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<u>Notice No</u>	<u>Contents</u>	<u>Page</u>
III <i>Preparatory acts</i>		
Council		
2010/C 122 E/01	Position (EU) No 4/2010 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council concerning the rights of passengers in bus and coach transport and amending Regulation (EC) No 2006/2004 Adopted by the Council on 11 March 2010 ⁽¹⁾	1
2010/C 122 E/02	Position (EU) No 5/2010 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council concerning the rights of passengers when travelling by sea and inland waterway and amending Regulation (EC) No 2006/2004 Adopted by the Council on 11 March 2010 ⁽¹⁾	19
2010/C 122 E/03	Position (EU) No 6/2010 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 Adopted by the Council on 15 March 2010 ⁽¹⁾	38

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⁽¹⁾ Text with EEA relevance

III

(Preparatory acts)

COUNCIL

POSITION (EU) No 4/2010 OF THE COUNCIL AT FIRST READING

**with a view to the adoption of a Regulation of the European Parliament and of the Council
concerning the rights of passengers in bus and coach transport and amending
Regulation (EC) No 2006/2004**

Adopted by the Council on 11 March 2010

(Text with EEA relevance)

(2010/C 122 E/01)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE
EUROPEAN UNION,

- (2) Since the bus or coach passenger is the weaker party to the transport contract, all passengers should be granted a minimum level of protection.

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91(1) thereof,

Having regard to the proposal from the European Commission,

- (3) Union measures to improve passengers' rights in the bus and coach transport sector should take account of the specific characteristics of this sector, which consists largely of small -and medium-sized undertakings.

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of the Regions,

- (4) Taking into account the specific characteristics of special regular services and own-account transport operations, these types of transport should be left outside the scope of this Regulation. Special regular services should include dedicated services for the carriage of disabled persons and persons with reduced mobility, carriage of workers between home and work, carriage to and from the educational institution for school pupils and students.

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Action by the Union in the field of bus and coach transport should aim, among other things, at ensuring a high level of protection for passengers, that is comparable with other modes of transport, wherever they travel. Moreover, full account should be taken of the requirements of consumer protection in general.

- (5) Taking into account the specific characteristics of urban, suburban and regional regular services, Member States should be granted the right to exempt these types of transport from the application of a significant part of this Regulation. In order to identify urban, suburban and regional regular services, Member States should take into account criteria such as distance, frequency of services, number of scheduled stops, type of buses or coaches employed, ticketing schemes, fluctuations in passenger numbers between services in peak and off-peak periods, bus codes and timetables.

⁽¹⁾ Opinion of 16 July of 2009 (OJ C 317, 23.12.2009, p. 99).

⁽²⁾ Position of the European Parliament of 23 April 2009 (not yet published in the Official Journal) and position of the Council of 11 March 2010. Position of the European Parliament of ... (not yet published in the Official Journal).

- (6) Passengers and, as a minimum, persons whom the passenger had, or would have had, a legal duty to maintain should enjoy adequate protection in the event of accidents arising out of the use of the bus or coach, taking into account Directive 2009/103/EC of the European Parliament and of the Council of 16 September 2009 relating to insurance against civil liability in respect of the use of motor vehicles and the enforcement of the obligation to insure against such liability ⁽¹⁾.
- (7) In choosing the national law applicable to compensation for death or personal injury as well as for loss of or damage to luggage due to accidents arising out of the use of the bus or coach, Regulation (EC) No 864/2007 of the European Parliament and of the Council of 11 July 2007 on the law applicable to non-contractual obligations (Rome II) ⁽²⁾ and Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I) ⁽³⁾ should be taken into account.
- (8) Passengers should, in addition to compensation in accordance with applicable national law in the event of death or personal injury or loss of or damage to luggage due to accidents arising out of the use of the bus or coach, be entitled to assistance with regard to their immediate practical needs following an accident. Such assistance could include first aid, accommodation, food, clothes and transport.
- (9) Bus and coach passenger services should benefit citizens in general. Consequently, disabled persons and persons with reduced mobility, whether caused by disability, age or any other factor, should have opportunities for using bus and coach services that are comparable to those of other citizens. Disabled persons and persons with reduced mobility have the same rights as all other citizens with regard to free movement, freedom of choice and non-discrimination.
- (10) In the light of Article 9 of the United Nations Convention on the Rights of Persons with Disabilities and in order to give disabled persons and persons with reduced mobility opportunities for bus and coach travel comparable to those of other citizens, rules for non-discrimination and assistance during their journey should be established. Those persons should therefore be accepted for carriage and not refused transport on the grounds of their disability or reduced mobility, except for reasons which are justified on the grounds of safety or of the design of vehicles or infrastructure. Within the framework of relevant legislation for the protection of workers, disabled persons and persons with reduced mobility should enjoy the right to assistance at terminals and on board vehicles. In the interest of social inclusion, the persons concerned should receive the assistance free of charge. Carriers should establish access conditions, preferably using the European Standardisation system.
- (11) In deciding on the design of new terminals, and as part of major refurbishments, terminal managing bodies should, where possible, take into account the needs of disabled persons and persons with reduced mobility. In any case, terminal managing bodies should designate points where such persons can notify their arrival and need for assistance.
- (12) In order to respond to the needs of disabled persons and persons with reduced mobility, staff should be adequately trained. With a view to facilitating the mutual recognition of national qualifications of drivers, disability awareness training could be provided as a part of the initial qualification or periodic training as referred to in Directive 2003/59/EC of the European Parliament and of the Council of 15 July 2003 on the initial qualification and periodic training of drivers of certain road vehicles for the carriage of goods or passengers ⁽⁴⁾. In order to ensure coherence between the introduction of the training requirements and the time-limits set out in that Directive, a possibility for exemption during a limited period of time should be allowed.
- (13) Where possible, organisations representative of disabled persons or persons with reduced mobility should be consulted or involved in the organisation of the disability-related training.
- (14) Rights of bus and coach passengers should include the receipt of information regarding the service before and during the journey. All essential information provided to bus and coach passengers should also be provided in alternative formats accessible to disabled persons and persons with reduced mobility.
- (15) This Regulation should not restrict the rights of carriers to seek compensation from any person, including third parties, in accordance with the applicable national law.
- (16) Inconvenience experienced by passengers due to cancellation or long delay of their journey should be reduced. To this end, passengers departing from terminals should be adequately looked after and informed. Passengers should also be able to cancel their journey and have their tickets reimbursed or to continue their journey or to obtain re-routing under satisfactory conditions.

⁽¹⁾ OJ L 263, 7.10.2009, p. 11.

⁽²⁾ OJ L 199, 31.7.2007, p. 40.

⁽³⁾ OJ L 177, 4.7.2008, p. 6.

⁽⁴⁾ OJ L 226, 10.9.2003, p. 4.

- (17) Through their professional associations, carriers should cooperate in order to adopt arrangements at national or European level with the involvement of stakeholders, professional associations and associations of customers, passengers and disabled persons, aiming to improve care for passengers, especially in the event of cancellations and long delays.
- (18) This Regulation should not affect the rights of passengers established by Council Directive 90/314/EEC of 13 June 1990 on package travel, package holidays and package tours ⁽¹⁾. This Regulation should not apply in cases where a package tour is cancelled for reasons other than cancellation of the bus or coach transport service.
- (19) Passengers should be fully informed of their rights under this Regulation, so that they can effectively exercise those rights.
- (20) Passengers should be able to exercise their rights by means of appropriate complaint procedures implemented by carriers or, as the case may be, by submission of complaints to the body or bodies designated to that end by the relevant Member State.
- (21) Member States should ensure compliance with this Regulation and designate a competent body or bodies to carry out supervision and enforcement tasks. This does not affect the rights of passengers to seek legal redress from courts under national law.
- (22) Taking into account the procedures established by Member States for the submission of complaints, a complaint concerning assistance should preferably be addressed to the body or bodies designated for the enforcement of this Regulation in the Member State where the boarding point or alighting point is situated.
- (23) Member States should lay down penalties applicable to infringements of this Regulation and ensure that those penalties are applied. Those penalties should be effective, proportionate and dissuasive.
- (24) Since the objectives of this Regulation, namely to ensure an equivalent level of protection of and assistance to passengers in bus and coach transport throughout the Member States, cannot sufficiently be achieved by the Member States and can therefore by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (25) This Regulation should be without prejudice to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ⁽²⁾.
- (26) The enforcement of this Regulation should be based on 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 law (the Regulation on consumer protection cooperation) ⁽³⁾. That Regulation should therefore be amended accordingly.
- (27) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union, as referred to in Article 6 of the Treaty on European Union, bearing in mind also Council Directive 2000/43/EC of 29 June 2000 implementing the principle of equal treatment between persons irrespective of racial or ethnic origin ⁽⁴⁾ and Council Directive 2004/113/EC of 13 December 2004 implementing the principle of equal treatment between men and women in the access to and supply of goods and services ⁽⁵⁾.

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation establishes rules for bus and coach transport as regards the following:

- (a) non-discrimination between passengers with regard to transport conditions offered by carriers;
- (b) rights of passengers in the event of accidents arising out of the use of the bus or coach resulting in death or personal injury or loss of or damage to luggage;
- (c) non-discrimination and mandatory assistance for disabled persons and persons with reduced mobility;
- (d) rights of passengers in cases of cancellation or delay;
- (e) minimum information to be provided to passengers;

⁽²⁾ OJ L 281, 23.11.1995, p. 31.

⁽³⁾ OJ L 364, 9.12.2004, p. 1.

⁽⁴⁾ OJ L 180, 19.7.2000, p. 22.

⁽⁵⁾ OJ L 373, 21.12.2004, p. 37.

⁽¹⁾ OJ L 158, 23.6.1990, p. 59.

- (f) handling of complaints;
- (g) general rules on enforcement.

