

Explanatory Meeting on the Acquis with Albania and North Macedonia

Agenda for Chapter 28: Consumer and health protection

Date: 28 & 29 March 2019

Venue: Albert Borschette, Rue Froissart 36, 1040 Etterbeek – Meeting Room 1A

Chair: Marc JORNA (DG NEAR)

– 28 March 2019

09:00	Arrival of participants
09:30	Welcome and opening remarks by the Chair – Marc JORNA (DG NEAR)
ne	Introductory statement by Carina TORNBLOM (DG JUST) & Wojciech KALAMARZ (DG SANT
g speeches	Introductory statement by Mr. Sokol DEDJA, Deputy Minister for Europe and Foreign Affairs, AL
	Introductory statement by Mr. Bojan MARICHIKJ, Chief Negotiator, North Macedonia

CONSUMER PROTECTION

0:00
co GARCIA
CK, DG JUST E1

General principles of EU Consumer Policy and current Consumer Policy

[C2010/083/01](#)

Treaty on European Union, Title II: Provisions having general application , Article 12 (OJ C 83, 30.3.2010, p. 54)

[C2010/083/01](#)

Treaty on European Union, Title XV: Consumer protection, Article 169 (OJ C 83, 30.3.2010, p. 124)

[32009D0705](#) (EUR-Lex: 15.20.20)

Commission Decision 2009/705/EC of 14 September 2009 setting up a European Consumers Consultative Group (*OJ L 244, 1*

[32008L0048](#) (EUR-Lex: 15.20.40)

Directive 2008/48/EC of the European Parliament and of the Council of 23 April 2008 on **credit agreements for consumers** and amending Council Directive 87/102/EEC (Consumer Credit Directive).

(*OJ L 133, 22.5.2008, p. 66–92*)

Amended by:

Amended by [32008L0048R\(01\)](#) DATE Article 29

Corrected by [32008L0048R\(01\)](#)

Corrected by [32008L0048R\(02\)](#) (NL version only)

Corrected by [32008L0048R\(03\)](#)

Corrected by [32008L0048R\(04\)](#) (LV, IT, DE, FR, FI, LT versions only)

Corrected by [32008L0048R\(05\)](#)

Corrected by [32008L0048R\(06\)](#) (HR version only)

Amended by [32011L0090](#) Amendment Annex I P. II) from: 2011-12-05

Amended by [32014L0017](#) Addition Article 2.2 BI from: 2014-03-20

All consolidated versions:

[02008L0048-20140320](#)

[02008L0048-20111205](#)

[02008L0048-20080621](#)

[32002L0065](#) (EUR-Lex: 06.20.20 / 15.20.40)

Directive 2002/65/EC of the European Parliament and of the Council of 23 September 2002 concerning the **distance marketing of financial services** and amending Council Directive 90/619/EEC and Directives 97/7/EC and 98/27/EC (Distance Marketing for Financial Services Directive)

(*OJ L 271, 9.10.2002, p. 16*)

Amended by [32005L0029](#) (*OJ L 149, 11.6.2005, p. 22*)

Amendment proposed by 52005PC0603

Amended by [32007L0064](#) Addition Article 4.5 from 25/12/2007

Amended by [32007L0064](#) abolition Article 8 from 25/12/2007

[Consolidated version](#) (2007-12-25)

[32014L0092](#)

Directive 2014/92/EU of the European Parliament and of the Council of 23 July 2014 on the comparability of fees related to payment account switching and access to payment accounts with basic features (Text with EEA relevance)

(*OJ L 257, 28.8.2014, p. 214–246*)

INFO POINT

NOTE: this directive is being dealt within negotiating Chapter 9 (Financial Services). It is co-lead by DG JUST and DG Finan

0:20 LEWANSKA, ST 04	32014R0254 (EUR-Lex: 15.20.20) Regulation (EU) No 254/2014 of the European Parliament and of the Council of 26 February 2014 on a multiannual consumer years 2014-20 and repealing Decision No 1926/2006/EC (<i>OJ L 84, 20.3.2014, p. 42–56</i>) 31985L0374 (EUR-Lex: 15.20.40)
0:30	<i>Questions and Answers</i>
0:40	Coffee break
2:40 OEHR, zata POSNOW- ST E2	<p><u>Consumer and marketing law</u></p> <p>31993L0013 (EUR-Lex: 15.20.40) Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts (modified by Directive 2011/83/EU); (<i>p. 29</i>)</p> <p>31998L0006 (EUR-Lex: 15.20.40) Directive 98/6/EC of the European Parliament and of the Council of 16 February 1998 on consumer protection in the indications products offered to consumers (<i>OJ L 80, 18.3.1998, p. 27</i>) Corrected by 31998L0006R(01) (ES, NL, IT versions only) Relation 32004R2006</p> <p>31999L0044 (EUR-Lex: 15.20.40) Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods associated guarantees (modified by Directive 2011/83/EU) (<i>OJ L 171, 7.7.1999, p. 12</i>) Corrected by 31999L0044R(01) (NL, IT versions only) Relation 32004R2006 Amended by 32011L0083 Addition Article 8 BI from 12/12/2011 Consolidated versions 2011-12-12</p> <p>32005L0029 (EUR-Lex: 15.20.40) Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the Parliament and of the Council and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Consumer Directive') (Text with EEA relevance) (<i>OJ L 149, 11.6.2005, p. 22</i>)</p> <p>32008L0122 (EUR-Lex: 13.30.99) Directive 2008/122/EC of the European Parliament and of the Council of 14 January 2009 on the protection of consumers in respect of timeshare, long-term holiday product, resale and exchange contracts (Text with EEA relevance) (<i>OJ L 33, 3.2.</i></p>

