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# **'I/A' ITEM NOTE**

From:	Presidency
To:	Permanent Representatives Committee/Council
No. prev. doc.:	5623/17 + ADD 1 REV 1, 10170/17
Subject:	Proposal for a Regulation of the European Parliament and of the Council adapting a number of legal acts providing for the use of regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty of the Functioning of the European Union  - Presidency Progress Report

# I. INTRODUCTION

In the Inter-Institutional Agreement between the European Parliament, the Council of the European Union and the European Commission of 13 April 2016 on Better Law-Making<sup>1</sup> (hereafter 'the IIA') "the three institutions acknowledged the need for the alignment of all existing legislation to the legal framework introduced by the Lisbon Treaty, and in particular the need to give high priority to the prompt alignment of all basic acts which still refer to the regulatory procedure with scrutiny."<sup>2</sup>

A number of legislative acts in force still contain the regulatory procedure with scrutiny (hereafter 'RPS') and it continues to apply (in line with Article 12 of Regulation 182/2011) in those acts until they are formally amended and adapted to the Lisbon Treaty. In this regard, the Commission submitted two Proposals which cover the adaptation to the Lisbon Treaty of all remaining acts that still refer to the RPS. COM (2016)799 final<sup>3</sup> proposes the adaptation of 168 acts covering 13 different sections, whilst COM (2016)798 final<sup>4</sup> proposes the adaptation of 3 acts in the area of Justice. Acts referring to the RPS which are currently subject to a separate revision or for which a revision is envisaged, are not included in the Proposals<sup>5</sup>.

In order to maintain an appropriate degree of coordination and consistency of approach, the Maltese Presidency decided to activate the Friends of the Presidency group to examine the proposals and assess, for each legal act concerned, the adaptation proposed by the Commission. The Friends of the Presidency group ('RPS Adaptation') was activated by COREPER on 1 February 2017<sup>6</sup>.

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OJ L 123, 12.5.2016, p. 1.

<sup>&</sup>lt;sup>2</sup> Ibid, at point 27.

Proposal for a Regulation of the European Parliament and of the Council adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union. Document 5623/17 + ADD 1 REV 1.

Proposal for a Regulation of the European Parliament and of the Council adapting a number of legal acts in the area of Justice providing for the use of the regulatory procedure with scrutiny to Article 290 of the Treaty on the Functioning of the European Union. Document 5705/17 + ADD 1.

The Commission has provided a list of these acts in point 3 of the Explanatory Memorandum of COM (2016) 799 final.

<sup>&</sup>lt;sup>6</sup> Sec Doc 5707/17.

The Friends of the Presidency (RPS Adaptation) (hereafter 'FoP') started formal discussions on COM (2016)799 (hereafter, 'RPS Adaptation Proposal') under the Maltese Presidency during which five FoP meetings were held and the Presidency progress report<sup>7</sup> was presented to the June 2017 General Affairs Council.

Under the Estonian Presidency five FoP meetings were dedicated to discussions on the RPS Adaptation Proposal on 17 July, 21 September, 5 October, 7 November and 1 December 2017. The Estonian Presidency focussed its work on the remaining parts of the RPS Adaptation Proposal not discussed under the Maltese Presidency, which amounts to 90 acts in the following three Sections, namely:

Section VII: EUROSTAT

Section XI: MOBILITY AND TRANSPORT

Section XII: HEALTH AND FOOD SAFETY

Given the volume of the RPS Adaptation Proposal, the Estonian Presidency continued to follow the practice established by the Maltese Presidency that prior to each FoP meeting, the Presidency asked delegations to provide positions on the basis of a legal assessment provided by the Presidency, with Council Legal Service (CLS) input, assessing whether each empowerment present in the Commission proposal with respect to the Sections in question, is acceptable from a legal point of view. Delegations submitted comments in writing.

The meetings focussed on the provisions for which a discussion was deemed necessary. With regard to provisions on which there was broad support for the Presidency's initial assessment in the written comments, no discussion took place during the meetings<sup>8</sup>. After each meeting, the Presidency reverted back to the delegations with drafting suggestions for amendments which were necessary following the provisional conclusions reached during the meetings on the basis of the positions of delegations, both in writing and in the FoP meetings.