Article 2

Scope

1. This Regulation shall apply to passengers travelling with regular services:
 - (a) where the boarding point of the passenger is situated in the territory of a Member State; or
 - (b) where the boarding point of the passenger is situated outside the territory of a Member State and the alighting point of the passenger is situated in the territory of a Member State.
2. In addition, with the exception of Chapters III to VI, this Regulation shall apply to passengers travelling with occasional services where the initial boarding point or the final alighting point of the passenger is situated in the territory of a Member State.
3. This Regulation shall not apply to special regular services and own-account transport operations.
4. With the exception of Articles 4(2), 9 and 10(1), Member States may exempt urban, suburban and regional regular services, including cross-border services of that type, from the application of this Regulation.
5. With the exception of Articles 4(2), 9 and 10(1), Member States may, on a transparent and non-discriminatory basis, exempt domestic regular services from the application of this Regulation. Such exemptions may be granted for a period no longer than five years, which may be renewed twice.
6. For a maximum period of five years, Member States may, on a transparent and non-discriminatory basis, exempt from the application of this Regulation particular regular services because a significant part of the regular service, including at least one scheduled stop, is operated outside the Union. Such exemptions may be renewed.
7. Member States shall inform the Commission of exemptions of different types of services granted pursuant to paragraphs 4, 5 and 6. The Commission shall take appropriate action if such an exemption is deemed not to be in accordance with the provisions of this Article. By ... (*), the Commission shall submit to the European Parliament and the Council a report on exemptions granted pursuant to paragraphs 4, 5 and 6.
8. Nothing in this Regulation shall be understood as constituting technical requirements imposing obligations on carriers

(*) Five years after the date of application of this Regulation.

or terminal managing bodies to modify or replace buses or coaches or infrastructure or equipment at bus stops and terminals.

Article 3

Definitions

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

- (a) 'regular services' means services which provide for the carriage of passengers by bus or coach at specified intervals along specified routes, passengers being picked up and set down at predetermined stopping points;
- (b) 'special regular services' means regular services, by whomsoever organised, which provide for the carriage by bus or coach of specified categories of passengers to the exclusion of other passengers;
- (c) 'own-account transport operations' means operations carried out by bus or coach for non-commercial and non-profit-making purposes by a natural or legal person, whereby:
 - the transport activity is only an ancillary activity for that natural or legal person, and
 - the vehicles used are the property of that natural or legal person or have been obtained by that person on deferred terms or have been the subject of a long-term leasing contract and are driven by a member of the staff of the natural or legal person or by the natural person himself or by personnel employed by, or put at the disposal of, the undertaking under a contractual obligation;
- (d) 'occasional services' means services which do not fall within the definition of regular services and the main characteristic of which is the carriage by bus or coach of groups of passengers constituted on the initiative of the customer or the carrier himself;
- (e) 'transport contract' means a contract of carriage between a carrier and a passenger for the provision of one or more regular or occasional services;
- (f) 'ticket' means a valid document or other evidence of a transport contract;
- (g) 'carrier' means a natural or legal person, other than a tour operator or ticket vendor, offering transport by regular or occasional services to the general public;
- (h) 'performing carrier' means a natural or legal person other than the carrier, who actually performs the carriage wholly or partially;

- (i) 'ticket vendor' means any intermediary concluding transport contracts on behalf of a carrier;
- (j) 'travel agent' means any intermediary acting on behalf of a passenger for the conclusion of transport contracts;
- (k) 'tour operator' means an organiser or retailer, other than the carrier, within the meaning of Article 2(2) and (3) of Directive 90/314/EEC;
- (l) 'disabled person' or 'person with reduced mobility' means any person whose mobility when using transport is reduced as a result of any physical disability (sensory or locomotory, permanent or temporary), intellectual disability or impairment, or any other cause of disability, or as a result of age, and whose situation needs appropriate attention and adaptation to his particular needs of the services made available to all passengers;
- (m) 'access conditions' means relevant standards, guidelines and information on the accessibility of buses and/or of designated terminals including their facilities for disabled persons or persons with reduced mobility;
- (n) 'reservation' means a booking of a seat on board a bus or coach for a regular service at a specific departure time;
- (o) 'terminal' means a staffed terminal where according to the specified route a regular service is scheduled to stop for passengers to board or alight, equipped with facilities such as a check-in counter, waiting room or ticket office;
- (p) 'bus stop' means any point other than a terminal where according to the specified route a regular service is scheduled to stop for passengers to board or alight;
- (q) 'terminal managing body' means an organisational entity in a Member State responsible for the management of a designated terminal;
- (r) 'cancellation' means the non-operation of a regular service which was previously scheduled;
- (s) 'delay' means a difference between the time the regular service was scheduled to depart in accordance with the published timetable and the time of its actual departure.

Article 4

Tickets and non-discriminatory contract conditions

1. Carriers shall provide a ticket to the passenger, unless other documents give entitlement to transport. A ticket may be issued in an electronic format.
2. Without prejudice to social tariffs, the contract conditions and tariffs applied by carriers shall be offered to the general public without any direct or indirect discrimination based on

the nationality of the final customer or on the place of establishment of the carriers, or ticket vendors within the Union.

Article 5

Other performing parties

1. If the performance of the obligations under this Regulation has been entrusted to a performing carrier, ticket vendor or any other person, the carrier, travel agent, tour operator or terminal managing body, who has entrusted such obligations, shall nevertheless be liable for the acts and omissions of that performing party.

2. In addition, the party to whom the performance of an obligation has been entrusted by the carrier, travel agent, tour operator or terminal managing body shall be subject to the provisions of this Regulation with regard to the obligation entrusted.

Article 6

Exclusion of waiver

1. Obligations to passengers pursuant to this Regulation shall not be limited or waived, in particular by a derogation or restrictive clause in the transport contract.

2. Carriers may offer contract conditions that are more favourable for the passenger than the conditions laid down in this Regulation.

CHAPTER II

COMPENSATION AND ASSISTANCE IN THE EVENT OF ACCIDENTS

Article 7

Death or personal injury to passengers and loss of or damage to luggage

1. Passengers shall, in accordance with applicable national law, be entitled to compensation for death or personal injury as well as to loss of or damage to luggage due to accidents arising out of the use of the bus or coach. In case of death of a passenger, this right shall as a minimum apply to persons whom the passenger had, or would have had, a legal duty to maintain.

2. The amount of compensation shall be calculated in accordance with applicable national law. Any maximum limit provided by national law to the compensation for death and personal injury or loss of or damage to luggage shall on each distinct occasion not be less than:

- (a) EUR 220 000 per passenger;

- (b) with regard to urban, suburban and regional regular or occasional services EUR 500 per item of luggage and with regard to all other regular or occasional services EUR 1 200 per item of luggage. In the event of damage to wheelchairs, other mobility equipment or assistive devices the amount of compensation shall always be equal to the cost of replacement or repair of the equipment lost or damaged.

Article 8

Immediate practical needs of passengers

In the event of an accident arising out of the use of the bus or coach, the carrier shall provide reasonable assistance with regard to the passengers' immediate practical needs following the accident. Any assistance shall not constitute recognition of liability.

CHAPTER III

RIGHTS OF DISABLED PERSONS AND PERSONS WITH REDUCED MOBILITY

Article 9

Right to transport

1. Carriers, travel agents and tour operators shall not refuse to accept a reservation from, to issue or otherwise provide a ticket to or to take on board a person on the grounds of disability or of reduced mobility.
2. Reservations and tickets shall be offered to disabled persons and persons with reduced mobility at no additional cost.

Article 10

Exceptions and special conditions

1. Notwithstanding Article 9(1), carriers, travel agents and tour operators may refuse to accept a reservation from, to issue or otherwise provide a ticket to or to take on board a person on the grounds of disability or of reduced mobility:
 - (a) in order to meet applicable safety requirements established by international, Union or national law, or in order to meet health and safety requirements established by the competent authorities;
 - (b) where the design of the vehicle or the infrastructure, including bus stops and terminals, makes it physically impossible to take on board, alight or carry the disabled person or person with reduced mobility in a safe and operationally feasible manner.
2. In the event of a refusal to accept a reservation or to issue or otherwise provide a ticket on the grounds referred to in paragraph 1, carriers, travel agents and tour operators shall make reasonable efforts to inform the person concerned about an acceptable alternative service operated by the carrier.

3. If a disabled person or a person with reduced mobility, who holds a reservation or has a ticket and has complied with the requirements of Article 14(1)(a), is nonetheless refused permission to board on the grounds of his disability or reduced mobility, that person and any accompanying person pursuant to paragraph 4 of this Article shall be offered the choice between:

- (a) the right to reimbursement, and where relevant a return service free of charge to the first point of departure, as set out in the transport contract, at the earliest opportunity; and
- (b) except where not feasible, continuation of the journey or re-routing by reasonable alternative transport services to the place of destination set out in the transport contract.

The right to reimbursement of the money paid for the ticket shall not be affected by the failure to notify in accordance with Article 14(1) (a).

4. Under the same conditions set out in paragraph 1(a), a carrier, travel agent or tour operator may require that a disabled person or person with reduced mobility be accompanied by another person who is capable of providing the assistance required by the disabled person or person with reduced mobility, if this is strictly necessary. Such an accompanying person shall be transported free of charge and, where feasible, seated next to the disabled person or person with reduced mobility.

5. When carriers, travel agents or tour operators have recourse to paragraph 1, they shall immediately inform the disabled person or person with reduced mobility of the reasons therefor, and, upon request, inform the person in question in writing within five working days of the request.

Article 11

Accessibility and information

1. In cooperation with organisations representative of disabled persons or persons with reduced mobility, carriers and terminal managing bodies shall, where appropriate through their organisations, establish, or have in place, non-discriminatory access conditions for the transport of disabled persons and persons with reduced mobility.
2. The access conditions provided for in paragraph 1 shall be made publicly available by carriers and terminal managing bodies physically or on the Internet in the same languages as those in which information is generally made available to all passengers.
3. Tour operators shall make available the access conditions provided for in paragraph 1 which apply to journeys included in package travel, package holidays and package tours which they organise, sell or offer for sale.