	<p>32009L0022 (EUR-Lex: 15.20.40) Directive 2009/22/EC of the European Parliament and of the Council of 23 April 2009 on injunctions for the protection of consumers (Codified version) (<i>OJ L 110, 1.5.2009, p. 30–36</i>)</p> <p>32011L0083 (EUR-Lex: 15.20.40) Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, amending Council Directive 93/13/EEC and Directive 1999/44/EC of the European Parliament and of the Council and repealing Council Directive 85/577/EEC and Directive 97/7/EC of the European Parliament and of the Council (<i>OJ L 304, 22.11.2011, p. 64–88</i>)</p> <p>32015L2302 (EU-Lex: 15.20.20 & 15.20.40) Directive (EU) 2015/2302 of the European Parliament and of the Council of 25 November 2015 on package travel and linked travel arrangements, amending Regulation (EC) No 2006/2004 and Directive 2011/83/EU of the European Parliament and of the Council and repealing Directive 90/314/EEC (<i>OJ L 326 of 11 December 2015, p. 1</i>)</p> <p>New Deal for Consumers legislative proposals</p> <ul style="list-style-type: none"> • COM(2018) 184: Proposal on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC. • COM(2018) 185: Proposal to amend Directive 93/13/EEC on unfair terms in consumer contracts, Directive 98/6/EC on comparative advertising, Directive 2005/29/EC concerning unfair business-to-consumer practices and Directive 2011/83/EU on consumer rights, as regards better enforcement and modernisation of EU consumer law.
2:50	Questions and Answers
4:20	Lunch break
4:35 CARRIAT, ST A2	<p>32006L0114 (EUR-Lex: 15.20.40) Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (<i>OJ L 376, 27.12.2006, p. 21–27</i>)</p> <p>52015PC0634 (EUR-Lex: 13.30.00.00 & 15.20.10.00) Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on certain aspects concerning the supply of digital content COM/2015/0634 final - 2015/0287 (COD) of 9.12.2015</p> <p>52017PC0637 (EUR-Lex: 06.20.30.00; 13.30.00.00 & 15.20.10.00) Amended proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on certain aspects concerning the online and other distance sales of goods, amending Regulation (EC) No 2006/2004 of the European Parliament and of the Council, Directive 2009/22/EC of the European Parliament and of the Council and repealing Directive 1999/44/EC of the European Parliament and of the Council, COM/2017/0637 final - 2015/0288 (COD) of 31.10.2017</p>

5:30
nie DARMANIN,
IOTZOVA,
ph DECKER,
ST E3

Consumer enforcement and redress

32007D0076

Commission Decision of 22 December 2006 implementing Regulation (EC) No 2006/2004 of the European Parliament and of the Council on cooperation between national authorities responsible for the enforcement of consumer protection laws as regards mutual assistance (document number C(2006) 6903) (Text with EEA relevance) (2007/76/EC)

32008D0282

Commission Decision of 17 March 2008 amending Decision 2007/76/EC implementing Regulation (EC) No 2006/2004 of the European Parliament and of the Council on cooperation between national authorities responsible for the enforcement of consumer protection laws as regards mutual assistance (*OJ L 89, 1.4.2008, p. 26–28*)

32011D0141

Commission Decision of 1 March 2011 amending Decision 2007/76/EC implementing Regulation (EC) No 2006/2004 of the European Parliament and of the Council on cooperation between national authorities responsible for the enforcement of consumer protection laws as regards mutual assistance (notified under document C(2011) 1165) (*OJ L 59, 4.3.2011, p. 63–65*)

32015R1051

Commission Implementing Regulation (EU) 2015/1051 of 1 July 2015 on the modalities for the exercise of the functions of the online dispute resolution platform, on the modalities of the electronic complaint form and on the modalities of the cooperation between contact points for in Regulation (EU) N° 524/2013 of the European Parliament and of the Council on online dispute resolution for consumer protection (the Regulation on consumer ODR) (*OJ L 171 of 2 July 2015, p. 1*)