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Although Member States were able to raise specific provisions that were not proposed to be discussed at the end of each Section.

# II. STATE-OF-PLAY OF THE ANNEX

#### SECTION VII - EUROSTAT

**Horizontal comment**: As regards the duration of the delegation of powers, in all cases in this section for which the Presidency provisionally concluded that there was an agreement for delegated acts, the Presidency also provisionally concluded that the delegation of powers should be limited to five years, with the possibility of a tacit renewal (Option 2 of the standard article on exercise of the delegation in the appendix to the Common Understanding of the IIA). The Presidency will revert back with drafting suggestions reflecting that outcome.

- Act 55, Council Regulation (EEC) No 3924/91 of 19 December 1991 on the establishment of a Community survey of industrial production: The Presidency provisionally concluded to remove Act 55 from the RPS Adaptation exercise in view of Commission proposal COM(2017) 114 final, which is a proposal for repealing Council Regulation (EEC) No 3924/91.
- 2. **Act 56**, Council Regulation (EEC) No 696/93 of 15 March 1993 on the statistical units for the observation and analysis of the production system in the Community: The Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to remove the empowerment.
- 3. **Act 57**, Council Regulation (EC) No 1165/98 of 19 May 1998 concerning short-term statistics: The Presidency provisionally concluded to remove Act 57 from the RPS Adaptation exercise in view of Commission proposal COM(2017) 114 final, which is a proposal for repealing Council Regulation (EEC) No 1165/98.
- 4. Act 58, Council Regulation (EC) No 530/1999 of 9 March 1999 concerning structural statistics on earnings and on labour costs: The Presidency provisionally concluded that for one empowerment there was an agreement with the Commission proposal to adopt implementing acts (IAs) and that for two other empowerments it would revert back with drafting suggestions amending the Commission proposal to provide for IAs.

- 5. Act 59, Regulation (EC) No 2150/2002 of the European Parliament and of the Council of 25 November 2002 on waste statistics: The Presidency provisionally concluded that for two empowerments there was an agreement with the Commission proposal to adopt delegated acts (DAs) and IAs. For the other empowerments, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to remove one empowerment, to provide for IAs in the case of another empowerment and to introduce a specific wording to avoid significant additional burden or costs (hereafter 'safeguard clause') in the case of one empowerment for DAs.
- 6. **Act 60**, Regulation (EC) No 437/2003 of the European Parliament and of the Council of 27 February 2003 on statistical returns in respect of the carriage of passengers, freight and mail by air: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt IAs. For the other empowerments, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs in the case of one empowerment and to introduce a safeguard clause in the case of one empowerment for DAs.
- 7. **Act 61**, Regulation (EC) No 450/2003 of the European Parliament and of the Council of 27 February 2003 concerning the labour cost index: The Presidency provisionally concluded that there was an agreement with the Commission proposal for some empowerments to adopt IAs and DAs. For other empowerments, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs and to introduce a safeguard clause in the case of one empowerment for DAs.
- 8. **Act 62**, Regulation (EC) No 808/2004 of the European Parliament and of the Council of 21 April 2004 concerning Community statistics on the information society: The Presidency provisionally concluded to remove Act 62 from the RPS Adaptation exercise in view of Commission proposal COM(2017) 114 final, which is a proposal for repealing the Regulation (EC) No 808/2004.

- 9. **Act 63**, Regulation (EC) No 1161/2005 of the European Parliament and of the Council of 6 July 2005 on the compilation of quarterly non-financial accounts by institutional sector: The Presidency provisionally concluded that there was an agreement with the Commission proposal for two empowerments to adopt DAs. In the case of two other empowerments, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs and to remove one empowerment.
- 10. Act 64, Regulation (EC) No 1552/2005 of the European Parliament and of the Council of 7 September 2005 on statistics relating to vocational training in enterprises: the Presidency provisionally concluded that there was an agreement with the Commission proposal for one empowerment to adopt IAs and for another empowerment to adopt DAs, while introducing a safeguard clause in the case of the latter empowerment. For the other empowerments, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for a number of IAs and to remove two empowerments, one of them being obsolete.
- 11. **Act 65**, Regulation (EC) No 1893/2006 of the European Parliament and of the Council of 20 December 2006 establishing the statistical classification of economic activities NACE Revision 2 and amending Council Regulation (EEC) No 3037/90 as well as certain EC Regulations on specific statistical domains: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 12. **Act 66**, Regulation (EC) No 458/2007 of the European Parliament and of the Council of 25 April 2007 on the European system of integrated social protection statistics (ESSPROS): The Presidency provisionally concluded that there was an agreement with the Commission proposal for one empowerment to adopt DAs. For two other empowerments, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs.