4. The information on access conditions referred to in paragraphs 2 and 3 shall be physically distributed at the request of the passenger.

5. Carriers, travel agents and tour operators shall ensure that all relevant general information concerning the journey and the conditions of carriage is available in appropriate and accessible formats for disabled persons and persons with reduced mobility including, where applicable, online booking and information. The information shall be physically distributed at the request of the passenger.

Article 12

Designation of terminals

Member States shall designate bus and coach terminals where assistance for disabled persons and persons with reduced mobility shall be provided. Member States shall inform the Commission thereof. The Commission shall make available a list of the designated bus and coach terminals on the Internet.

Article 13

Right to assistance at designated terminals and on board buses and coaches

1. Subject to the access conditions provided for in Article 11(1), carriers and terminal managing bodies shall, within their respective areas of competence, at terminals designated by Member States, provide assistance free of charge to disabled persons and persons with reduced mobility as specified in part (a) of Annex I.

2. Subject to the access conditions provided for in Article 11(1), carriers shall, on board buses and coaches, provide assistance free of charge to disabled persons and persons with reduced mobility as specified in part (b) of Annex I.

Article 14

Conditions under which assistance is provided

1. Carriers and terminal managing bodies shall cooperate in order to provide assistance to disabled persons and persons with reduced mobility on condition that:

- (a) the person's need for such assistance is notified to carriers, terminal managing bodies, travel agents or tour operators at the latest two working days before the assistance is needed; and
- (b) the persons concerned present themselves at the designated point:
 - (i) at the time stipulated in advance by the carrier which shall be no more than 60 minutes before the published departure time; or
 - (ii) if no time is stipulated, no later than 30 minutes before the published departure time.

2. In addition to paragraph 1, disabled persons or persons with reduced mobility shall notify the carrier, travel agent or tour operator at the time of reservation or advance purchase of the ticket of their specific seating needs, provided that the need is known at that time.

3. Carriers, terminal managing bodies, travel agents and tour operators shall take all measures necessary to facilitate the receipt of notifications of the need for assistance made by disabled persons or persons with reduced mobility. This obligation shall apply at all designated terminals and their points of sale including sale by telephone and via the Internet.

4. If no notification is made in accordance with paragraphs 1(a) and 2, carriers, terminal managing bodies, travel agents and tour operators shall make every reasonable effort to ensure that the assistance is provided in such a way that the disabled person or person with reduced mobility is able to board the departing service, to change to the corresponding service or to alight from the arriving service for which he has purchased a ticket.

5. The terminal managing body shall designate a point inside or outside the terminal at which disabled persons or persons with reduced mobility can announce their arrival and request assistance. The point shall be clearly signposted and shall offer basic information about the terminal and assistance provided, in accessible formats.

Article 15

Transmission of information to a third party

If travel agents or tour operators receive a notification referred to in Article 14(1)(a) they shall, within their normal office hours, transfer the information to the carrier or terminal managing body as soon as possible.

Article 16

Training

1. Carriers and, where appropriate, terminal managing bodies shall establish disability-related training procedures, including instructions, and ensure that:

- (a) their personnel, other than drivers, including those employed by any other performing party, providing direct assistance to disabled persons and persons with reduced mobility are trained or instructed as described in Annex II, part a) and b); and
- (b) their personnel, including drivers, who deal directly with the travelling public or with issues related to the travelling public, are trained or instructed as described in Annex II, part a).

2. A Member State may for a maximum period of two years from ... (*) grant an exemption from the application of paragraph(1)(b) with regard to training of drivers.

(*) Date of application of this Regulation.

*Article 17***Compensation in respect of wheelchairs and other mobility equipment**

1. Carriers and terminal managing bodies shall be liable where they have caused loss of or damage to wheelchairs, other mobility equipment or assistive devices, resulting from the provision of assistance. The loss or damage shall be compensated by the carrier or terminal managing body liable for that loss or damage.
2. The compensation referred to in paragraph 1 shall be equal to the cost of replacement or repair of the equipment or devices lost or damaged.
3. Where necessary, every effort shall be undertaken to rapidly provide temporary replacement equipment or devices. The wheelchairs, other mobility equipment or assistive devices shall, where possible, have technical and functional features similar to those lost or damaged.

*Article 18***Exemptions**

1. Without prejudice to Article 2(4), Member States may exempt domestic regular services from the application of all or some of the provisions of this Chapter, provided that they ensure that the level of protection of disabled persons and persons with reduced mobility under their national rules is at least the same as under this Regulation.
2. Member States shall inform the Commission of exemptions granted pursuant to paragraph 1. The Commission shall take appropriate action if such an exemption is deemed not to be in accordance with the provisions of this Article. By (*), the Commission shall submit to the European Parliament and the Council a report on exemptions granted pursuant to paragraph 1.

CHAPTER IV

PASSENGER RIGHTS IN THE EVENT OF CANCELLATION OR DELAY*Article 19***Continuation, re-routing and reimbursement**

1. Where a carrier reasonably expects a regular service to be cancelled or delayed in departure from a terminal for more than 120 minutes, the passenger shall immediately be offered the choice between:
 - (a) continuation or re-routing to the final destination, under comparable conditions, as set out in the transport contract, at the earliest opportunity;
 - (b) reimbursement of the ticket price, and, where relevant, a return service by bus or coach free of charge to the first point of departure, as set out in the transport contract, at the earliest opportunity.

(*) Five years after the date of application of this Regulation.

2. Where a regular service is cancelled or delayed in departure from a bus stop for more than 120 minutes, passengers shall have the right to such continuation or re-routing or reimbursement of the ticket price from the carrier.

3. The payment of reimbursement provided for in paragraphs 1(b) and 2 shall be made within 14 days after the offer has been made or request has been received. The payment shall cover the full cost of the ticket at the price at which it was purchased, for the part or parts of the journey not made, and for the part or parts already made if the journey no longer serves any purpose in relation to the passenger's original travel plan. In case of travel passes or season tickets the payment shall be equal to its proportional part of the full cost of the pass or ticket. The reimbursement shall be paid in money, unless the passenger accepts another form of reimbursement.

*Article 20***Information**

1. In the event of cancellation or delay in departure of a regular service, passengers departing from terminals shall be informed by the carrier or, where appropriate, the terminal managing body, of the situation as soon as possible and in any event no later than 30 minutes after the scheduled departure time, and of the estimated departure time as soon as this information is available.
2. If passengers miss, according to the timetable, a connecting service due to a cancellation or delay, the carrier or, where appropriate, the terminal managing body, shall make reasonable efforts to inform the passengers concerned of alternative connections.
3. The carrier or, where appropriate, the terminal managing body, shall ensure that disabled persons and persons with reduced mobility receive the information required under paragraphs 1 and 2 in accessible formats.

*Article 21***Assistance in case of cancelled or delayed departures**

For a journey of a scheduled duration of more than three hours the carrier shall, in case of cancellation or delay in departure from a terminal of more than two hours, offer the passenger free of charge:

- (a) snacks, meals or refreshments in reasonable relation to the waiting time or delay, provided they are available on the bus or in the terminal, or can reasonably be supplied;
- (b) assistance to find a hotel room or other accommodation as well as assistance to arrange transport between the terminal and the place of accommodation in cases where a stay of one or more nights becomes necessary.

In applying this Article the carrier shall pay particular attention to the needs of disabled persons and persons with reduced mobility and any accompanying persons.

Article 22

Further claims

Nothing in this Chapter shall preclude passengers from seeking damages in accordance with national law before national courts in respect of loss resulting from cancellation or delay of regular services.

CHAPTER V

GENERAL RULES ON INFORMATION AND COMPLAINTS

Article 23

Right to travel information

Carriers and terminal managing bodies shall, within their respective areas of competence, provide passengers with adequate information throughout their travel. Where feasible this information shall be provided in accessible formats upon request.

Article 24

Information on passenger rights

1. Carriers and terminal managing bodies shall, within their respective areas of competence, ensure that passengers are provided with appropriate and comprehensible information regarding their rights under this Regulation at the latest on departure. The information shall be provided at terminals and where applicable, on the Internet. At the request of a disabled person or person with reduced mobility the information shall be provided in an accessible format. This information shall include contact details of the enforcement body or bodies designated by the Member State pursuant to Article 27(1).

2. In order to comply with the information requirement referred to in paragraph 1, carriers and terminal managing bodies may use a summary of the provisions of this Regulation prepared by the Commission in all the official languages of the institutions of the European Union and made available to them.

Article 25

Complaints

Carriers shall set up or have in place a complaint handling mechanism for the rights and obligations set out in Articles 4, 8 and 9 to 24.

Article 26

Submission of complaints

If a passenger covered by this Regulation wants to make a complaint to the carrier with regard to Articles 4, 8 and 9 to 24, he shall submit it within three months from the date on which the regular service was performed or when a regular service should have been performed. Within one month of

receiving the complaint, the carrier shall give notice to the passenger that his complaint has been substantiated, rejected or is still being considered. The time taken to provide the final reply shall not be longer than three months from the receipt of the complaint.

CHAPTER VI

ENFORCEMENT AND NATIONAL ENFORCEMENT BODIES

Article 27

National enforcement bodies

1. Each Member State shall designate a new or existing body or bodies responsible for the enforcement of this Regulation as regards regular services from points situated on its territory and regular services from a third country to such points. Each body shall take the measures necessary to ensure compliance with this Regulation.

Each body shall, in its organisation, funding decisions, legal structure and decision-making, be independent of carriers, tour operators and terminal managing bodies.

2. Member States shall inform the Commission of the body or bodies designated in accordance with this Article.

3. Any passenger may submit a complaint, in accordance with national law, to the appropriate body designated under paragraph 1, or to any other appropriate body designated by a Member State, about an alleged infringement of this Regulation.