32013L0011

Directive 2013/11/EU of the European Parliament and of the Council of 21 May 2013 on **alternative dispute resolution for consumer protection** and amending Regulation (EC) No 2006/2004 and Directive 2009/22/EC (Directive on consumer ADR) (*OJ L 165, 18.6.2013, p. 1*)

32013R0524

Regulation (EU) No 524/2013 of the European Parliament and of the Council of 21 May 2013 on **online dispute resolution for consumer protection** and amending Regulation (EC) No 2006/2004 and Directive 2009/22/EC (Regulation on consumer ODR) (*OJ L 165, 18.6.2013, p. 1*)
Amended by [32009L0022](#) (*OJ L 110, 1.5.2009, p. 30–36*)

32004R2006 (EUR-Lex: 15.20.40)

Regulation (EC) No 2006/2004 of the European Parliament and of the Council of 27 October 2004 on **cooperation between national authorities responsible for the enforcement of consumer protection laws** (the Regulation on consumer protection cooperation) (Text with EEA relevance) (*OJ L 364, 9.12.2004, p. 1*)

Amended by [32005L0029](#) (*OJ L 149, 11.6.2005, p. 22*), [32009L0136](#) (*OJ L 149, 11.6.2009, p. 1*), [32010R1177](#), [32011R0181](#), and [32011R0954](#) (*OJ L 259, 4.10.2011, p. 1–4*)

[Consolidated version](#) only for reference

	<p>32017R2394 Regulation (EU) 2017/2394 of the European Parliament and of the Council of 12 December 2017 on cooperation between national authorities responsible for the enforcement of consumer protection laws and repealing Regulation (EC) No 2006/2004 (Text with EEA relevance) (<i>OJ L 345, 27.12.2017, p. 1–26.</i>)</p>
5:40	<i>Questions and Answers</i>
5:50	Coffee break
6:10 AVAGGI, ST E.4	<p><u>Product Safety and Rapid Alert System</u></p> <p>31987L0357 (EUR-Lex: 13.30.99) Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which may be other than they are, endanger the health or safety of consumers (Dangerous imitations Directive) (<i>OJ L 192, 11.7.1987, p. 1–10</i>) Incorporated by 21994A0103(69) (<i>OJ L 1, 3.1.1994, p. 492</i>)</p> <p>32001L0095 (EUR-Lex: 15.20.30) Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance) (<i>OJ L 11, 15.1.2002, p. 4</i>)</p> <p>Commission Decision of 9 November 2018 laying down guidelines for the management of the Community Rapid Information System (RAPEX) not yet published</p> <p>Commission Decision C(2004) 1493 of 23 April 2004 on compliance of certain standards with the general safety requirements of Directive 2001/95/EC and the publication of their references in the Official Journal (<u>Decision not published in the OJ</u>):</p> <p>52017XC0811(14) (EUR-Lex: 15.20.30.00) Commission communication in the framework of the implementation of the Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (<i>OJ C 267, 11.08.2017</i>)</p>
6:20	<i>Questions and Answers</i>
7:10 ÖNNEN, DG 7 B.1	<p>31985L0374 COUNCIL DIRECTIVE of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products (85/374/EEC)</p>
7:20	<i>Questions and Answers</i>

HEALTH PROTECTION

7:30

ch KALAMARZ,
NTE C.4

Legal base:

[C2010/083/01](#)

Treaty on European Union, Title XIV: Public health, Article 168 (*OJ C 83, 30.3.2010, p. 122*)

8:00

GROSS,
na LUNGU,
GORANOV,
NTE B.4, B.5 &

Medicinal Products (pharmaceuticals)

[32001L0083](#) (EUR-Lex 13.30.15)

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended); (*OJ L 311, 28.11.2001, p. 67–128*)

[32001L0082](#) (EUR-Lex 13.30.15)

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for veterinary use (as amended); (*OJ L 311, 28.11.2001, p. 1–66*);

New Regulations:

[32019R0004](#)

Regulation (EU) 2019/4 of the European Parliament and of the Council of 11 December 2018 on the manufacture, placing on the market and distribution of medicated feed, amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC (1)

[32019R0005](#)

Regulation (EU) 2019/5 of the European Parliament and of the Council of 11 December 2018 amending Regulation (EC) No 726/2004 of the European Parliament and of the Council on the Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (1)

[32019R0006](#)

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products for human use and repealing Directive 2001/82/EC (1)

[32001L0020](#)

Directive 2001/20/EC of European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations, directives and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (*OJ L 121, 1.5.2001, p. 34–44*)[32014R0536](#)

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance) (*OJ L 158, 27.5.2014, p. 1–76*)

[32003L0094](#)

Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and investigational medicinal products for human use; (*OJ L 262, 14.10.2003, p. 22–26*)

[32005L0028](#)

