advantage to the dairies. In this regards, Germany explained the following:
- (19) The contaminants monitoring qualified as an additional component to the official food safety surveillance system which was based on Union and national law and served the preventive and healthcare oriented consumer protection as well as the risk based crises management.
- (20) The contaminants monitoring could not be qualified as routine control. The controls under the contaminants monitoring were executed on the basis of samples after the milk is collected by the milk transportation vehicles. The sampling schedule was developed by specially control bodies to which this task is assigned officially. The assigned bodies determined from which vehicles and when the samples will be taken and what will be the duration of the controls. The assigned bodies also determined the contaminants to be analysed.
- (21) When determining the control schedule and the contaminants subject to analyse the assigned bodies based themselves on previous analyses, on results gathered beforehand, on existent health and food safety risks, on regional particularities, on environmental factors, incidents and other similar reasons. The control schedule and the contaminants could vary depending on the region and can periodically be changed. Not all contaminants for which legal limits exist were controlled. On the other hand, other contaminants that are not subject to legal limits but are considered, based on analyses, to bear health risk could be controlled. Controls focussed therefore on different priorities over time — in some cases the controls of radioactive contaminants preceded, in other cases the controls on aflatoxin or dioxin; it was also possible to carry out the controls in accordance with regional priorities.
- (22) The information obtained in the course of these controls was used to determine the status of a given milk region with respect to its exposure to given contaminants that have health risk effects. This information was further used by the competent public authorities to take preventive health measures in the form of official food safety and health controls, legislative measures, dissemination of information and others. This type of control fell under the system of 'official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution' referred to in Article 17(2) of Regulation (EC) No 178/2002.
- (23) In particular, the information obtained from the controls was used to adjust the official control plans pursuant to Regulation (EC) No 882/2004. In general, Regulation (EC) No 178/2002 requested Member States to base the food safety measures on a risk assessment using objective, transparent and independent scientific information and data. This requirement was further specified in Regulation (EC) No 852/2004 and Regulation (EC) No 854/2004. The results obtained from the contaminants monitoring were used by the competent German food safety authorities as a basis for such risk assessment and measures.
- (24) In accordance with Article 17(2) of Regulation (EC) No 178/2002, Member States were obliged to maintain other activities as appropriate to the circumstances to guarantee food safety alongside the system of official controls. Although those activities were not concretely listed in that provision Germany argued that the Member States bodies that maintain such appropriate control activities in addition to the official controls did not violate State aid rules. Based on this approach, Germany argued that the contaminants monitoring represented a control which is complementary to the food safety official control.
- (25) The same approach was followed in other Union legal acts in the field of food safety. The first paragraph of Article 3 of Regulation (EC) No 882/2004 provided for the execution of regular official controls and the

second paragraph of that Article envisaged the execution of additional official ad hoc controls; those controls had to be risk based. Also Directive 96/23/EC followed this structure: Article 11 thereof provided for complementary official sample tests in addition to the regular official tests. Further on, the Commission Recommendation on the reduction of the presence of dioxins, furans and PCBs in feed and food sets out action levels that were below the legal limits set out in Regulation (EC) No 1881/2006 and served a tool for competent authorities and operators to detect cases where it was appropriate to identify a source of contamination and to take measures for its reduction or elimination.