A Member State may decide:

- (a) that the passenger as a first step shall submit a complaint with regard to Articles 4, 8 and 9 to 24 to the carrier; and/or
- (b) that the national enforcement body or any other appropriate body designated by the Member State shall act as an appeal body for complaints not resolved under Article 26.

Article 28

Report on enforcement

By 1 June ... (*) and every two years thereafter, the enforcement bodies designated pursuant to Article 27(1) shall publish a report on their activity in the previous two calendar years, containing in particular a description of actions taken in order to implement this Regulation and statistics on complaints and sanctions applied.

Article 29

Cooperation between enforcement bodies

National enforcement bodies as referred to in Article 27(1) shall, whenever appropriate, exchange information on their work and decision-making principles and practices. The Commission shall support them in this task.

(*) Two years after the date of the application of this Regulation.

Article 30

Penalties

Member States shall lay down rules on penalties applicable to infringements of the provisions of this Regulation and shall take all the measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those rules and measures to the Commission by ... (*) and shall notify it without delay of any subsequent amendment affecting them.

CHAPTER VII

FINAL PROVISIONS

Article 31

Report

The Commission shall report to the European Parliament and the Council by ... (**), on the operation and effects of this Regulation. The report shall be accompanied, where necessary, by legislative proposals implementing in further detail the provisions of this Regulation, or amending it.

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

Done at ...

For the European Parliament

The President

...

Article 32

Amendment to Regulation (EC) No 2006/2004

In the Annex to Regulation (EC) No 2006/2004 the following point is added:

‘18. Regulation (EU) No .../2010 of the European Parliament and of the Council of ... on the rights of passengers in bus and coach transport (*).

(*) OJ ...’

Article 33

Entry into force

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

It shall apply from ... (***).

Article 34

Publication

This Regulation shall be published in the *Official Journal of the European Union*.

For the Council

The President

...

(*) Date of the application of this Regulation.

(**) Three years after the date of application of this Regulation.

(***) Two years after the date of publication.

ANNEX I

Assistance provided to disabled persons and persons with reduced mobility**(a) Assistance at designated terminals**

Assistance and arrangements necessary to enable disabled persons and persons with reduced mobility to:

- communicate their arrival at the terminal and their request for assistance at designated points;
- move from the designated point to the check-in counter, waiting room and embarkation area;
- board the vehicle, with the provision of lifts, wheelchairs or other assistance needed, as appropriate;
- load their luggage;
- retrieve their luggage;
- alight from the vehicle;
- carry a recognised assistance dog on board a bus or coach;
- proceed to the seat.

(b) Assistance on board

Assistance and arrangements necessary to enable disabled persons and persons with reduced mobility to:

- be provided with essential information on a journey in accessible formats subject to request made by the passenger;
- board/alight during pauses in a journey, if there are personnel other than the driver on board.

ANNEX II

Disability-related training**(a) Disability-awareness training**

Training of staff that deal directly with the travelling public includes:

- awareness of and appropriate responses to passengers with physical, sensory (hearing and visual), hidden or learning disabilities, including how to distinguish between the different abilities of persons whose mobility, orientation, or communication may be reduced;
- barriers faced by disabled persons and persons with reduced mobility, including attitudinal, environmental/physical and organisational barriers;
- recognised assistance dogs, including the role and the needs of an assistance dog;
- dealing with unexpected occurrences;
- interpersonal skills and methods of communication with deaf people and people with hearing impairments, people with visual impairments, people with speech impairments, and people with a learning disability;
- how to handle wheelchairs and other mobility aids carefully so as to avoid damage (if any, for all staff who are responsible for luggage handling).

(b) Disability-assistance training

Training of staff directly assisting disabled persons and persons with reduced mobility includes:

- how to help wheelchair users make transfers into and out of a wheelchair;
 - skills for providing assistance to disabled persons and persons with reduced mobility travelling with a recognised assistance dog, including the role and the needs of those dogs;
 - techniques for escorting visually impaired passengers and for the handling and carriage of recognised assistance dogs;
 - an understanding of the types of equipment which can assist disabled persons and persons with reduced mobility and a knowledge of how to handle such an equipment;
 - the use of boarding and alighting assistance equipment used and knowledge of the appropriate boarding and alighting assistance procedures that safeguard the safety and dignity of disabled persons and persons with reduced mobility;
 - understanding of the need for reliable and professional assistance. Also awareness of the potential of certain disabled passengers to experience feelings of vulnerability during travel because of their dependence on the assistance provided;
 - a knowledge of first aid.
-

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

On 4 December 2008, the Commission presented the proposal for a Regulation of the European Parliament and the Council concerning the rights of passengers in bus and coach transport and amending Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws ⁽¹⁾.

On 23 April 2009, the European Parliament voted its opinion at first reading ⁽²⁾.

On 17 December 2009, the Council reached a political agreement on the draft Regulation. Following legal/linguistic revision, the Council adopted its position at first reading on 11 March 2010, in accordance with the ordinary legislative procedure laid down in Article 294 of the Treaty on the Functioning of the European Union.

In carrying out its work, the Council took account of the opinion of the European Economic and Social Committee. The Committee of Regions declined to give an opinion.

II. ANALYSIS OF THE POSITION AT FIRST READING

1. General

The proposal for a Regulation of the European Parliament and the Council concerning the rights of passengers in bus and coach transport forms part of the general objective of the European Union to ensure equal treatment of passengers, irrespective of the mode of transport they have chosen to travel with. Legislation of similar nature has already been adopted for passengers travelling by air ⁽³⁾ or by rail ⁽⁴⁾. It contains provisions on liability in the event of death or injury of passengers and loss of or damage to their luggage, automatic solutions when travel is interrupted, treatment of complaints and means of redress, passenger information and other initiatives. Furthermore, it lays down rules on information and assistance to disabled persons and persons with reduced mobility (PRMs).

Although the Council agreed with the Commission as regards the objective of the proposal, the Council's approach involved major adaptations of the original proposal. A number of the proposed provisions were not acceptable because they imposed too heavy administrative burdens ensuing costs on carriers and national administrations, without bringing an added value for passengers that would outweigh these inconveniences. Others were redrafted taking into account the different legislations in place in Member States, in order to avoid conflict between this draft Regulation proposal and existing national and European legislation. Finally, other provisions were redrafted with a view to simplifying and clarifying the Regulation.

Resulting from this approach, the Council first reading position modifies, to a certain extent, the original Commission proposal by redrafting it and deleting several provisions of the text. This implies that all amendments introduced in the European Parliament's first reading opinion related to these deleted provisions were not accepted by the Council.

The Council aims at a balanced solution that takes into account the rights of passengers as well as the need to ensure the economic viability of the operators of the bus and coach industry, which consists largely of small and medium-sized undertakings, and therefore integrated EP amendment 3 into its first reading position.

⁽¹⁾ Doc. 16933/08.

⁽²⁾ A6-0250/2009.

⁽³⁾ Regulation (EC) No 261/2004 of the European Parliament and of the Council of 11 February 2004 establishing common rules on compensation and assistance to passengers in the event of denied boarding and of cancellation or long delay of flights, and repealing Regulation (EEC) No 295/91, OJ L 46, 17.2.2004, p. 1, and Regulation (EC) No 1107/2006 of the European Parliament and of the Council of 5 July 2006 concerning the rights of disabled persons and persons with reduced mobility when travelling by air, OJ L 204, 26.7.2006, p. 1.

⁽⁴⁾ Regulation (EC) No 1371/2007 of the European Parliament and of the Council of 23 October 2007 on rail passengers' rights and obligations, OJ L 315, 3.12.2007, p. 14.

2. Key policy issues

(i) *Scope of application*

In the Commission's initial proposal, the Regulation was to be applied in general to the carriage of passengers by bus and/or coach undertakings by means of regular services. Member States were only allowed to exempt urban, suburban and regional transport covered by public service contracts, if such contracts ensured a comparable level of passenger rights to that required in the Regulation. In addition, the European Parliament introduced one amendment allowing Member States to exclude under the above-mentioned condition from the scope the urban and suburban transport but not the regional transport.

The Council could not accept the scope as proposed by the Commission, nor the EP amendments related to it (amendments 1, 2 and 81), because it considered that urban, sub-urban and regional transport fall within the framework of subsidiarity.

Including regional transport into the scope, as proposed by the European Parliament, might pose problems both for passengers and for the industry. In big urban areas companies are usually operating a whole transport network including bus services, subway services, commuter trains and tram services. Frequently, all these services are of urban, suburban and regional character. Restricting the exemption only to urban and suburban services would mean that parts of these networks would be subject to rules which are designed for long distance. The companies operating these networks would then, within the same network, have to handle several systems of compensation, some of them not being really suitable for this type of transport. It would also confuse passengers travelling within these networks because they would face difficulties in knowing what rules are effectively applicable.

Furthermore, since there is a possibility for an exemption of regional railway services in the existing rail passenger rights regulation, not having a corresponding provision in the bus passenger rights regulation might distort competition between the two sectors. And bus and rail services often serve as an alternative to each other.

Therefore Council could not accept the EP amendments related to the scope. The Council thus proposes that the draft Regulation should apply to passengers travelling with national and international regular services, but with a possibility at national level to exempt urban, suburban and regional regular services. In addition, the Council introduces a provision ensuring that certain basic rights are applied to all bus and coach services without exception (i.e. non-discriminatory contract conditions and tariffs and right to transport for disabled persons and persons with reduced mobility as well as related derogations).

Member States are authorised to grant an exemption of maximum five years, which may be renewed twice, from the application of the provisions of this Regulation to domestic regular services. In addition, Member States can grant an exemption of maximum five years, renewable, to particular regular services a significant part of which, including at least one scheduled stop, is operated outside the EU.