Commission Directive 2005/28/EC of 8 of April 2005 laying down principles and detailed guidelines for good clinical practice for investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of medicinal products; (*OJ L 91, 9.4.2005, p. 13–19*)

[31991L0412](#)

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products; (*OJ L 228, 17.8.1991, p. 70–73*)

[32004R0726](#)

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance) (*OJ L 136, 30.4.2004, p. 1–33*)

[32000R0141](#)

Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (Text with EEA relevance) (*OJ L 12, 22.1.2000, p. 1–5*)

[32006R1901](#)

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance) (*OJ L 378, 27.12.2006, p. 1–19*)

[32001L0083](#) (EUR-Lex 13.30.15)

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (as amended); (*OJ L 311, 28.11.2001, p. 67–128*) [32001L0082](#) (EUR-Lex 13.30.15)

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for veterinary use (Text with EEA relevance) (*OJ L 311, 28.11.2001, p. 1–66*);

[32001L0020](#)

Directive 2001/20/EC of European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations, administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (*OJ L 121, 1.5.2001, p. 34–44*) [32014R0536](#)

Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (Text with EEA relevance) (*OJ L 158, 27.5.2014, p. 1–76*)

[32003L0094](#)

Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and investigational medicinal products for human use; *OJ L 262, 14.10.2003, p. 22–26* [32003R094](#)

Commission Directive 2005/28/EC of 8 of April 2005 laying down principles and detailed guidelines for good clinical practice for investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products; (*OJ L 91, 9.4.2005, p. 13–19*) [31991L0412](#)

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products; (*OJ L 228, 17.8.1991, p. 70–73*) [32004R0726](#)

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance) *OJ L 136, 30.4.2004, p. 1–33* [32000R0141](#)

Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (Text with EEA relevance) *OJ L 22, 22.1.2000, p. 1–5*, [32006R1901](#)

Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004. (Text with EEA relevance); (*OJ L 378, 27.12.2006, p. 1–19*) [32007R1394](#)

REGULATION (EC) No 1394/2007 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (Text with EEA relevance) (*OJ L 308, 10.12.2007, p. 121*)

8.10

Questions and Answers

– 29 March 2019

	PUBLIC HEALTH
	COSMETIC PRODUCTS AND MEDICAL DEVICES
9:20 EROY OVÁ, Roman DG GROW D.4	<u>Cosmetic Products</u> 32009R1223 (EUR-Lex: 13.30.16) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (<i>OJ L 342, 22.12.2009, p 59</i>) (Text with EEA relevance)
9:40	<i>Questions and Answers</i>
10:15 MOKRY, DG D.4	<u>Medical Devices</u> 32017R0745 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (<i>OJ L 117, 5.5.2017, p. 1–17</i>), repealing Council Directives 90/385/EEC and 93/42/EEC 2017R0746 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices (<i>OJ L 117, 5.5.2017, p. 176–332</i>), repealing Directive 98/79/EC and Commission Decision 2010/227/EU
10:30	<i>Questions and Answers</i>
11:10 BROMEN, NTE B.2	<u>Tobacco control</u> 32014L0040 (EUR Lex: 03.60.64 / 15.20.20) Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations, administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products (<i>OJ L 127, 29.4.2014, p. 1–38</i>) 32014L0109 Commission Delegated Directive 2014/109/EU of 10.10.2014 amending Annex II to Directive 2014/40/EU of the European Parliament and of the Council by establishing the library of picture warnings to be used on tobacco products . (<i>OJ L 360, 17.12.2014, p. 22–27</i>) 32003L0033 (EUR-Lex: 15.30) Directive 2003/33/EC of the European Parliament and of the Council of 26 May 2003 on the approximation of the laws, regulations, administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (<i>OJ L 152, 27.5.2003, p. 1–10</i>)