- 13. **Act 67**, Regulation (EC) No 716/2007 of the European Parliament and of the Council of 20 June 2007 on Community statistics on the structure and activity of foreign affiliates: The Presidency provisionally concluded to remove Act 67 from the RPS Adaptation exercise in view of Commission proposal COM(2017) 114 final, which is a proposal for repealing the Regulation (EC) No 716/2007.
- 14. **Act 68**, Regulation (EC) No 862/2007 of the European Parliament and of the Council of 11 July 2007 on Community statistics on migration and international protection and repealing Council Regulation (EEC) No 311/76 on the compilation of statistics on foreign workers: The Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs and to remove one empowerment.
- 15. **Act 69**, Regulation (EC) No 1445/2007 of the European Parliament and of the Council of 11 December 2007 establishing common rules for the provision of basic information on Purchasing Power Parities and for their calculation and dissemination: The Presidency provisionally concluded that there was an agreement with the Commission proposal for one empowerment to adopt IAs. For two other empowerments, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs in one case, and, in the other case, to split the content of the empowerment into elements to be laid down by DAs under a safeguard clause and elements for which the empowerment is removed.
- 16. Act 70, Regulation (EC) No 177/2008 of the European Parliament and of the Council of 20 February 2008 establishing a common framework for business registers for statistical purposes and repealing Council Regulation (EEC) No 2186/93: The Presidency provisionally concluded to remove Act 70 from the RPS Adaptation exercise in view of Commission proposal COM(2017) 114 final, which is a proposal for repealing the Regulation (EC) No 177/2008.

- 17. **Act 71**, Regulation (EC) No 295/2008 of the European Parliament and of the Council of 11 March 2008 concerning structural business statistics: The Presidency provisionally concluded to remove Act 71 from the RPS Adaptation exercise in view of Commission proposal COM(2017) 114 final, which is a proposal for repealing the Regulation (EC) No 295/2008.
- 18. **Act 72**, Regulation (EC) No 451/2008 of the European Parliament and of the Council of 23 April 2008 establishing a new statistical classification of products by activity (CPA) and repealing Council Regulation (EEC) No 3696/93: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs and to revert back with drafting suggestions amending the Commission proposal to introduce a safeguard clause for that empowerment.
- 19. **Act 73**, Regulation (EC) No 452/2008 of the European Parliament and of the Council of 23 April 2008 concerning the production and development of statistics on education and lifelong learning: The Presidency provisionally concluded that there was an agreement with the Commission proposal for one empowerment to adopt IAs. For the other empowerment, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs.
- 20. Act 74, Regulation (EC) No 453/2008 of the European Parliament and of the Council of 23 April 2008 on quarterly statistics on Community job vacancies: The Presidency provisionally concluded that there was an agreement with the Commission proposal for one empowerment to adopt IAs. For the other empowerments the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for a number of IAs and to remove one empowerment.
- 21. **Act 75**, Regulation (EC) No 763/2008 of the European Parliament and of the Council of 9 July 2008 on population and housing censuses: The Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs.

- 22. Act 76, Regulation (EC) No 1099/2008 of the European Parliament and of the Council of 22 October 2008 on energy statistics: The Presidency provisionally concluded that there was an agreement with the Commission proposal for four of the empowerments to adopt DAs. For the other two empowerments for DAs, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to introduce a safeguard clause in the case of one of the empowerments and, as for the other empowerment, to split its content into elements to be laid down by DAs and elements for which the empowerment is removed.
- 23. Act 77, Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work: The Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs.
- 24. **Act 78**, Regulation (EC) No 1185/2009 of the European Parliament and of the Council of 25 November 2009 concerning statistics on pesticides: The Presidency provisionally concluded that there was an agreement with the Commission proposal for one empowerment to adopt DAs. For another empowerment, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs. As regards one empowerment, the Presidency provisionally concluded to postpone the discussion.