- (26) Furthermore, Union legislation aiming at ensuring a high level of protection of human health and consumers' interests in relation to food (Article 1 of Regulation (EC) No 178/2002) provided that the food safety measures had to be justified by independent, objective and transparent risk assessments on the basis of the existing scientific data. The results of the contaminants monitoring were used as a basis to comply with those principles as further specified in Regulation (EC) No 852/2004 and Regulation (EC) No 854/2004. In addition, as regards the dioxin and PCB controls Germany refers to Commission Recommendation on the reduction of the presence of dioxins, furans and PCBs in feed and food.
- (27) Moreover, the results of the controls were also used to identify long-term trends, to analyse the risk factors and reasons and to maintain databases for scientific and crisis preventive purposes. The gathered information was a useful source for further reaching political and administrative decisions for case studies and dissemination of neutral information.
- (28) The samples for the controls were taken from pools (one pool consists of milk collected by a milk transportation vehicle from several milk producers whereby the number of the milk producers could vary). The dairy enterprises were not informed about the sampling and the controls. Nor were they informed about the control results. Therefore, the tests were not used and were not useful for them in order to place their products on the market or as a tool to determine the products' quality or the products' price. Only in case the tests showed that the presence of contaminant is high or that legal limits were reached or exceeded the control bodies started separate investigations and informed the dairy enterprises concerned about this investigation.
- (29) If in the course of the contaminants monitoring the assigned body found out values that were high but below the legal limits it would start an assessment process to identify the source of the contamination — like feed, disinfection means, environmental incidents, and others. The enterprise(s) that caused this contamination had to take measures to eliminate the source of contamination at own expenses. This assessment was useful for preventive purposes.
- (30) If in the course of the contaminants monitoring the assigned body detected values that exceed the legal limits or a presence of a substance that is prohibited by law, a full additional control was initiated. The competent authority would then issue a milk delivery ban and order additional tests. The contaminated milk quantity was disposed off. If the contamination values exceeding the legal limits were detected again, the competent authority would apply sanctions in accordance with German administrative or, as the case may be, criminal law. Thus, the contaminants monitoring was for the dairy enterprises either neutral (if no problems were detected) or connected to negative consequences (if the legal limits for the contaminants were found to be exceeded). The milk delivery ban would only be lifted when tests demonstrated that the milk was free of contamination.
- (31) Germany concludes that the contaminants monitoring did not constitute a task inherent to the dairy industry but a measure for the protection of consumers and in particular for the protection of consumers' health. The consumer protection was an objective pursued by the TFEU, in particular in accordance with Article 4(2) in connection with Article 169(1) thereof and by the Charter of Fundamental Rights of the European Union ⁽¹⁾, in particular in accordance with Article 38 thereof.
- (32) Furthermore, the contaminants monitoring corresponded to the clear obligation of the Member States to guarantee that official food safety controls are carried out and therefore the costs for these controls were to be borne by the Member State.

⁽¹⁾ OJ C 364, 18.12.2000, p. 1.

- (33) Germany states that the dairy enterprises undertook own controls to verify the compliance of the milk with the legal limits for contaminants. The costs for these self-controls were covered by the dairy enterprises themselves. The obligation for those self-controls followed from Article 17(1) of Regulation (EC) No 178/2002. The food safety obligations of the dairy enterprises, as regards harmful substances, were furthermore specified in other legal acts, for example Regulation (EC) No 1881/2006, Regulation (EC) No 396/2005 and Commission Regulation (EU) No 37/2010 ⁽¹⁾.
- (34) There was no national legal provision that the dairy enterprises had to bear the costs for the official controls and there was no obligation to pay fees to them. The dairy enterprises had to bear the costs for their own controls of compliance with the food safety legislation and the legal limits of contaminants and residues which are different from the public controls under the contaminants monitoring.

3.2. Other comments from Germany

- (35) Germany justified the right of the Member States to carry out control measures such as the contaminants monitoring. This followed from the demarcation of the competences conferred by the Treaties (TEU and TFEU) on the Union institutions and the Member States as regards the implementation of Union law. Reference was made to Articles 290 and 291 of the TFEU that defined the respective roles of the Union institutions and the Member States. Accordingly, the Member States were primary responsible to guarantee the implementation of Union legislation. Functions such as control fell under their responsibility. Reference was also made to Joined Cases 205 to 215/82 ⁽²⁾ where the Court stated that in accordance with the general principles on which the institutional system of the Union was based and which governed the relations between the Union and the Member States, it was for the Member States to ensure that Union provisions are implemented within their territory.
- (36) Consequently, Germany argued that it would have breached Article 291 TFEU only if it had carried out less controls than those imposed by Article 17(2) of Regulation (EC) No 178/2002 and not, as in the current case, when it carried out additional controls that were complementary to the official food safety control and which were in compliance with the said provision of Regulation (EC) No 178/2002.
- (37) In reply to a question from the Commission as regards the possible application of the rules on the Services of General Economic Interest (SGEI), Germany rebuffed the character of the contaminants monitoring as such within the meaning of the Communication from the Commission on the application of the European Union State aid rules to compensation granted for the provision of services of general economic interest ⁽³⁾. On the opposite, Germany stated that the contaminants monitoring qualified as non-economic activity. In this context, Germany referred to Cases C-364/92, C-343/95 and C-288/11P ⁽⁴⁾ where it was maintained that a task involving the exercise of public regulatory authority that aimed at guaranteeing the public safety was not of an economic nature, since that activity constitute a task the public interest which was intended to protect the whole population. Moreover, the fact that such task was assigned to a private body did not change its character as public. In the current case of contaminants monitoring the assigned control bodies exercised a public task that contributed to the improvement of the healthcare system. The State was obliged to guarantee a high level of healthcare protection in accordance with both Union law ⁽⁵⁾ and the German federal constitutional law and the State enjoyed in this regard discretionary powers.
- (38) In reply to Commission question whether the provision of Article 17(2) of Regulation (EC) No 178/2002 imposed on Member States a clear and precise obligation in the meaning of Case T-351/02 to the extent that the imputability on the State can be excluded, Germany answered that in Case T-351/02 the question concerned the imputability on the State, whereas in the present case the issue was the presence of an advantage for the dairy enterprises.