Furthermore, in connection with the scope, a specific provision establishes that Member States who can ensure that the level of protection of disabled persons and persons with reduced mobility under their national rules is at least the same as under this Regulation can preserve their national rules in full.

(ii) *Changes to the infrastructure*

As regards the infrastructure, the Council is ready to encourage and support any initiative regarding new equipment and infrastructure, which has to be acquired or built bearing in mind the needs of disabled persons and PRMs, as clearly stated in a recital. However, this Regulation is set in the framework of the legislation on consumer protection and therefore it cannot include obligations in respect of technical requirements for the carriers to modify or replace vehicles or infrastructure and equipment at terminals. Therefore all EP amendments regarding changes in infrastructure could not be accepted (amendments 6-10).

(iii) *Compensation and assistance in the event of accidents*

The Commission proposal sets out the rules on bus and/or coach undertakings' liability for passengers and their luggage. Passengers would benefit from harmonised rules on liability of bus and/or coach undertakings. For any damage up to the amount of EUR 220 000, a bus and/or coach undertaking should have strict liability, i.e. not having the possibility to exclude its liability by proving that the accident was not caused by its fault. For damages above EUR 220 000 the liability would be based on fault, but unlimited. Passengers suffering an accident would be entitled to advance payments in order to address economic difficulties that they or their families might face as a consequence of death or injury.

However, the existing liability regimes in force in the Member States are very different as regards the basis for liability (strict unlimited liability, strict liability with force majeure exemptions and fault-based liability), and they cannot be reconciled. Furthermore, legislation in the different Member States is partly built on Directive 2009/103/EC, relating to insurance against civil liability in respect of the use of motor vehicles and the enforcement of the obligation to insure against such liability ('Motor Insurance Directive'), and partly on national legislation going beyond EU law. These texts already regulate liability for bus passengers and it is essential to avoid conflicts between the present text and the above mentioned 'Motor Insurance Directive'.

Therefore, the Council adopted an approach building on the existing system, adding at the same time some basic elements of harmonisation. A minimum threshold per passenger and per item of luggage is proposed: 220 000 EUR per passenger in case of death or personal injury. In case of loss of or damage to luggage, 500 EUR with regard to urban, suburban and regional services and 1 200 EUR with regard to other regular services. This would align the compensation for luggage with the corresponding provisions in the 'railway Regulation', while taking into account the specificities of urban, suburban and regional transport. As regards wheelchairs, other mobility equipment or assistive devices, the Council text provides for them to be always compensated in full, instead of being treated like ordinary luggage, even when damages are caused during the provision of assistance (in the spirit of EP amendment 46).

In addition, the text has been adapted to provide for assistance to passengers with regard to their immediate practical needs following an accident. Such a provision is not contained in the 'Motor Insurance Directive' and represents a real benefit for bus passengers, while not increasing significantly the administrative burden for bus and/or coach companies.

In the light of the above, the Council could not accept the Commission's proposed approach nor the EP amendments related to liability (amendments 18-24).

(iv) *Rights of disabled persons and persons with reduced mobility (PRM)*

The Council wholeheartedly supports the Commission's objective to ensure that disabled persons and persons with reduced mobility have non-discriminatory access to bus and coaches. The Council therefore follows the Commission proposal closely, although modifying some provisions in order to make them feasible and introducing certain simplifications and clarifications. Regarding this Chapter, the Council integrated several EP amendments in its text, either totally, or partially or in spirit.

Concerning the exceptions to the right to transport, the Commission had proposed that a disabled persons could be denied transport with reference to safety requirements or the size of the vehicle. The Council has provided for a number of improvements, referring to the 'design' of the vehicle instead of the 'size', thus integrating in substance or in spirit EP amendments 26 and 27. Moreover, the Council has also accepted amendment 73 as regards the choice to be offered to a disabled person or a PRM when embarkation is denied.

According to the initial proposal, the carrier could require a disabled person or person with reduced mobility to be accompanied by another person who is capable of providing assistance. In the Council first reading position, if the carrier makes such a request with respect to a passenger service, the accompanying person shall be carried free of charge and, where feasible, seated next to the disabled person or PRM. This provision integrates in substance EP amendment 29.

The Council first reading text provides for non discriminatory access conditions as well as for making them publicly available in a suitable format for disabled persons and PRMs, thus accepting, partially or completely, EP amendments 31 and 32. Moreover, the Commission shall make available on the internet a list of bus and coach terminals designated by Member States where assistance for disabled persons and PRM is provided, as in EP amendment 36.

As for the assistance to disabled persons and persons with reduced mobility, such assistance will be provided on the condition that the person concerned notifies the carrier or the terminal operator at the latest two working days in advance (the Commission had proposed 48 hours) and is present in the designated point at least 60 minutes before the published departure time. Thus the Council could not accept amendment 39 proposing a shorter period of 24 hours. Furthermore, if the person has specific needs of seating, the passenger should notify the carrier of such needs at the time of reservation, if the need is known at that time. This additional requirement, introduced by the Council, will allow for the carrier to cater for those specific needs and to give the best possible service to the person concerned.

Concerning the assistance on board, the Council has limited the scope of the Commission's initial proposal. The Council's text establishes that information has to be provided in accessible format as well as assistance for boarding and alighting during pauses in a journey, the latter, however, only if there are personnel other than the driver on board. This takes account of the fact that most vehicle are operated by the driver alone and therefore providing assistance during the journey will have an impact on the driver hours, thus on safety requirements.

Help to disabled persons and PRMs has to be provided free-of-charge at staffed terminals designated by the Member States and the personnel providing direct assistance to these persons should have received adequate training allowing them to assist such persons. Personnel, including drivers, who deal directly with the travelling public should receive disability-awareness training.

(v) *Passenger Rights in the event of cancellation or delay*

The Commission proposal provided for obligations of bus and/or coach undertakings in the event of interrupted journeys, due to cancellation of a service or delays. The undertakings should pay compensation amounting to 100 % of the ticket price, if they failed to provide alternative services or the required information.

While the Council fully supports the principle that carriers and terminal operators should take care of their passengers, it has modified the Commission proposal, taking into account the specific structure of the bus and coaches industry. A different treatment was agreed regarding passengers departing from terminals and passengers departing from bus stops, as it is neither possible nor reasonable to provide, for example, the same level of information on delays at a bus stop compared to a staffed terminal.

In the event of a delay of over two hours or a cancellation of the journey, the passenger may choose either to continue the journey using the same mode of transport, or to call for a transfer or to ask for the reimbursement of his/her ticket (paid within 14 days after the event and, if necessary, a return trip free of charge). In the case of a delay of more than two hours on journeys lasting over three hours, for passengers departing from a terminal, the carrier will be under the obligation to give passengers a meal or refreshments, in the spirit of EP amendment 53, but will not be under the obligation to provide accommodation, although the carrier must assist in finding accommodation. However, bus and coach passengers will not benefit from additional indemnities (paid in addition to the price of the ticket) as it is the case for maritime and rail passengers. Thus EP amendments related to compensation and accommodation have not been retained (amendments 49, 50, 51, 52, 54 and 55).

The European Parliament introduced some amendments regarding compensation and assistance in the event of delays in arrival and related exemptions in case of “force majeure” (amendments 56 and 57), thus relieving the carrier from being held liable for damage if it is caused by circumstances not connected with the operation of their services and which they could not have foreseen. The Council did not take on board such amendments as its text does not foresee any provisions on compensation in the event of delays in arrival.

Such compensations would be an additional liability for bus and coach undertakings and would create an excessive burden; moreover, drivers would be put under pressure to respect the timetable at any cost, thus putting road safety at risk.

Amendment 58 concerning information in formats accessible to disabled persons and persons with reduced mobility was taken on board by the Council.

(vi) *General rules on information, complaint handling and national enforcement bodies*

According to the Council position at first reading, carriers and terminal managing bodies, within their respective areas of competence, provide adequate information to passengers throughout their travel, in accessible format where feasible. Furthermore, they shall inform passengers about their rights in an appropriate and comprehensible way, in the spirit of EP amendment 62.

As regards complaints, the Commission proposal contained rules on how carriers should handle them, in particular the far-reaching legal consequences of not replying to complaints.

The Council, though agreeing in principle with the Commission proposal, introduces more flexibility into the system in order to avoid any unforeseen consequences for the Member States’ legal systems or administrative structures. In this context and in order to avoid additional bureaucracy, the Council did not take on board EP amendment 64, which introduced an obligation for bus and/or coach undertakings to issue annually a detailed report on complaints received.

In addition, the Parliament proposed that the national enforcement bodies should be independent (amendment 65). The Council first reading position specifies more clearly that these bodies should be independent of carriers, tour operators and terminal operators.

(vii) *Date of application of the Regulation*

The Commission had proposed that the Regulation will enter into force 20 days after publication in the Official Journal of the EU and will apply a year after that date.

The Council first reading position provides that the Regulation will apply two years after its publication, thus accepting EP amendment 69 in substance.

3. Other amendments adopted by the European Parliament

Further amendments not included in the Council first reading position concern:

- changes to the definitions of ‘transport contract’ (amendment 13), ‘ticket vendor’ (amendment 14), ‘tour operator’ (amendment 15), ‘cancellation’ (amendment 16);
- proposed new definition of ‘accessible formats’ (amendment 17);
- reference to ‘persons incapable of travelling without assistance because of their elderly or age’ (amendment 34);
- assistance adapted to the individual needs of disabled persons or persons with reduced mobility (amendment 35);

- need to ensure that the passenger receives a confirmation of the notification of his or her assistance needs (amendment 40);
- any compensation awarded under the Regulation, which may be deducted from any additional compensation granted (amendment 59);
- penalties applicable to infringements of the Regulation, which could include ordering the payment of compensation (amendment 68);
- amendments 70, 71 and 72 concerning the Annexes to the Regulation.