# SECTION XI – MOBILITY AND TRANSPORT

**Horizontal comment:** As regards the duration of the delegation of powers, in all cases in this section for which the Presidency provisionally concluded that there was an agreement for delegated acts, the Presidency also provisionally concluded that the delegation of powers should be limited to five years, with the possibility of a tacit renewal (Option 2 of the standard article on exercise of the delegation in the appendix to the Common Understanding of the IIA). The Presidency reverted back with drafting suggestions reflecting that outcome.

- 25. **Act 102,** Council Regulation (EEC) No 3922/91 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation: The Presidency provisionally concluded to remove that Act from the RPS Adaptation exercise given that Regulation (EC) No 216/2008 provides for deletion of Annex III to Regulation (EEC) No 3922/91, to which the RPS empowerment is related.
- 26. **Act 103,** Council Directive 95/50/EC of 6 October 1995 on uniform procedures for checks on the transport of dangerous goods by road: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 27. **Act 104,** Council Directive 97/70/EC of 11 December 1997 setting up a harmonised safety regime for fishing vessels of 24 meters in length and over: The Presidency provisionally concluded that there was an agreement with the Commission proposal for empowerments to adopt DAs and IAs.
- 28. **Act 105,** Directive 2000/59/EC of the European Parliament and of the Council of 27 November 2000 on port reception facilities for ship-generated waste and cargo residue: The Presidency provisionally concluded to postpone the discussion on the RPS Adaptation of that act given that a new Commission proposal concerning that act is expected to be adopted soon.
- 29. **Act 106**, Directive 2001/96/EC of the European Parliament and of the Council of 4 December 2001 establishing harmonised requirements and procedures for the safe loading and unloading of bulk carriers: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 30. **Act 107,** Directive 2002/59/EC of the European Parliament and of the Council of 27 June 2002 establishing a Community vessel traffic monitoring and information system and repealing Council Directive 93/75/EEC: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs.

- 31. **Act 108**, Regulation (EC) No 2099/2002 of the European Parliament and of the Council of 5 November 2002 establishing a Committee on Safe Seas and the Prevention of Pollution from Ships (COSS) and amending the Regulations on maritime safety and the prevention of pollution from ships: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt a DAs.
- 32. **Act 109**, Directive 2003/25/EC of the European Parliament and of the Council of 14 April 2003 on specific stability requirements for ro-ro passenger ships: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 33. **Act 110,** Directive 2003/59/EC of the European Parliament and of the Council of 15 July 2003 on initial qualification and periodic training of drivers of certain road vehicles for the carriage of goods or passengers, amending Council Regulation (EEC) No 3820/85 and Council Directive 91/439/EEC and repealing Council Directive 76/914/EEC: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 34. **Act 111,** Regulation (EC) No 782/2003 of the European Parliament and of the Council of 14 April 2003 on the prohibition of organotin compounds on ships: The Presidency provisionally concluded that there was an agreement with the Commission proposal for one of the empowerments to adopt DAs. For the other empowerment, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs.
- 35. **Act 112,** Directive 2004/52/EC of the European Parliament and of the Council of 29 April 2004 on the interoperability of electronic road toll systems in the Community: The Presidency provisionally concluded to remove that Act from the RPS Adaptation exercise given that Commission recast proposal COM(2017) 280 final also covers the RPS empowerments.