⁽¹⁾ Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

⁽²⁾ Judgment of the Court of 21 September 1983 — *Deutsche Milchkontor GmbH and others v Federal Republic of Germany*, Joined Cases 205 to 215/82, ECLI:EU:C:1983:233.

⁽³⁾ OJ C 8, 11.1.2012, p. 4.

⁽⁴⁾ Judgment of the Court of 19 January 1994, C-364/92 — *SAT Fluggesellschaft v Eurocontrol*, ECLI:EU:C:1994:7, Judgment of the Court of 18 March 1997, C-343/95 — *Calì & Figli v Servizi Ecologici Porto di Genova*, ECLI:EU:C:1997:160, Judgment of the Court of 19 December 2012, C-288/11P — *Mitteldeutsche Flughafen and Flughafen Leipzig-Halle v Commission*, ECLI:EU:C:2012:821.

⁽⁵⁾ Article 35 of the Charter of Fundamental Rights of the European Union, Article 114(3) and Article 168(1) of TFEU, Article 2(2) of the German Constitution (*Grundgesetz*).

- (39) In addition, Nordrhein-Westfalen argued that sub-measure NW1 was not selective because it targeted the whole dairy industry in that Federal State (Land). Nordrhein-Westfalen enjoyed legal sovereignty allowing it to define the material and the regional scope of the sub-measure. Nordrhein-Westfalen emphasised again that the measure served to carry out general healthcare controls and was in the public interest.

4. COMMENTS FROM INTERESTED PARTIES

- (40) Between 6 and 18 February 2014, the Commission received a total of 10 letters from interested parties with comments on the support granted in respect of the sub-measures ⁽¹⁾.
- (41) In its letter registered by the Commission on 6 February 2014 the Milchwirtschaftlicher Verein Allgäu-Schwaben e.V. stated that the programmes for controls of residuals and contaminants in milk products had to be seen as an addition to the national monitoring programme and served the consumer protection and crisis prevention. The association pointed out that the samples were taken from different undertakings in order to gain an overview of the different Bavarian regions. The results were disseminated. In this way preventive strategies and measures could be developed that would lead eventually to a reduction of the contamination levels. For those reasons, the measure did not confer any advantage to the controlled dairy undertakings.
- (42) In its letter registered by the Commission on 10 February 2014 the Gewerkschaft Nahrung-Genuss-Gaststätten Region Allgäu stated that the monitoring of the levels of contaminants and radioactive substances in milk products formed a very important part of the consumer protection. This measure was very valuable not for the given dairy undertakings but for all milk consumers.
- (43) In its letter registered by the Commission on 10 February 2014, the Landeskontrollverband Nordrhein-Westfalen e.V. stated that it supported the opinion of the *Land* Nordrhein-Westfalen (that was submitted to the Commission as a part of Germany's submission of 20 September 2013).
- (44) In its letter registered by the Commission on 10 February 2014, the Landesvereinigung der Milchwirtschaft NRW e.V. stated that it supported the opinion of the *Land* Nordrhein-Westfalen (that was submitted to the Commission as a part of Germany's submission of 20 September 2013).
- (45) In its letter registered by the Commission on 11 February 2014, the Landesvereinigung Thüringer Milch e.V. stated that it supported the opinion of the Freistaat Thüringen (that was submitted to the Commission as a part of Germany's submission of 20 September 2013).
- (46) In its letter registered by the Commission on 13 February 2014, the Genossenschaftsverband Bayern stated that the monitoring programme to detect residuals and contaminants in milk and milk products did not confer competitive advantages on the dairy enterprises. This programme served in the first place the creation of capacities to react in case of crisis, the protection of the consumers against unsafe products and like this it served the public interest. The samples were undertaken in an irregular manner, the dairy enterprises did not keep any records nor were they informed about the result unless the legal limits were exceeded. On the contrary, the dairy enterprises carried out on their own a more comprehensive and detailed quality safety system that could not be compared to the contaminants monitoring.
- (47) In its letter registered by the Commission on 14 February the Milchwirtschaftliche Arbeitsgemeinschaft Rheinland-Pfalz e.V. stated that sub-measure RP 3 did not qualify as State aid because there was no advantage granted to undertakings or a given production sector that distorted or threatened to distort competition or affected trade between Member States. The association argued that the levy was not used to cover the costs for controls that the dairy enterprises were obliged to carry out pursuant to Regulation (EC) No 852/2004, Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽²⁾ and Regulation (EC) No 854/2004. On the contrary, the controls at stake were carried out on behalf of the public authorities, as