	<p>32010L0013 (EUR-Lex: 06.20.20.50) Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions of law, regulation or administrative action in Member States concerning the provisions of audio-visual media services (Audiovisual Directive) (<i>OJ L 95, 15.4.2010, p. 1-24</i>) INFO POINT – MAY ALSO BE DEALT WITH UNDER CH 10</p> <p>32004D0513 (EUR-Lex: 11.30.40 / 15.30) Council Decision 2004/513/EC of 2 June 2004 concerning the conclusion of the WHO Framework Convention on Tobacco 15.6.2004, p. 8)</p> <p>32003H0054 (EUR-Lex: 15.30) Council Recommendation 2003/54/EC of 2 December 2002 on the prevention of smoking and on initiatives to improve tobacco 25.1.2003, p. 31–34)</p> <p>32009H1205(01) (EUR-Lex: 15.30) Council Recommendation 2009/C 296/02 of 30 November 2009 on smoke-free environments (<i>OJ C 296, 5.12.2009, p. 4–14</i>)</p>
1.25	Questions and Answers
1.45	Coffee break
2.15 LENGYEL, NTE B.2	<p><u>Patients' rights in cross-border healthcare</u></p> <p>32011L0024 (EUR-Lex: 15.30) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in healthcare (<i>OJ L 88, 4.4.2011, p. 45–65</i>)</p> <p>32012L0052 (EUR-Lex: 15.30) Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measure to facilitate the recognition of measures issued in another Member State (<i>OJ L 356, 22.12.2012, p. 68–70</i>)</p> <p>32014D0286 (EUR-Lex: 15.30) 2014/286/EU: COMMISSION DELEGATED DECISION of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (Text with EEA relevance) (<i>OJ L 147, 17.5.2014, p. 79–87</i>)</p> <p>32014D0287 (EUR-Lex: 15.30) 2014/287/EU: Commission Implementing Decision of 10 March 2014 setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such networks (Text with EEA relevance) (<i>OJ L 147, 17.5.2014, p. 79–87</i>)</p> <p>52018DC0651 (EUR-Lex) REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare COM/2018/651 final</p>

<p>Dimitris COLOU, a ONAITE, NTE B.3</p>	<p><u>EHealth</u></p> <p><u>32011D0890</u> Commission Implementing Decision of 22 December 2011 providing the rules for the establishment, the management and the network of national responsible authorities on eHealth (Dec. 2011/890/EU) (<i>OJ L 344</i>, 28.12.2011, p. 48–50) COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on enabling the digital transformation of health in the Digital Single Market; empowering citizens and building a healthier society (COM/2018/233 final) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A233%3AFIN</p> <p>Council conclusions on Health in the Digital Society — making progress in data-driven innovation in the field of health (2017/1413) (<i>OJ L 308</i>, 21.10.2017, p. 1–10) https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2017:440:0003:0009:EN:PDF</p>
<p>2:25</p>	<p><i>Questions and Answers</i></p>
<p>2:50 D MC GEEHAN, NTE B.4</p>	<p><u>Blood, tissues, cells and organs</u></p> <p><u>32002L0098</u> (EUR-Lex: 15.30) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (2002/98/EC) (<i>OJ L 31</i>, 18.1.2003, p. 30–40)</p> <p><u>32004L0033</u> (EUR-Lex: 15.30) Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council regarding certain technical requirements for blood and blood components (<i>OJ L 91</i>, 30.3.2004, p. 25–39)</p> <p><u>32011L0038</u> (EUR-Lex: 15.30) Commission Implementing Directive 2011/38/EU of 11 April 2011 amending Annex V to Directive 2004/33/EC with regards to values for platelets concentrates at the end of the shelf life (<i>OJ L 97</i>, 12.4.2011, p. 28–29)</p> <p><u>32005L0061</u> (EUR-Lex: 15.30) Commission Directive 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council regarding traceability requirements and notification of serious adverse reactions and events (<i>OJ L 256</i>, 1.10.2005, p. 32–40)</p> <p><u>32005L0062</u> (EUR-Lex: 15.30) Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council regarding Community standards and specifications relating to a quality system for blood establishments (<i>OJ L 256</i>, 1.10.2005, p. 41–42)</p> <p><u>32004L0023</u> (EUR-Lex: 15.30) Directive 2004/23/EC of the European Parliament and the Council of 31 March 2004 on setting standards of quality and safety for the procurement, testing, processing, preservation, storage and distribution of human tissues and cells (<i>OJ L 102</i>, 7.4.2004, p. 1–10)</p> <p><u>32006L0017</u> (EUR-Lex: 15.30)</p>

	<p>Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells (<i>OJ L 38, 9.2.2006, p. 14–15</i>) 32006/L0086 (EUR-Lex: 15.30)</p> <p>Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the processing, preservation, storage and distribution of human tissues and cells (<i>OJ L 294, 25.10.2006, p. 32–50</i>) 32012L0039 (EUR-Lex: 15.30)</p> <p>Commission Directive 2012/39/EU of 26 November 2012 amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells (<i>OJ L 327, 27.11.2012, p. 24–25</i>) 32010D0453 (EUR-Lex: 15.30)</p> <p>2010/453/EU: Commission Decision of 3 August 2010 establishing guidelines concerning the conditions of inspections and on the training and qualification of officials, in the field of human tissues and cells provided for in Directive 2004/23/EC of the European Parliament and of the Council (<i>OJ L 213, 13.8.2010, p. 48–50</i>) 32010L0053 (EUR-Lex: 13.10.30.20 / 15.20.30)</p> <p>Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (<i>OJ L 207, 6.8.2010, p. 14</i>) 32012L0025 (EUR-Lex: 15.30)</p> <p>Commission implementing Directive 2012/25/EU of 9 October 2012 laying down information procedures for the exchange, between Member States, of human organs intended for transplantation (<i>OJ L 275, 10.10.2012, p. 27–32</i>) 52012XG1221(02)</p> <p>Council Conclusions on organ donation and transplantation (2012/C 396/03)</p>
3:00	<i>Questions and Answers</i>
4:30	Lunch Break
5:00 ne LEFEBVRE, NTE C.2	<p><u>Health information</u></p> <p><u>Information points on:</u></p> <p>The European Core Health Indicators (ECHI), Council conclusions of December 2013</p> <p>The below lists EU health / population statistical legal bases (under Chapter 18):</p> <p>32008R1338 (EUR-Lex: 05.20.20.10) Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on health and safety at work (<i>OJ L 354, 31.12.2008, p. 70–81</i>)</p> <p>32011R0328 (EUR-Lex: 05.20.20.10)</p>