III. CONCLUSION

In establishing its position at first reading, the Council has taken full account of the proposal of the Commission and the European Parliament's opinion at first reading. With respect to the amendments proposed by the European Parliament, the Council observes that a considerable number of amendments have – in spirit, partially or fully – already been included in its first reading position.

POSITION (EU) No 5/2010 OF THE COUNCIL AT FIRST READING

with a view to the adoption of a Regulation of the European Parliament and of the Council concerning the rights of passengers when travelling by sea and inland waterway and amending Regulation (EC) No 2006/2004

Adopted by the Council on 11 March 2010

(Text with EEA relevance)

(2010/C 122 E/02)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 91(1) and 100(2) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

After consulting the Committee of Regions,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) Action by the Union in the field of maritime and inland waterway transport should aim, among other things, at ensuring a high level of protection for passengers that is comparable with other modes of transport. Moreover, full account should be taken of the requirements of consumer protection in general.
- (2) Since the maritime and inland waterway passenger is the weaker party to the transport contract, all passengers should be granted a minimum level of protection. Nothing should prevent carriers from offering contract conditions more favourable for the passenger than the conditions laid down in this Regulation.
- (3) The protection of passengers should cover not only passenger services between ports situated in the territory of the Member States, but also passenger services between such ports and ports situated outside the territory of the Member States, taking into account the risk of distortion of competition on the passenger transport market. Therefore the term 'Union carrier' should, for the purpose of this Regulation, be interpreted as broadly as possible, but without affecting other legislation of the Union, such as Council Regulation (EEC) No 4056/86 of 22 December 1986 laying down detailed rules for the application of Articles 85 and 86 of the

Treaty to maritime transport ⁽³⁾ and Council Regulation (EEC) No 3577/92 of 7 December 1992 applying the principle of freedom to provide services to maritime transport within Member States (maritime cabotage) ⁽⁴⁾.

- (4) The single market for maritime and inland waterway passenger services should benefit citizens in general. Consequently, disabled persons and persons with reduced mobility, whether caused by disability, age or any other factor, should have opportunities for using passenger services and cruises that are comparable to those of other citizens. Disabled persons and persons with reduced mobility have the same rights as all other citizens with regard to free movement, freedom of choice and non-discrimination.
- (5) In the light of Article 9 of the United Nations Convention on the Rights of Persons with Disabilities and in order to give disabled persons and persons with reduced mobility opportunities for maritime and inland waterway travel comparable to those of other citizens, rules for non-discrimination and assistance during their journey should be established. Those persons should therefore be accepted for carriage and not refused transport on the grounds of their disability or lack of mobility, except for reasons which are justified on the grounds of health and safety and established by the competent authorities. They should enjoy the right to assistance in ports and on board passenger ships. In the interests of social inclusion, the persons concerned should receive this assistance free of charge. Carriers should establish access conditions, preferably using the European standardisation system.
- (6) In deciding on the design of new ports and terminals, and as part of major refurbishments, the bodies responsible for those facilities should, where necessary, take into account the needs of disabled persons and persons with reduced mobility. Similarly, carriers should, where necessary, take such needs into account when deciding on the design of new and newly refurbished passenger ships in accordance with Directive 2009/45/EC of the European Parliament and of the Council of 6 May 2009 on safety rules and standards for passenger ships ⁽⁵⁾ and Directive 2006/87/EC of the European Parliament and of the Council of 12 December 2006 laying down technical requirements for inland waterway vessels ⁽⁶⁾.

⁽¹⁾ Opinion of 16 of July 2009 (OJ C 317, 23.12.2009, p. 89).

⁽²⁾ Position of the European Parliament of 23 April 2009 (not yet published in the Official Journal) and Council Decision ...

⁽³⁾ OJ L 378, 31.12.1986, p. 4.

⁽⁴⁾ OJ L 364, 12.12.1992, p. 7.

⁽⁵⁾ OJ L 163, 25.6.2009, p. 1.

⁽⁶⁾ OJ L 389, 30.12.2006, p. 1.

- (7) Assistance given at ports situated in the territory of a Member State should, among other things, enable disabled persons and persons with reduced mobility to proceed from a designated point of arrival at a port to a passenger ship and from a passenger ship to a designated point of departure at a port, including embarking and disembarking.
- (8) In organising assistance to disabled persons and persons with reduced mobility, and the training of their personnel, carriers should cooperate with organisations representative of disabled persons and persons with reduced mobility. In that work they should also take into account the relevant provisions of the International Convention and Code on Standards of Training, Certification and Watchkeeping for Seafarers as well as the Recommendation of the International Maritime Organisation on the Design and Operation of passenger ships to respond to elderly and disabled persons' needs.
- (9) Passengers should be adequately informed in the event of cancellation or delay of any passenger service or cruise. That information should help passengers to make the necessary arrangements and, if needed, to obtain information about alternative connections.
- (10) Inconvenience experienced by passengers due to the cancellation or long delay of their journey should be reduced. To this end, passengers should be adequately looked after and should be able to cancel their journey and have their tickets reimbursed or to obtain re-routing under satisfactory conditions.
- (11) Carriers should provide for the payment of compensation for passengers in the event of the cancellation or delay of a passenger service based on a percentage of the ticket price, except when the cancellation or delay occurs due to weather conditions endangering the safe operation of the ship or to extraordinary circumstances, which could not have been avoided even if all reasonable measures had been taken.
- (12) Weather conditions endangering the safe operation of the ship should include, but not be limited to, strong winds, heavy seas, strong currents, difficult ice conditions and extremely high or low water levels.
- (13) Extraordinary circumstances should include, but not be limited to, terrorist attacks, labour conflicts, landing any sick, injured or dead person, search and rescue operations at sea or on inland waterways, measures necessary to protect the environment, decisions taken by traffic management bodies or port authorities, or decisions by the competent authorities with regard to public order and safety as well as to cover urgent transport needs.
- (14) With the involvement of stakeholders, professional associations and associations of customers, passengers, disabled persons and persons with reduced mobility, carriers should cooperate in order to adopt arrangements at national or European level for improving care and assistance offered to passengers whenever their travel is interrupted, notably in the event of long delays or cancellation of travel.
- (15) This Regulation should not affect the rights of passengers established by Council Directive 90/314/EEC of 13 June 1990 on package travel, package holidays and package tours ⁽¹⁾. This Regulation should not apply in cases where a package tour is cancelled for reasons other than cancellation of the passenger service or the cruise.
- (16) Passengers should be fully informed of their rights under this Regulation, so that they can effectively exercise those rights. Rights of passengers should include the receipt of information regarding the passenger service or cruise before and during the journey. All essential information provided to passengers should also be provided in formats accessible to disabled persons and persons with reduced mobility.
- (17) Passengers should be able to exercise their rights by means of appropriate complaint procedures implemented by carriers or, as the case may be, by the submission of complaints to the body or bodies designated to that end by the Member State. Carriers should respond to complaints by passengers within a certain period of time, bearing in mind that the non-reaction to a complaint might be held against them.
- (18) Taking into account the procedures established by a Member State for the submission of complaints, a complaint concerning assistance in a port or on board a ship should preferably be addressed to the body or bodies designated for the enforcement of this Regulation in the Member State where the port of embarkation is situated and, for passenger services from a third country, where the port of disembarkation is situated.
- (19) Member States should ensure compliance with this Regulation and designate a competent body or bodies to carry out supervision and enforcement tasks. This does not affect the rights of passengers to seek legal redress from courts under national law.
- (20) Member States should lay down penalties applicable to infringements of this Regulation and ensure that those penalties are applied. The penalties should be effective, proportionate and dissuasive.

⁽¹⁾ OJ L 158, 23.6.1990, p. 59.

(21) Since the objectives of this Regulation, namely to ensure a high level of protection of and assistance to passengers throughout the Member States and to ensure that economic agents operate under harmonised conditions in a single market, cannot sufficiently be achieved by the Member States and can therefore, by reason of the scale or effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(22) The enforcement of this Regulation should be based on 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 the consumer protection law (the Regulation on consumer protection cooperation)⁽¹⁾. That Regulation should therefore be amended accordingly.

(23) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data⁽²⁾ should be strictly respected and enforced in order to guarantee respect for the privacy of natural and legal persons, and ensure that the information and reports requested serve solely to fulfil the obligations laid down in this Regulation and are not used to the detriment of such persons.

(24) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union, as referred to in Article 6 of the Treaty on European Union,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This Regulation establishes rules as regards the following:

(a) non-discrimination between passengers with regard to transport conditions offered by carriers;

(b) non-discrimination and assistance for disabled persons and persons with reduced mobility;

(c) the rights of passengers in cases of cancellation or delay;

(d) minimum information to be provided to passengers;

(e) the handling of complaints;

(f) general rules on enforcement.

Article 2

Scope

1. This Regulation shall apply in respect of passengers travelling:

(a) on passenger services where the port of embarkation is situated in the territory of a Member State;

(b) on passenger services where the port of embarkation is situated outside the territory of a Member State and the port of disembarkation is situated in the territory of a Member State, provided that the service is operated by a Union carrier;

(c) on a cruise where the port of embarkation is situated in the territory of a Member State. However, Articles 16(2), 18, 19 and 20(1) and (4) shall not apply to those passengers.

2. This Regulation shall not apply in respect of passengers travelling:

(a) on ships certified to carry up to 36 passengers;

(b) on ships which have a crew responsible for the operation of the ship composed of not more than three persons or where the distance of the overall passenger service is less than 500 metres, one way; or

(c) on excursion and sightseeing tours other than cruises.

3. Member States may, for a period of two years from ... (*), exempt from the application of this Regulation sea going ships of less than 300 gross tons operated in domestic transport, provided that the rights of passengers under this Regulation are adequately ensured under national law.

4. Member States may exempt from the application of this Regulation passenger services covered by public service obligations, public service contracts or integrated services provided that the rights of passengers under this Regulation are adequately guaranteed under national law.

⁽¹⁾ OJ L 364, 9.12.2004, p. 1.