⁽¹⁾ The Commission received comments from the Landesvereinigung der Milchwirtschaft Niedersachsen e.V. in general on all measures financed via the milk levy and not only on the sub-measures at stake here. The association argued that there was no aid. Full description of these comments is given in Commission Decision C(2015) 6295 final of 18 September 2015 concerning State aid SA.35484 (2013/C) (ex SA.35484 (2012/NN)) granted by Germany in respect of milk quality tests pursuant to the Milk and Fat Law.

⁽²⁾ Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

samples and were not of a routine nature. Thus, the controls at stake were part of the public crisis prevention and management in accordance with Article 17(2) of Regulation (EC) No 178/2002. Therefore, the association concludes that the payment of those controls did not relieve the dairy enterprises from their own costs but constituted costs the public authorities bear due to their public food safety function.

- (48) Alternatively, the Milchwirtschaftliche Arbeitsgemeinschaft Rheinland-Pfalz e.V. stated that if sub-measure RP 3 was to be qualified as State aid, their compatibility for the period as from the year 2007 had to be assessed in accordance with Chapter IV.J of the Community Guidelines for State Aid in the Agriculture and Forestry Sector 2007 to 2013 ⁽¹⁾.
- (49) In its letter registered by the Commission on 18 February 2014, DHB-Netzwerk Haushalt e.V stated that the pollutants monitoring programme, the programme for assessment of the radioactivity and the analyses of the nutrition substances represented an important contribution towards consumer protection and consumer awareness. The association underlined the neutrality of the control results (which were not influenced by the dairy industry), the quick recognition of harmful substances in milk products and the possibility to react rapidly in crisis situations.
- (50) In its letter registered by the Commission on 18 February 2014, the Landesvereinigung der Bayerischen Milchwirtschaft e.V. stated that the controls to identify harmful substances in the milk and milk products were important for the trust of consumers in the safety of milk products. Those controls served as an early detection system to detect and to fight off risks or to take the necessary preventive measures.

5. ASSESSMENT OF THE EXISTENCE OF AID

- (51) In the opening Decision the Commission has taken the view that the sub-measures appeared to have all the characteristics of State aid. The Commission stated that Germany failed to present the applicable law in the field of food safety official control and contaminants monitoring that entrust this task on the State. The Commission assessed that the obligation to carry out the contaminants monitoring concerns the dairies so that they received advantage if the controls were executed and paid by the State.
- (52) During the formal investigation procedure Germany and the interested parties argued that the contaminants monitoring did not confer any advantage on the dairies. Germany presented comprehensive information on the legal, administrative and factual elements of the sub-measures. Therefore, it is necessary to re-examine the question of the presence of aid and in particular the presence of advantage for the dairies.
- (53) In accordance with Article 107(1) TFEU 'any aid granted by a Member State or through State resources in any form whatsoever which distorts or threatens to distort competition by favouring certain undertakings or the production of certain goods shall, in so far as it affects trade between Member States, be incompatible with the internal market'.
- (54) The conditions laid down in Article 107(1) TFEU are cumulative. Therefore, in order to determine whether a measure constitutes State aid within the meaning of Article 107(1) TFEU, all the above mentioned conditions need to be fulfilled. As a result, if one of the conditions is not fulfilled, the relevant measure cannot be considered to be State aid.
- (55) The condition for the presence of aid will be examined before the other conditions laid down in Article 107(1) TFEU because the main argument of Germany and the interested parties was that the sub-measures did not confer any advantage on the dairies.
- (56) The arguments of Germany and the interested parties are based on the existence of different control tasks provided for in Union and national food safety law and in particular the division between the official controls

⁽¹⁾ OJ C 319, 27.12.2006, p. 1.

undertaken by the competent bodies and the self-controls undertaken by the dairy enterprises. According to Germany in this regard, the contaminants monitoring undertaken by the assigned bodies and financed publicly by the milk levy is complementary to the official food safety control and is distinguished from the self-controls carried out by the dairy enterprises themselves for which the latter bear the costs. Therefore, the dairies do not receive any advantage from the fact that the State carries out the contaminants monitoring.