<p>KARCHER, DG E C.4</p>	<p>Commission Regulation (EU) No 328/2011 of 5 April 2011 implementing Regulation (EC) No 1338/2008 of the European Parliament and of the Council on Community statistics on public health and health and safety at work, as regards statistics on causes of death (Text with EEA relevance) (<i>OJ L 90, 6.4.2011, p. 22–24</i>)</p> <p>32011R0349 (EUR-Lex: 05.20.20.10)</p> <p>Commission Regulation (EU) No 349/2011 of 11 April 2011 implementing Regulation (EC) No 1338/2008 of the European Parliament and of the Council on Community statistics on public health and health and safety at work, as regards statistics on accidents at work (Text with EEA relevance) (<i>OJ L 97, 12.4.2011, p. 3–8</i>)</p> <p><u>Risk assessment</u></p> <p>32007D0708 (EUR-Lex: 15.20.30) 2007/708/EC: Commission Decision of 31 October 2007 amending the list of experts appointed as members of the Scientific Committee on Consumer Safety in the field of consumer safety, public health and the environment and the prolongation of their term of office (<i>OJ L 287, 1.11.2007, p. 25–28</i>)</p> <p>32008D0721 2008/721/EC: Commission Decision of 5 August 2008 setting up an advisory structure of Scientific Committees and experts in the field of consumer safety, public health and the environment and repealing Decision 2004/210/EC (Text with EEA relevance) (<i>OJ L 243, 20.8.2008, p. 30</i>)</p> <p>European Parliament Resolution of 2 April 2009 on health concerns associated with electromagnetic fields (2008/2211 (INI))</p> <p>31999H0519 (EUR-Lex: 15.30) Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 100 kHz) (<i>OJ L 199, 30.7.1999, p. 59–70</i>)</p>
<p>5:10</p>	<p><i>Questions and Answers</i></p>
	<p>COMMUNICABLE DISEASES:</p>
<p>5.40 VAN LOOCK, INTE C.3</p>	<p><u>Surveillance and reporting</u></p> <p>32013D1082 (EUR-Lex 15.30) Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health repealing Decision No 2119/98/EC (1) (Text with EEA relevance) (<i>OJ L 293, 5.11.2013, p. 1–15</i>)</p> <p>32014D0504</p>

2014/504/EU: Commission Implementing Decision of 25 July 2014 implementing Decision No 1082/2013/EU of the European Parliament and of the Council with regard to the template for providing the information on preparedness and **response planning in relation to serious threats to health** (notified under document C(2014) 5180) (Text with EEA relevance) (*OJ L 223, 29.7.2014, p. 25–36*)

[32018D0945](#)

Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related special health threats by epidemiological surveillance as well as relevant case definitions (Text with EEA relevance) (*OJ L 170, 6.7.2018, p. 1–74*)

[32000D0057](#) (EUR-Lex: 15.30)

Commission Decision No 2000/57/EC of 22 December 1999 on the **early warning and response system for the prevention and control of communicable diseases** under Decision No 2119/98/EC of the European Parliament and of the Council (*OJ L 21, 26.1.2000, p. 1–6*) [consolidated with amendments](#)

[32009H0703\(01\)](#) (EUR-Lex: 16.10.20)

Council Recommendation of 9 June 2009 on **patient safety, including the prevention and control of healthcare associated infections** (*OJ L 151, 3.7.2009, p. 1–6*) [html pdf](#)

[32002H0077](#) (EUR-LEX: 15.30)

Council Recommendation of 15 November 2001 on the **prudent use of antimicrobial agents in human medicine** (*OJ L 34, 5.12.2001, p. 1–2*) [html pdf](#)

[52001DC0333](#) (EUR-Lex: 15.30)

COM/2001/0333 final Volume I: Communication from the Commission on a **Community Strategy against antimicrobial resistance**

[32009H1019](#) (EUR-Lex: 15.30)

Council Recommendation of 22 December 2009 on **seasonal influenza vaccination** (*OJ L 348, 29.12.2009, p. 71–72*) [html pdf](#)