⁽²⁾ OJ L 281, 23.11.1995, p. 31.

(*) Date of application of this Regulation.

5. Nothing in this Regulation shall be understood as constituting technical requirements imposing obligations on carriers, terminal operators or other entities to modify or replace ships, infrastructure, equipment in ports, and port terminals.

Article 3

Definitions

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

- (a) 'disabled person' or 'person with reduced mobility' means any person whose mobility when using transport is reduced as a result of any physical disability (sensory or locomotor, permanent or temporary), intellectual disability or impairment, or any other cause of disability, or as a result of age, and whose situation needs appropriate attention and adaptation to his particular needs of the service made available to all passengers;
- (b) 'territory of a Member State' means a territory to which the Treaty applies as referred to in Article 355 thereof, under the conditions set out therein;
- (c) 'access conditions' means relevant standards, guidelines and information on the accessibility of port terminals and ships including their facilities for disabled persons or persons with reduced mobility;
- (d) 'carrier' means a natural or legal person offering transport by passenger services or cruises to the general public;
- (e) 'Union carrier' means a carrier established within the territory of a Member State or offering transport by passenger services operated to or from the territory of a Member State;
- (f) 'passenger service' means a commercial passenger transport service by sea or inland waterways operated according to a published timetable;
- (g) 'integrated services' means interconnected transport services within a determined geographical area with a single information service, ticketing scheme and timetable;
- (h) 'performing carrier' means a person other than the carrier, who actually performs the carriage wholly or partially;
- (i) 'inland waterway' means a natural or artificial navigable inland body of water, or system of interconnected bodies of water, used for transport, such as lakes, rivers or canals or any combination of these;
- (j) 'port' means a place or a geographical area made up of such improvement works and facilities as to permit the reception of ships from which passengers regularly embark or disembark;
- (k) 'port terminal' means a terminal, staffed by a carrier or a terminal operator, in a port with facilities, such as check-in, ticket counters or lounges, and staff for the embarkation or disembarkation of passengers travelling on passenger services or on a cruise;
- (l) 'ship' means a vessel used for navigation at sea or on inland waterways;
- (m) 'transport contract' means a contract of carriage between a carrier and a passenger for the provision of one or more passenger services or cruises;
- (n) 'ticket' means a valid document or other evidence of a transport contract;
- (o) 'ticket vendor' means any retailer concluding transport contracts on behalf of a carrier;
- (p) 'travel agent' means any retailer acting on behalf of a passenger for the conclusion of transport contracts;
- (q) 'tour operator' means an organiser, other than a carrier, within the meaning of Article 2(2) and (3) of Directive 90/314/EEC;
- (r) 'reservation' means a booking of a specific departure of a passenger service or a cruise;
- (s) 'terminal operator' means a private or public body in the territory of a Member State responsible for the administration and management of a port terminal;
- (t) 'cruise' means a transport service by sea or inland waterway, operated exclusively for the purpose of pleasure or recreation, supplemented by accommodation and other facilities, exceeding two overnight stays on board.
- (u) 'shipping incident' means shipwreck, capsizing, collision or stranding of the ship, explosion or fire in the ship, or defect in the ship.

Article 4

Tickets and non-discriminatory contract conditions

1. Carriers shall issue a ticket to the passenger, unless under national law other documents give entitlement to transport. A ticket may be issued in an electronic format.

2. Without prejudice to social tariffs, the contract conditions and tariffs applied by carriers or ticket vendors shall be offered to the general public without any direct or indirect discrimination based on the nationality of the final customer or on the place of establishment of carriers or ticket vendors within the Union.

Article 5

Other performing parties

1. If the performance of the obligations under this Regulation has been entrusted to a performing carrier, ticket vendor or any other person, the carrier, travel agent, tour operator or terminal operator, who has entrusted such obligations, shall nevertheless be liable for the acts and omissions of that performing party, acting within that party's scope of employment.

2. In addition to paragraph 1, the party to whom the performance of an obligation has been entrusted by the carrier, travel agent, tour operator or terminal operator shall be subject to the provisions of this Regulation, including provisions on liabilities and defences, with regard to the obligation entrusted.

Article 6

Exclusion of waiver

Obligations pursuant to this Regulation shall not be limited or waived, in particular by a derogation or restrictive clause in the transport contract.

CHAPTER II

RIGHTS OF DISABLED PERSONS AND PERSONS WITH REDUCED MOBILITY

Article 7

Right to transport

1. Carriers, travel agents and tour operators shall not refuse to accept a reservation, to issue or otherwise provide a ticket or to embark persons on the grounds of disability or of reduced mobility.

2. Reservations and tickets shall be offered to disabled persons and persons with reduced mobility at no additional cost.

Article 8

Exceptions and special conditions

1. Notwithstanding Article 7(1), carriers, travel agents and tour operators may refuse to accept a reservation from, to issue or otherwise provide a ticket to or to embark a person, on the grounds of disability or of reduced mobility:

- (a) in order to meet applicable health and safety requirements established by international, Union or national law or in

order to meet health and safety requirements established by the competent authorities;

- (b) where the design of the passenger ship or port infrastructure and equipment, including port terminals, makes it impossible to carry out the embarkation, disembarkation or carriage of the disabled person or person with reduced mobility in a safe or operationally feasible manner.

2. In the event of a refusal to accept a reservation or to issue or otherwise provide a ticket on the grounds referred to in paragraph 1, carriers, travel agents and tour operators shall make reasonable efforts to propose to the person concerned an acceptable alternative transport on a passenger service or a cruise operated by the carrier.

3. If a disabled person or a person with reduced mobility, who holds a reservation or has a ticket and has complied with the requirements in Article 11(2), is any way denied embarkation on the grounds of his disability or reduced mobility, that person and any accompanying person pursuant to paragraph 4 of this Article shall be offered the choice between the right to reimbursement and re-routing as provided for in Annex I. The right to the option of a return journey or re-routing shall be conditional upon all health and safety requirements being met.

4. Under the same conditions set out in paragraph 1, carriers, travel agents and tour operators may require that a disabled person or person with reduced mobility be accompanied by another person who is capable of providing the assistance required by the disabled person or person with reduced mobility. As regards passenger services, such an accompanying person shall be carried free of charge.

5. When carriers, travel agents and tour operators have recourse to paragraphs 1 or 4, they shall immediately inform the disabled person or person with reduced mobility of the specific reasons therefor. Those reasons shall be notified to the disabled person or person with reduced mobility, no later than five working days after that person was informed. In case of refusal according to paragraph 1(a), reference shall be made to the applicable health and safety requirements.

Article 9

Accessibility and information

1. In cooperation with organisations representative of disabled persons or persons with reduced mobility, carriers and terminal operators shall, where appropriate through their organisations, establish, or have in place, non-discriminatory access conditions for the transport of disabled persons and persons with reduced mobility.

2. The access conditions provided for in paragraph 1 shall be made publicly available by carriers and terminal operators physically or on the Internet in the same languages as those in which information is generally made available to all passengers.

3. Tour operators shall make available the access conditions provided for in paragraph 1 which apply to journeys included in package travel, package holidays and package tours which they organise, sell or offer for sale.

4. Carriers, travel agents and tour operators shall ensure that all relevant information, including online reservation and information, concerning the conditions of carriage, journey information and access conditions is available in appropriate and accessible formats for disabled persons and persons with reduced mobility.

Article 10

Right to assistance in ports and on board ships

Subject to the access conditions provided for in Article 9(1), carriers and terminal operators shall, within their respective areas of competence, provide assistance free of charge to disabled persons and persons with reduced mobility, as specified in Annexes II and III, in ports, including embarkation and disembarkation, and on board ships.

Article 11

Conditions under which assistance is provided

1. Carriers and terminal operators shall, within their respective areas of competence, provide assistance to disabled persons and persons with reduced mobility as set out in Article 10 under the following conditions:

- (a) the carrier or the terminal operator is notified of the person's need for such assistance at the latest two working days before the assistance is needed, and;
- (b) the disabled person or person with reduced mobility presents himself at the port or at the designated point as referred to in Article 12(3):

- (i) at a time stipulated in writing by the carrier which shall be not more than 60 minutes before the published embarkation time, or

- (ii) if no embarkation time is stipulated, no later than 60 minutes before the published departure time.

2. In addition to paragraph 1, disabled persons or persons with reduced mobility shall notify the carrier, at the time of reservation or advance purchase of the ticket, of their specific needs with regard to accommodation or seating or their need to bring medical equipment, provided the need is known at that time.

3. A notification made in accordance with paragraphs 1(a) and 2 may always be submitted to the travel agent or the tour operator with which the ticket was purchased. Where the ticket permits multiple journeys, one notification shall be sufficient provided that adequate information on the timing of subsequent journeys is provided.

4. If no notification is made in accordance with paragraphs 1(a) and 2, carriers and terminal operators shall make all reasonable efforts to ensure that the assistance is provided in such a way that the disabled person or person with reduced mobility is able to embark, disembark and travel on the ship.

5. Where a disabled person or person with reduced mobility is accompanied by a recognised assistance dog, that dog shall be accommodated together with that person, provided that the carrier, travel agent or tour operator is notified in accordance with applicable national rules on the carriage of recognised assistance dogs on board passenger ships, where such rules exist.

Article 12

Reception of notifications and designation of meeting points

1. Carriers, terminal operators, travel agents and tour operators shall take all measures necessary for the reception of notifications made in accordance with Article 11(1)(a) and 11(2). That obligation shall apply at all their points of sale, including sale by telephone and over the Internet.

2. If travel agents or tour operators receive the notification referred to in paragraph 1 they shall, within their normal office hours, transfer the information to the carrier or terminal operator without delay.

3. Carriers and terminal operators shall designate a point inside or outside port terminals at which disabled persons or persons with reduced mobility can announce their arrival and request assistance. That point shall be clearly signposted and shall offer basic information about the port terminal and assistance provided, in accessible formats.