- (57) In order to verify whether those arguments are valid it is necessary to analyse (1) where to place the contaminants monitoring in the system of control responsibilities as established by Union and national food safety law, namely whether it is carried out as an obligation attributed to the State or attributed to the private food operators (dairies) and (2) based on the outcome, if the execution of the contaminants monitoring confers an advantage on the dairy enterprises in the sense of Article 107(1) TFEU.

5.1. Control responsibilities under Union and national food safety law

- (58) As set out in the opening Decision the period of investigation begins on 28. November 2001 (see recital 152 of the opening Decision). The analysis of the relevant provisions of food safety law will cover the period running from that date.

5.1.1. Union food safety law

5.1.1.1. Union law related to contaminants in food, including milk

- (59) Council Regulation (EEC) No 315/93 ⁽¹⁾ establishes certain basic principles regarding contaminants in food, notably that (1) food containing a contaminant of an amount that is unacceptable from a public health viewpoint and in particular at a toxicological level, shall not be placed on the market; and (2) maximum levels must be set for certain contaminants in order to protect public health.
- (60) Commission Regulation (EC) No 466/2001 ⁽²⁾ and Regulation (EC) No 1881/2006 set out the maximum levels of certain contaminants in food. They cover in particular the following contaminants in milk: aflatoxins, lead (Pb), dioxin, polychlorinated dibenzofurans and polychlorinated biphenyls (PCBs).
- (61) In accordance with the legal acts referred to in recitals 59 and 60 it is prohibited to place certain foodstuffs (including milk) on the market where those foodstuffs contain certain contaminants at a level exceeding the maximum level set out in those legal acts. Those legal acts also require Member States to adopt appropriate surveillance measures to control the presence of contaminants in foodstuffs.
- (62) Furthermore, the Commission in its Recommendation on the reduction of the presence of dioxins, furans and PCBs in food ⁽³⁾ recommends action levels and target levels for food, including milk, in order to stimulate a proactive approach to reduce the presence of dioxins and dioxin-like PCBs in food. The action levels are, in particular, a tool for competent authorities and operators to highlight those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination. The Commission further recommends that Member States perform, proportionate to their production, use and consumption of foodstuffs, including milk, random monitoring of the presence of dioxins and dioxin-like PCBs and — if possible — non-dioxin-like PCBs in foodstuffs, including milk. With respect to cases of non-compliance with the provisions of Regulation (EC) No 466/2001, and to cases where levels of dioxins and/or dioxin-like PCBs in excess of the action levels are found, the Commission recommends that Member States, in cooperation with operators, initiate investigations to identify the source of contamination and take measures to reduce or eliminate the source of contamination.
- (63) It can be concluded that Union law related to contaminants in food, including milk, contains (1) legal limits for certain food contaminants, including contaminants in milk, which are directly addressed to the food operators who are not allowed to place on the market food, including milk, that is not compliant with those limits; and

⁽¹⁾ Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1).

⁽²⁾ Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs (OJ L 77, 16.3.2001, p. 1).

⁽³⁾ OJ L 67, 9.3.2002, p. 69.

(2) the obligation of the Member States to carry out surveillance of the compliance with those legal limits. In addition, there is a recommendation at Union level (Commission Recommendation) addressed to the Member States to survey the action levels of dioxin and similar contaminants and to take preventive measures.

5.1.1.2. Union law related to residues in animal products, including milk

- (64) Directive 96/23/EC requires Member States to adopt measures in order to monitor the substances and groups of residues listed in Annex I to that Directive. The substances and residues monitored in the case of milk are certain compounds, antibacterial substances, anthelmintics, non-steroidal anti-inflammatory drugs, organochlorides, organophosphorus, chemical elements, mycotoxins.
- (65) Directive 96/23/EC obliges the Member States to monitor certain animal products, including milk, for the purpose of detecting the presence of residues and substances. For that reason, the Member States submit to the Commission monitoring plans for approval. In addition, Member States may have official random checks without prior notice conducted throughout the production chain of raw materials of animal origin, including milk.
- (66) Furthermore, Directive 96/23/EC provides for a self-monitoring and co-responsibility on the part of operators. The owners or persons in charge of the establishment of initial processing of primary products of animal origin (namely milk) have to take all necessary measures, in particular by carrying out their own checks, to satisfy themselves that the products brought into the establishment do not contain residue levels or prohibited substances which exceed maximum permitted limits.
- (67) It can be concluded that Union law related to residuals in animal products, including milk, contains (1) a list of harmful substances and residuals in milk that needs to be monitored; (2) the task of the Member States to monitor and undertake additional checks on the presence of those substances and residuals in milk; (3) the obligation of the economic operators engaged in milk production and processing to carry out self-controls.