- 36. **Act 113,** Directive 2004/54/EC of the European Parliament and of the Council of 29 April 2004 on minimum safety requirements for tunnels in the trans-European road network: The Presidency provisionally concluded to come back with drafting suggestions amending the Commission proposal by deleting the empowerment to adopt DAs.
- 37. **Act 114,** Regulation (EC) No 725/2004 of the European Parliament and of the Council of 31 March 2004 on enhancing ship and port facility security: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs, including under the urgency procedure where proposed, and for the empowerments to adopt IAs.
- 38. **Act 115,** Regulation (EC) No 785/2004 of the European Parliament and of the Council of 21 April 2004 on insurance requirements for air carriers and aircraft operators: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs.
- 39. **Act 116**, Regulation (EC) No 789/2004 of the European Parliament and of the Council of 21 April 2004 on the transfer of cargo and passenger ships between registers within the Community and repealing Council Regulation (EEC) No 613/91: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 40. Act 117, Regulation (EC) No 868/2004 of the European Parliament and of the Council of 21 April 2004 concerning protection against subsidisation and unfair pricing practices causing injury to Community air carriers in the supply of air services from countries not members of the European Community: The Presidency provisionally concluded to remove that Act from the RPS Adaptation exercise given that Commission proposal COM(2017) 289 final provides for a repeal and replacement of Regulation (EC) No 868/2004.

- 41. **Act 118,** Directive 2005/44/EC of the European Parliament and of the Council of 7 September 2005 on harmonised river information services (RIS) on inland waterways in the Community: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 42. **Act 119**, Directive 2005/65/EC of the European Parliament and of the Council of 26 October 2005 on enhancing port security: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs, including under the urgency procedure.
- 43. Act 120, Regulation (EC) No 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating air carrier, and repealing Article 9 of Directive 2004/36/EC: In the light of the on-going negotiation on the revision of Regulation (EC) No 216/2008, in which amendments to Article 15 of Regulation (EC) No 2111/2005 were introduced, the Presidency provisionally concluded to postpone the discussion on that Act until the adoption of the revision of Regulation (EC) No 216/2008.
- 44. **Act 121,** Directive 2006/126/EC of the European Parliament and of the Council of 20 December 2006 on driving licences: The Presidency provisionally concluded that there was an agreement with the Commission proposal for all empowerments to adopt DAs except for one empowerment. As regards that empowerment, the Presidency provisionally concluded that there was an agreement for keeping the empowerment for DAs while removing certain elements from it and, thus, for amending the Commission proposal by deleting those elements from the empowerment concerned.

- 45. **Act 122**, Regulation (EC) No 336/2006 of the European Parliament and of the Council of 15 February 2006 on the implementation of the International Safety Management Code within the Community and repealing Council Regulation (EC) No 3051/95: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 46. **Act 123,** Directive 2007/59/EC of the European Parliament and of the Council of 23 October 2007 on the certification of train drivers operating locomotives and trains on the railway system in the Community: The Presidency provisionally concluded that there was an agreement with the Commission proposal for some empowerments to adopt DAs, including with the urgency procedure where proposed, and for other empowerments, the Presidency provisionally concluded to revert back with drafting suggestions, amending the Commission proposal to provide for IAs.
- 47. **Act 124**, Regulation (EC) No 1371/2007 of the European Parliament and of the Council of 23 October 2007 on rail passengers' rights and obligations: The Presidency provisionally concluded to remove that Act from the RPS Adaptation exercise given that by COM(2017) 548 final the Commission proposes a recast of Regulation (EC) No 1371/2007, which also covers the RPS empowerments.
- 48. **Act 125**, Directive 2008/68/EC of the European Parliament and of the Council of 24 September 2008 on the inland transport of dangerous goods: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 49. **Act 126**, Directive 2008/96/EC of the European Parliament and of the Council of 19 November 2008 on road infrastructure safety management: For one of the empowerments, the Presidency provisionally concluded that there was an agreement with the Commission proposal to adopt DAs. For the other empowerment, the Presidency provisionally concluded to revert back with drafting suggestions, amending the Commission proposal to provide for IAs.