[52005DC0607](#) (EUR-Lex: 15.30)

COM/2005/0607 final: Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on **Pandemic Influenza Preparedness and Response Planning in the European Community** [html pdf](#)

[52005DC0605](#) (EUR-Lex: 15.30)

COM/2005/0605 final Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on **strengthening coordination on generic preparedness planning for public health emergencies at EU level** [html pdf](#)

Strategy for Generic Preparedness Planning - Technical guidance on generic preparedness planning for public health emergencies

[52009DC0569](#) (EUR-Lex: 15.30)

COM/2009/0569 final : Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – **Combating HIV/AIDS in the European Union and neighbouring countries** [pdf](#)

Council conclusions on Childhood immunisation: successes and challenges of European childhood immunisation and the way forward

	<p><u>European Centre for disease prevention and control</u></p> <p>32004R0851 (EUR-Lex: 15.30) Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (<i>OJ L 142, 30.4.2004, p. 1–11</i>) html pdf</p> <p>List of 80 core competences for field epidemiology in Europe pdf</p> <p>European core curriculum for training for infection control practitioners pdf</p> <p>Core functions of microbiology reference laboratories for communicable diseases pdf</p> <p>European Legionnaires’ Disease Surveillance Network (ELDSNet) pdf</p> <p>The European Surveillance System (TESSy) http://ecdc.europa.eu/en/activities/surveillance/TESSy/Pages/TESSy.aspx</p> <p>Presidency note: European Union action following the attacks in the United States – Update of the “road map” pdf</p> <p><u>Health security</u></p> <p>52006DC0699 (EUR-Lex: 01.40) COM/2006/0699 final: Communication from the Commission to the Council on transitional prolongation and extension of the Health Security Committee in view of a future general revision of the structures dealing with health threats at EU level</p>
5:50	<i>Questions and Answers</i>
	NON-COMMUNICABLE DISEASES
6.10 KELLER, NTE C.1	<p><u>Cancer</u></p> <p>32018D0718(02) C/2018/4492 Commission Decision of 17 July 2018 setting up a Commission expert group ‘Steering Group on Health Promotion, Prevention and Management of Non-Communicable Diseases’ and repealing the Decision setting up a Commission expert group on Cancer Control and the Decision establishing a Commission expert group on Cancer Control (Text with EEA relevance.) (<i>OJ C 251, 18.7.2018</i>)</p> <p>Council Conclusions on action against cancer (27 July 2010)</p> <p>Council Conclusions on reducing the burden of cancer (10 June 2008)</p> <p>32003H0878 (EUR-Lex: 15.30) Council Recommendation of 2 December 2003 on cancer screening (<i>OJ L 327, 16.12.2003, p. 34</i>)</p> <p>52009DC0291 (EUR-Lex 15.30)</p>

	<p>COM/2009/291 final: Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Action Against Cancer : European Partnership</p> <p><u>Mental health</u> MSHMS</p> <p>Council conclusions on ‘The European Pact for Mental Health and Well-being: results and future action’ (Conclusions 11/3093) (32003H0488 (EUR-Lex: 15.30))</p> <p>Council Recommendation of 18 June 2003 on the prevention and reduction of health-related harm associated with drug dependence (2003/377/EC) (32003H0488 (EUR-Lex: 15.30))</p> <p>Council Recommendation of 15 November 2001 on combating stress and depression-related problems (2001/115/EC) (52002XG0109(01) (EUR-Lex: 15.30))</p> <p>Council conclusions of 15 November 2001 on combating stress and depression-related problems (<i>OJ C 6, 9.1.2002, p. 1</i>)</p> <p>Council Recommendation of 2 June 2003 on combating stigma and discrimination in relation to mental illness (2003/377/EC) (52003XG0617(01) (EUR-Lex: 05.20))</p> <p>Council Conclusions of 2 June 2003 on combating stigma and discrimination in relation to mental illness (<i>OJ C 141, 17.6.2003, p. 1</i>)</p> <p>Council conclusions 9805/05 on a Community Mental Health Action of 3 June 2005</p> <p><u>Rare diseases</u> ISHP</p> <p>Commission Decision of 27 July 2010 on the appointment of the members of the European Union Committee of Experts on Rare Diseases (2010/140/EC) (32010D0728 (EUR-Lex: 15.30 / 01.40))</p> <p>Commission Decision of 27 July 2010 on the appointment of the members of the European Union Committee of Experts on Rare Diseases (2010/140/EC) (<i>OJ C 204, 28.7.2010, p. 2–5</i>)</p> <p>Rec. 2009/C 151/02: Council Recommendation of 9 June 2009 on an action in the field of rare diseases (<i>OJ C 151, 3.7.2009, p. 1</i>)</p> <p>Commission Decision of 17 July 2018 setting up a Commission expert group ‘Steering Group on Health Promotion and Management of Non-Communicable Diseases’ and repealing the Decision setting up a Commission expert group on rare diseases (2018/4492/EC) (<i>OJ C 251, 18.7.2018, p. 9–10</i>)</p> <p>Decision establishing a Commission expert group on Cancer Control (Text with EEA relevance.) (<i>OJ C 251, 18.7.2018, p. 9–10</i>)</p>
6:20	<i>Questions and Answers</i>
6:30	Coffee break
	SOCIAL AND ENVIRONMENTAL DETERMINANTS OF HEALTH
7:00 BALOGH, ANTE C.4	<p><u>Health inequalities</u> MSHMS</p> <p>Council Conclusions on closing health gaps within the EU through concerted action to promote healthy lifestyle behaviours, 1–11 June 2010</p> <p>Council conclusions on equity in health of 8 June 2010</p> <p><u>Information points on:</u></p> <p>52010DC0133 (EUR-Lex: 05.20.05)</p>