5.1.1.3. Horizontal Union law related to food safety control

- (68) Regulation (EC) No 178/2002 lays down the general principles and responsibilities in matters of food safety. As regards the responsibilities, Article 17 of Regulation (EC) No 178/2002 provides for the following:
- ‘(1) Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.
- (2) Member States shall enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. For that purpose, they shall maintain a system of official controls and other activities as appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution. Member States shall also lay down the rules on measures and penalties applicable to infringements of food and feed law. The measures and penalties provided for shall be effective, proportionate and dissuasive.’
- (69) In accordance with Article 2 of Regulation (EC) No 178/2002 food includes milk whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.
- (70) The responsibilities described in Article 17 of Regulation (EC) No 178/2002 refer to both, the food operators and the national competent authorities. Article 17 of Regulation (EC) No 178/2002 clearly distinguishes between the food business operators (namely dairy enterprises) who are responsible for their own controls inside their establishments to comply with the food law requirements, including the obligation to respect legal limits for contaminants and residues on the one hand, and, on the other hand, the Member States authorities who are responsible to monitor and verify the compliance with the food law requirements. The activities of the Member States authorities in this respect are twofold: Member States have to carry out official controls in a strict sense and Member States have to undertake additional appropriate activities such as food safety surveillance and other monitoring activities covering all stages of production, processing and distribution.

- (71) Regulation (EC) No 882/2004 lays down, amongst others, further rules on the official controls of the Member States as regards food of animal origin, including milk. It provides for that Member States develop official national control plans and regularly update them in the light of developments. Adjustment and amendments of the control plans may be made in the light of, or in order to take account of, factors including the emergence of new diseases or other health risks or scientific findings as provided for in Article 42(3) of Regulation (EC) No 882/2004.
- (72) It can be concluded that Union provisions on food (including milk) safety controls provide for two different levels of responsibility that are required to exist in parallel: the food business operators' (dairy enterprises') responsibility to comply with the food safety requirements and the Member States' control responsibility to verify that the relevant requirements of food law are complied with by food business operators. Furthermore, the Member States are responsible for carrying out the food safety official controls in a strict sense and additional appropriate activities as monitoring activities including monitoring of health risks which can facilitate the adjustment of their controls to new developments.

5.1.2. National food safety law

- (73) Before the entry into force of Regulation (EC) No 178/2002, the German Food Law (Section 8 of the *Lebensmittel- und Bedarfsgegenständegesetz*) contained a prohibition to produce and to place on the market food that is dangerous to the human health. This ban was directed to all food producers, including those of milk. The official controls were regulated in Section 40 of the German Food Law. In accordance with that provision, the competent official authorities were obliged to carry out the necessary tests and samples.
- (74) After the entry into force of Regulation (EC) No 178/2002, Union law provides for a directly applicable obligation of the food producers to produce and to place on the market safe food and a directly applicable obligation of the Member States to carry out official controls. The German Food and Feed Safety Law contains further clarifications with respect to those obligations, including rules on the distribution of the competences between the federal and the regional level and the preparation and the execution of the official control plans. The costs for the food operators (including dairies) own controls are to be borne by the enterprises themselves. The costs for the official controls, including the contaminants monitoring, are covered by the State.
- (75) As regards the contaminants monitoring it is regarded as complementary to the food safety official control in a strict sense. The contaminants monitoring is a monitoring activity as provided for in Sections 50 und 51 of the Food and Feed Safety Law. The exact relation between the food safety official controls and the contaminants monitoring is described in the German submission (see recitals 18 to 34). Its characteristics can be summarised as follows:
- (76) The contaminants monitoring is of a preventive nature. The main subject of that monitoring is not to observe whether the legal limits are complied with (as this is the subject of the food safety official controls) but to observe the development in the presence of the contaminants within the legal limits and to detect higher values than the usual ones which can give an early warning or signals for potential risks.
- (77) The parameters (the exact contaminants to be checked, the time schedule, the regions) of the contaminants monitoring are proposed by special bodies assigned by the competent food safety authorities of the *Länder*. Those parameters are determined ad hoc on the basis of a risk assessment. Those parameters are approved by the competent food safety authorities of the *Länder*. The contaminant monitoring is executed by the bodies assigned by the competent food safety authorities of the *Länder*. Those *Länder* exercise a steering function over the bodies assigned to carry out the contaminants monitoring executing the contaminants monitoring.
- (78) The contaminants monitoring that is complementary to the food safety official control contributes in the following ways to the latter — the results of the contaminants monitoring are used to adjust and to amend the official control plans, where deemed necessary, and to undertake further preventive measures such as those that are able to detect health risks early on, the dissemination of information to the public on health and environment risks, the establishment of databases and analysing the data available and the submission of proposals for legislative amendments.