- 50. Act 127, Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002: The Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs for two empowerments and removing one empowerment.
- 51. **Act 128**, Directive 2009/15/EC of the European Parliament and of the Council of 23 April 2009 on common rules and standards for ship inspection and survey organisations and for the relevant activities of maritime administrations: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 52. Act 129, Directive 2009/18/EC of the European Parliament and of the Council of 23 April 2009 establishing the fundamental principles governing the investigation of accidents in the maritime transport sector and amending Council Directive 1999/35/EC and Directive 2002/59/EC of the European Parliament and of the Council: The Presidency provisionally concluded that there was an agreement with the Commission proposal for two of the empowerments to adopt DAs. For one empowerment, the Presidency provisionally concluded to revert back with drafting suggestions, amending the Commission proposal to provide for IAs.
- 53. **Act 130**, Directive 2009/33/EC of the European Parliament and of the Council of 23 April 2009 on the promotion of clean and energy-efficient road transport vehicles: The Presidency provisionally concluded to remove that Act from the RPS Adaptation exercise given that Commission proposal COM(2017) 653 final, which is a proposal for amending Directive 2009/33/EU, also covers the RPS empowerments.
- 54. **Act 131**, Regulation (EC) No 391/2009 of the European Parliament and of the Council of 23 April 2009 on common rules and standards for ship inspection and survey organisations: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs.

- 55. **Act 132**, Regulation (EC) No 392/2009 of the European Parliament and of the Council of 23 April 2009 on the liability of carriers of passengers by sea in the event of accidents: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs.
- 56. Act 133, Regulation (EC) No 1071/2009 of the European Parliament and of the Council of 21 October 2009 establishing common rules concerning the conditions to be complied with to pursue the occupation of road transport operator and repealing Council Directive 96/26/EC: The Presidency provisionally concluded to remove that Act from the RPS Adaptation exercise given that Commission proposal COM(2017) 281 final, which is a proposal for amending Regulation (EC) No 1071/2009, also covers the RPS empowerments.
- 57. **Act 134**, Regulation (EC) No 1072/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international road haulage market: The Presidency provisionally concluded to remove that Act from the RPS Adaptation exercise given that Commission proposal COM(2017) 281 final, which is a proposal for amending Regulation (EC) No 1072/2009, also covers the RPS empowerments.
- 58. **Act 135,** Regulation (EC) No 1073/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international market for coach and bus services, and amending Regulation (EC) No 561/2006: The Presidency provisionally concluded to remove that Act from the RPS Adaptation exercise given that Commission proposal COM(2017) 647 final, which is a proposal for amending Regulation (EC) No 1073/2009, also covers the RPS empowerments.

#### SECTION XII – HEALTH AND FOOD SAFETY

**Horizontal comment**: As regards the duration of the delegation of powers, in all cases in this section for which the Presidency provisionally concluded that there was an agreement for delegated acts, the Presidency also provisionally concluded that the delegation of powers should be limited to five years, with the possibility of a tacit renewal (Option 2 of the standard article on exercise of the delegation in the appendix to the Common Understanding of the IIA). The Presidency reverted back with drafting suggestions reflecting that outcome.

- 59. **Act 136,** Council Directive 89/108/EEC of 21 December 1988 on the approximation of the laws of the Member States relating to quick-frozen foodstuffs for human consumption: For one of the empowerments, the Presidency provisionally concluded that there was an agreement with the Commission proposal to adopt DAs. For the other empowerment, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs.
- 60. Act 137, Directive 1999/2/EC of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation: The Presidency provisionally concluded that there was an agreement with the Commission proposal for two empowerments to adopt DAs, including under the urgency procedure where proposed. For one empowerment, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal by deleting the empowerment to adopt DAs.
- 61. **Act 138,** Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 62. **Act 139,** Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs.

- 63. **Act 140,** 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: The Presidency provisionally concluded that there was an agreement with the Commission proposal for all empowerments to adopt DAs except for one empowerment. For that empowerment, the Presidency provisionally concluded to postpone the discussion given the parallelism between this empowerment and an empowerment in Regulation (EC) No 726/2004 until the finalization of the discussions on those empowerments within the Council Working Party on Pharmaceuticals and Medical devices.
- 64. **Act 141,** Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs.
- 65. **Act 142,** Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs, including under the urgency procedure where proposed.
- 66. Act 143, Directive 2002/46/EC of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs, including under the urgency procedure where proposed, and for the empowerment to adopt IAs.
- 67. **Act 144,** 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: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs, including under the urgency procedure, and for the empowerment to adopt IAs.