COM/2010/0133 final: Commission [Communication on social and economic integration of the Roma in Europe](#), April 2010
[Commission Communication on an EU Framework for National Roma Integration Strategies up to 2020 of 5 April 2011](#)
[Council conclusions on an EU Framework for National Roma Integration Strategies up to 2020, 15 May 2011](#)
[COM/2012/226 final](#): Commission Communication “National Roma Integration Strategies: a first step in the implementation of the EU Framework for National Roma Integration Strategies up to 2020”, 21 May 2012

[32000Y0731\(03\)](#) (EUR-Lex: 15.30)

Council resolution of 29 June 2000 on action on health determinants (*OJ C 218, 31.7.2000, p. 8*)

Prevention of injury and promotion of safety ISHP

[32007H0718\(01\)](#) (EUR-Lex: 15.30)

Council Recommendation of 31 May 2007 on the prevention of injury and the promotion of safety (*OJ C 164, 18.7.2007, p. 1–*

Healthy lifestyle – Nutrition

[Strategy on Nutrition, Overweight and Obesity-related health issues, 30 May 2007](#)

[EU physical activity guidelines, 10 October 2008](#)

[EU Framework for national salt initiatives, 1 January 2008](#)

[EU Framework for National Initiatives on Selected Nutrients, 1 February 2011](#)

[Saturated Fat Annex, 12 June 2012](#)

[EU Action Plan on Childhood Obesity, 24 February 2014](#)

[Council Conclusion on Nutrition and Physical Activity, 20 June 2014](#)

[Added Sugars Annex, 15 December 2015](#)

[Council conclusions on Food Product Improvement, 17 June 2016](#)

[Council conclusions on Childhood Obesity, 16 June 2017](#)

[Council conclusions on Healthy Nutrition for Children, 22 June 2018](#)

Healthy lifestyle - Alcohol and drugs abuse prevention MSHMS/ISHP

[52009XG1212\(04\)](#) (EUR-Lex: 15.30)

Council Conclusions on alcohol and health, 1 December 2009 (Cons. 2009/C 302/07) (*OJ C 302, 12.12.2009, p. 15*)

[52015XG1216\(01\)](#)

Council Conclusions on EU strategy to reduce alcohol-related harm, 30 November and 1 December 2006 (16165/06)

[32001X0620\(01\)](#) (EUR-Lex: 15.30)

Council Conclusions of 5 June 2001 on a Community strategy to reduce alcohol-related harm (*OJ C 175, 20.6.2001, p. 1*)

[32001H0458](#) (EUR-Lex: 15.30)

	<p>Council Recommendation of 5 June 2001 on the drinking of alcohol by young people, in particular children and adolescents (<i>C</i> p. 38)</p> <p>32003H0488 (EUR-Lex: 15.30)</p> <p>Council Recommendation of 18 June 2003 on the prevention and reduction of health-related harm associated with drug dependence (2003/372/EC) (<i>C</i> 3.7.2003, p. 31–33)</p>
7:10	<i>Questions and Answers</i>
7:15	<p><u>EU Health Programme</u></p> <p>32014R0282 (EUR-Lex 15.30)</p> <p>Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (<i>OJ L</i> 86, 21.3.2014, p. 1-13)</p> <p>32007D1350 (EUR-Lex: 15.30)</p> <p>Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of action in the field of health (2008–13) (Text with EEA relevance) (<i>OJ L</i> 301, 20.11.2007, p. 3–13)</p>
7:25	<i>Questions and Answers</i>
7:40	<i>General Questions and Answers</i>
7:50	<p><i>Public Administration Reform</i></p> <p>Marc Jorna - Chair</p>
8:00	<p><i>Closing remarks</i></p> <ul style="list-style-type: none"> ● <i>Marc Jorna - Chair</i> ● <i>David Cullen – Head of Unit, DG NEAR</i> ● <i>Michela Matuella – Head of Unit, DG NEAR</i>