- (79) It can, therefore, be concluded that:
- (1) the national food safety law conforms to the Union food safety law and introduces two levels of responsibility: one at the level of the dairies and one at the level of the Member State;
 - (2) the contaminants monitoring is performed as a part of the Member States' official control function and more precisely as 'another appropriate activity' in the sense of Article 17(2) of Regulation (EC) No 178/2002. Moreover, the contaminants monitoring stays in direct connection with the obligations of the Member States arising from Regulation (EC) No 466/2001 and Regulation (EC) No 1881/2006, Recommendation on the reduction of the presence of dioxins, furans and PCBs in food and Directive 96/23/EC to monitor and undertake additional checks on the presence of contaminants in milk;
 - (3) the contaminants monitoring is directly linked to the food safety official control performed by the Member State as it delivers information used to complement it;
 - (4) the contaminants monitoring is based on a risk assessment carried out by a publicly assigned body, it is performed following a publicly approved schedule which determines the regions, the time, the substances to be checked and which is updated in accordance with the risk assessment. It can therefore be concluded that the contaminants monitoring is not of a routine nature;
 - (5) the contaminants monitoring is carried out in the form of random sample tests, taken at the level of the milk collection transport vehicle; both the samples and the results are anonymous;
 - (6) the results of the tests are used for early risk detection and public preventive measures;
 - (7) the contaminants monitoring does not relieve the dairy enterprises from their obligation to perform their own checks to comply with the legal limits set for the levels of contaminants and residuals in milk.

5.2. The presence of advantage on the side of the dairy enterprises

- (80) Based on the above conclusions on the nature of the contaminants monitoring it has to be analysed if it confers an advantage on the dairy enterprises.
- (81) All types of measures that mitigate the normal burdens on the budget of an undertaking and which therefore, without being subsidies in the strict sense of the word, are of the same character and have the same effect confer an advantage on that undertaking ⁽¹⁾. Therefore, it is necessary to examine whether the contaminants monitoring financed by the state exempts the dairies from a burden normally to be borne by their budget.
- (82) The concept of a burden (charge) which is normally borne by the budget of an undertaking covers costs considered to be an inherent cost of the economic activity of that undertaking as well as additional costs which undertakings must bear by virtue of obligations imposed by the law applicable to the economic activity ⁽²⁾.
- (83) As regards the milk sector such inherent costs, including additional costs imposed by law, of the dairy enterprises are for example:
- the costs for establishing the quality of the milk that are inherent to the economic activity because they are necessary to determine the price of the milk ⁽³⁾,
 - the costs for food safety self-controls carried out by the dairy enterprises themselves in order to comply with the obligation to produce and to place on the market only milk that is safe for human consumption. Those controls are undertaken and paid by the dairies (see recitals 33 and 34).

⁽¹⁾ See judgment in Case T-538/11 *Kingdom of Belgium v European Commission*, paragraph 71, ECLI:EU:T:2015:188 and the case-law cited there

⁽²⁾ (See, by analogy, judgments in Case T-538/11 *Kingdom of Belgium v European Commission*, paragraph 76, ECLI:EU:T:2015:188; in Case C-172/03 *Heiser*, paragraph 38, EU:C:2005:130; in case C-126/01 *GEMO*, paragraphs 31, 32, ECLI:EU:C:2003:622; in Case C-251/97 *France v Commission*, paragraph 40, EU:C:1999:480; in Case 173/73 *Italy v Commission*, paragraphs 15 to 18, CLI:EU:C:1974:71

⁽³⁾ (see Commission Decision C(2015) 6295 final 18 September 2015 concerning State aid SA.35484 (2013/C) (ex SA.35484 (2012/NN)) granted by Germany in respect of milk quality tests pursuant to the Milk and Fat Law, recitals 136-140