- 68. **Act 145,** 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: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs and for the empowerment to adopt IAs.
- 69. Act 146, Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC: The Presidency provisionally concluded that there was an agreement with the Commission proposal for two of the empowerments to adopt DAs, including under the urgency procedure where proposed. For one empowerment, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs.
- 70. **Act 147,** Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs and for the empowerments to adopt IAs.
- 71. **Act 148,** Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 72. **Act 149,** Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs.

- 73. **Act 150,** Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs.
- 74. **Act 151,** Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs and for the empowerment to adopt IAs, except for one empowerment to adopt DAs. For that empowerment, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs for certain elements of the empowerment, while keeping the rest of the elements of the empowerment for DAs.
- 75. Act 152, Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs, including under the urgency procedure where proposed, and for the empowerments to adopt IAs.
- 76. **Act 153,** Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs: The Presidency provisionally concluded that there was an agreement with the Commission proposal for all empowerments to adopt DAs, except for one empowerment. For that empowerment, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs.
- 77. **Act 154,** 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: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs and for the empowerment to adopt IAs.

- 78. **Act 155,** 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: The Presidency provisionally concluded to remove that Act from the RPS Adaptation exercise given that Regulation (EU) 2017/625 repeals Regulation (EC) No 854/2004.
- 79. **Act 156,** Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs.
- 80. Act 157, Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004: The Presidency provisionally concluded that there was agreement with the Commission proposal for one of the empowerments to adopt DAs. For the other empowerment to adopt DAs, the Presidency provisionally concluded to postpone the discussion given the parallelism between this empowerment and an empowerment in Regulation (EC) No 726/2004 until the finalization of the discussions on those empowerments within the Council Working Party on Pharmaceuticals and Medical devices.
- 81. **Act 158**, Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs and for the empowerments to adopt IAs.
- 82. **Act 159,** Regulation (EC) No 1925/2006 of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods: The Presidency provisionally concluded there was an agreement with the Commission proposal for the empowerments to adopt DAs, including under the urgency procedure where proposed, and for the empowerments to adopt IAs.

- 83. **Act 160,** 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: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerment to adopt DAs.
- 84. **Act 161,** Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients: The Presidency provisionally concluded that there was an agreement with the Commission proposal for two of the empowerments to adopt DAs, including under the urgency procedure where proposed. For one empowerment, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs and for the possibility to adopt immediately applicable IAs.
- 85. **Act 162,** Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms: The Presidency provisionally concluded that there was an agreement with the Commission proposal for one of the empowerments to adopt DAs. For the other empowerment to adopt DAs, the Presidency provisionally concluded to come back with drafting suggestions amending the Commission proposal to exclude from the empowerment one part of an Annex.
- 86. **Act 163,** Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters: The Presidency provisionally concluded that there was an agreement with the Commission proposal for all empowerments to adopt DAs, including under the urgency procedure where proposed, except for one empowerment. For that empowerment, the Presidency provisionally concluded to revert back with drafting suggestions amending the Commission proposal to provide for IAs.

- 87. **Act 164,** Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs.
- 88. **Act 165,** Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs and for the empowerments to adopt IAs, including for immediately applicable IAs.
- 89. **Act 166,** Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC: The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs, including under the urgency procedure where proposed, and for the empowerments to adopt IAs.
- 90. Act 167, Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation): The Presidency provisionally concluded that there was an agreement with the Commission proposal for the empowerments to adopt DAs, including under the urgency procedure where proposed, and for the empowerments to adopt IAs.

# **III. CONCLUSIONS**

- 91. The Presidency considers that a significant further progress has been made on the RPS Adaptation Proposal with provisional support for an approach on 90 acts in Sections VII, XI and XII of the Annex to that proposal. Under the Estonian Presidency the first examination of all Sections of the Annex to Commission proposal COM (2016)799 final was completed by the Friends of Presidency group.
- 100. This considerably moves forward the process towards achieving the objectives of the IIA on Better Law-Making, in particular the need to give high priority to the prompt alignment of all basic acts which still refer to the regulatory procedure with scrutiny, a need acknowledged by the three institutions (paragraph 27 of the IIA).

<u>COREPER and Council</u> are invited to take note of the above Presidency progress report.