- (84) On the opposite, the costs for the contaminants monitoring are not an inherent cost of the production, processing and placing on the market of milk or additional costs which the undertakings must bear by virtue of their obligations imposed by law.
- (85) The contaminants monitoring is not related to individual dairies but is executed randomly, at the level of the milk collection, it is thus anonymous (see recitals 20 and 28). Moreover, it does not cover all quantities of the milk produced, transported and placed on the market, but just a fraction thereof and the frequency and the location of those controls is determined based on a risk assessment; thus it is not of a routine nature (see recitals 20 and 21).
- (86) Furthermore, the contaminants monitoring does not aim at establishing whether the legal limits for the presence of different harmful substances have been complied with. Firstly, the dairies carry out own controls for this purpose (see recital 83, second indent); and secondly, the contaminants monitoring aims at early detecting of risks by analysing values that are within the legal limits but higher than the usual ones for a given region (see recitals 26, 27, 29).
- (87) The dairies cannot use the contaminants monitoring and the results thereof to determine the quality of their milk. The contaminants monitoring is also not an indispensable condition to process the collected milk and to place on the market the produced milk products. Only if in the framework of the contaminants monitoring it is found out that the legal values are exceeded, measures which have negative consequences for the individual dairy will be adopted by the competent food safety authority in a separate procedure. (see recital 30)
- (88) The costs for the contaminants monitoring are not additional costs which the undertakings must bear by virtue of obligations imposed by law which apply to milk production (see recital 32, 33, 34). The obligation that exists for the dairies is to perform own food safety controls inside the enterprise in order to comply with the obligation to produce and to place on the market milk and milk products that are safe for human consumption including the compliance with legal limits for contaminants and residuals (see recital 83, second indent). The contaminants monitoring does not relieve the dairies from performing own safety controls in order to comply with their legal obligations' (see recital 34).
- (89) The contaminants monitoring qualifies as a task related to the official food safety controls for which the public authorities are responsible and which is financed by the State (see recitals 32, 63, 67, 72 and 79(2)) without relieving the dairy enterprises of their own food safety control obligation imposed by Union and national law.
- (90) Recent case law, namely the judgment of the General Court in Case T-538/11 *Kingdom of Belgium v European Commission* ⁽¹⁾ has reiterated that 'the concept of a charge which is normally borne by the budget of an undertaking covers, in particular, the additional costs which undertakings must bear by virtue of obligations imposed by law, regulation or agreement which apply to an economic activity' (see No 76 of the judgement). In that case the BSE screening tests were explicitly made compulsory for the undertakings concerned by law.
- (91) On the contrary, in the current case of contaminants monitoring the controls are not imposed on the dairies by law, regulation or agreement which apply to an economic activity. The controls imposed on the dairies by law, regulation or agreement which apply to an economic activity are described in recitals 63, point 1, 67, point 3, and 83, second dash, above. Those controls are necessary for the dairies to prove that they comply with the legal limits for the presences of contaminants as prescribed by the legislation.
- (92) The contaminant monitoring, however, is not a tool to prove a compliance with those legal limits. The objective of the contaminants monitoring is to detect values of presence of contaminants below the legal limits for preventive purposes as explained above and the controls are executed randomly and irregularly (see recital 76). The contaminants monitoring does not form part of the controls that are necessary for the dairies to prove that they comply with the legal limits for the presences of contaminants as prescribed by the legislation. Therefore, the findings of Case T-538/11 regarding the presence of advantage for the undertakings concerned by the compulsory BSE tests are not applicable to the current case of contaminants monitoring.
- (93) Consequently, the costs for the contaminants monitoring do not qualify as inherent costs of the economic activities of the dairies or as additional costs which they must bear by virtue of obligations imposed by law which apply to their economic activity.

⁽¹⁾ ECLI:EU:T:2015:188

- (94) For that reason, the contaminants monitoring does not exempt the dairies from charges that are normally borne by their budget and do not mitigate the normal burdens on their budget; therefore, the contaminants monitoring does not confer any advantage on them.
- (95) As result, as one of the conditions, of Article 107(1) TFEU, notably the presence of advantage, is not fulfilled, the Commission concludes that the contaminants monitoring does not constitute State aid within the meaning of Article 107(1) TFEU,

HAS ADOPTED THIS DECISION:

Article 1

The general healthcare activities pursuant to the Milk and Fat Law known as contaminants monitoring and referred to in the opening Decision as sub-measures BW 9, BY 5, HE 8, NI 2, NW 1, RP 3, SL 4 and TH 8 do not constitute aid within the meaning of Article 107(1) TFEU.

Article 2

This Decision is addressed to the Federal Republic of Germany.

Done at Brussels, 4 April 2016.

For the Commission
Phil HOGAN
Member of the Commission

CORRIGENDA**Corrigendum to Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) No 648/2012**

(Official Journal of the European Union L 173, 12 June 2014)

On page 98, Article 2(1)(18):

for: '(18) "competent authority" means a competent authority as defined in Article 2(1)(26) of Directive 2014/65/EU';

read: '(18) "competent authority" means a competent authority as defined in Article 4(1)(26) of Directive 2014/65/EU';.

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