Article 13

Quality standards for assistance

1. Terminal operators and carriers operating port terminals or passenger services with a total of more than 100 000 commercial passenger movements during the previous calendar year shall, within their respective areas of competence, set quality standards for the assistance specified in Annexes II and III and shall, where appropriate through their organisations, determine resource requirements for meeting those standards, in cooperation with organisations representative of disabled persons and persons with reduced mobility.

2. The quality standards provided for in paragraph 1 shall be made publicly available by terminal operators and carriers physically or on the Internet in accessible formats and in the same languages as those in which information is generally made available to all passengers.

*Article 14***Training and instructions**

Without prejudice to the International Convention and Code on Standards of Training, Certification and Watchkeeping for Seafarers and to the regulations adopted under the Revised Convention for Rhine Navigation and the Convention regarding the Regime of Navigation on the Danube, carriers and, where appropriate, terminal operators shall establish disability-related training procedures, including instructions, and ensure that:

- (a) their personnel, including those employed by any other performing party, providing direct assistance to disabled persons and persons with reduced mobility are trained or instructed as described in Annex IV, Parts A. and B, and
- (b) their personnel who are otherwise responsible for the reservation and selling of tickets or embarkation and disembarkation, including those employed by any other performing party, are trained or instructed as described in Annex IV, Part A.

*Article 15***Compensation in respect of mobility equipment or other specific equipment**

1. Carriers and terminal operators shall be liable for loss suffered as a result of the loss of or damage to mobility equipment or other specific equipment, used by a disabled person or person with reduced mobility, if the incident which caused the loss was due to the fault or neglect of the carrier or the terminal operator. The fault or neglect of the carrier shall be presumed for loss caused by a shipping incident.
2. The compensation referred to in paragraph 1 shall correspond to the replacement value of the equipment concerned or, where applicable, to the costs relating to repairs.
3. Paragraphs 1 and 2 shall not apply if Article 4 of 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 ⁽¹⁾ applies.
4. Moreover, every effort shall be undertaken to rapidly provide temporary replacement equipment.

CHAPTER III

OBLIGATIONS OF CARRIERS AND TERMINAL OPERATORS IN THE EVENT OF INTERRUPTED TRAVEL*Article 16***Information in case of cancelled or delayed departures**

1. In the case of a cancellation or a delay in departure of a passenger service or a cruise, passengers departing from port terminals shall be informed by the carrier or, where appropriate, by the terminal operator, of the situation as soon as possible

and in any event no later than 30 minutes after the scheduled time of departure, and of the estimated departure time and estimated arrival time as soon as this information is available.

2. If passengers miss a connecting transport service due to a cancellation or delay, the carrier and, where appropriate, the terminal operator shall make reasonable efforts to inform the passengers concerned of alternative connections.

3. The carrier or, where appropriate, the terminal operator, shall ensure that disabled persons or persons with reduced mobility receive the information required under paragraphs 1 and 2 in accessible formats.

*Article 17***Assistance in case of cancelled or delayed departures**

1. Where a carrier reasonably expects the departure of a passenger service or a cruise to be cancelled or delayed for more than 120 minutes beyond its scheduled time of departure, passengers departing from port terminals shall be offered free of charge snacks, meals or refreshments in reasonable relation to the waiting time, provided they are available, or can reasonably be supplied.
2. In the case of a cancellation or a delay in departure where a stay of one or more nights or a stay additional to that intended by the passenger becomes necessary, where and when physically possible, the carrier shall offer passengers departing from port terminals adequate accommodation free of charge on board, or ashore, and transport to and from the port terminal and place of accommodation in addition to the snacks, meals or refreshments provided for in paragraph 1. For each passenger, the carrier may limit the total cost of accommodation ashore, not including transport to and from the port terminal and place of accommodation, to EUR 120.
3. In applying paragraphs 1 and 2, the carrier shall pay particular attention to the needs of disabled persons and persons with reduced mobility and any accompanying persons.

*Article 18***Re-routing and reimbursement in case of cancelled or delayed departures**

1. Where a carrier reasonably expects a passenger service to be cancelled or delayed in departure from a port terminal for more than 120 minutes, the passenger shall immediately be offered the choice between:
 - (a) re-routing to the final destination, under comparable conditions, as set out in the transport contract, at the earliest opportunity;
 - (b) reimbursement of the ticket price and, where relevant, a return service free of charge to the first point of departure, as set out in the transport contract, at the earliest opportunity.

⁽¹⁾ OJ L 131, 28.5.2009, p. 24.

2. Where a passenger service is cancelled or delayed in departure from a port for more than 120 minutes, passengers shall have the right of such re-routing or reimbursement of the ticket price from the carrier.

3. The payment of the reimbursement provided for in paragraphs 1(b) and 2 shall be made within seven days, in cash, by electronic bank transfer, bank order or bank cheque of the full cost of the ticket at the price at which it was purchased, for the part or parts of the journey not made, and for the part or parts already made if the journey no longer serves any purpose in relation to the passenger's original travel plan.

Article 19

Compensation of the ticket price in case of delay in arrival

1. Without losing the right to transport, passengers may request compensation from the carrier if they are facing a delay in arrival at the final destination as set out in the transport contract. The minimum level of compensation shall be 25 % of the ticket price for a delay of at least:

- (a) one hour in case of a scheduled journey of up to four hours;
- (b) two hours in case of a scheduled journey of more than four hours, but not exceeding eight hours;
- (c) three hours in case of a scheduled journey of more than eight hours, but not exceeding 24 hours; or
- (d) six hours in case of a scheduled journey of more than 24 hours.

If the delay exceeds double the time set out in points (a) to (d), the compensation shall be 50 % of the ticket price.

2. Passengers who hold a travel pass or a season ticket and who encounter recurrent delays in arrival during its period of validity may request adequate compensation in accordance with the carrier's compensation arrangements. These arrangements shall state the criteria for determining delay in arrival and for calculation of compensation.

3. Compensation shall be calculated in relation to the price which the passenger actually paid for the delayed passenger service.

4. Where the transport is for a return journey, compensation for delay in arrival on either the outward or the return leg shall be calculated in relation to half of the price paid for the transport by that passenger service.

5. The compensation shall be paid within one month after the submission of the request for compensation. The compensation may be paid in vouchers and/or other services, provided

the terms are flexible, in particular as regards the period of validity and destination. The compensation shall be paid in money at the request of the passenger.

6. The compensation of the ticket price shall not be reduced by financial transaction costs such as fees, telephone costs or stamps. Carriers may introduce a minimum threshold under which payments for compensation will not be paid. This threshold shall not exceed EUR 10.

Article 20

Exemptions

1. Articles 17, 18 and 19 shall not apply to passengers with open tickets as long as the time of departure is not specified, except for passengers holding a travel pass or a season ticket.

2. Articles 17 and 19 shall not apply if the passenger is informed of the cancellation or delay before the purchase of the ticket or if the cancellation or delay is caused by the fault of the passenger.

3. Article 17(2) shall not apply where the cancellation or delay is caused by weather conditions endangering the safe operation of the ship.

4. Article 19 shall not apply where the cancellation or delay is caused by weather conditions endangering the safe operation of the ship or by extraordinary circumstances hindering the performance of the passenger service, which could not have been avoided even if all reasonable measures had been taken.

Article 21

Further claims

Nothing in this Regulation shall preclude passengers from seeking damages in accordance with national law in respect of loss resulting from cancellation or delay of transport services before national courts, including under Directive 90/314/EEC.

CHAPTER IV

GENERAL RULES ON INFORMATION AND COMPLAINTS

Article 22

Right to travel information

Carriers and terminal operators shall, within their respective areas of competence, provide passengers with adequate information throughout their travel in accessible formats and in the same languages as those in which information is generally made available to all passengers. Particular attention shall be paid to the needs of disabled persons and persons with reduced mobility.

*Article 23***Information on passenger rights**

1. Carriers and terminal operators shall, within their respective areas of competence, ensure that information on the rights of passengers under this Regulation is publicly available on board ships and in port terminals. The information shall be provided in accessible formats and in the same languages as those in which information is generally made available to all passengers. When providing this information particular attention shall be paid to the needs of disabled persons and persons with reduced mobility.

2. In order to comply with the information requirement referred to in paragraph 1, carriers and terminal operators may use a summary of the provisions of this Regulation prepared by the Commission in all the official languages of the institutions of the European Union and made available to them.

3. Carriers and terminal operators shall inform passengers in an appropriate manner on board ships and in port terminals, of the contact details of the enforcement body designated by the Member State pursuant to Article 25(1).

*Article 24***Complaints**

1. Carriers shall set up or have in place a complaint handling mechanism for rights and obligations covered by this Regulation.

2. If a passenger covered by this Regulation wants to make a complaint to the carrier, he shall submit it within two months from the date on which the service was performed or when a service should have been performed. Within one month of receiving the complaint, the carrier shall give notice to the passenger that his complaint has been substantiated, rejected or is still being considered. The time taken to provide the final reply shall not be longer than three months from the receipt of a complaint.

CHAPTER V

ENFORCEMENT AND NATIONAL ENFORCEMENT BODIES*Article 25***National enforcement bodies**

1. Each Member State shall designate a new or existing body or bodies responsible for the enforcement of this Regulation as regards passenger services and cruises from ports situated on its territory and passenger services from a third country to such ports. Each body shall take the measures necessary to ensure compliance with this Regulation.

Each body shall, in its organisation, funding decisions, legal structure and decision-making, be independent of carriers, tour operators and terminal operators.

2. Member States shall inform the Commission of the body or bodies designated in accordance with this Article.

3. Any passenger may submit a complaint, in accordance with national law, to the competent body designated under paragraph 1, or to any other competent body designated by a Member State, about an alleged infringement of this Regulation.

A Member State may decide:

(a) that the passenger as a first step shall submit the complaint covered by this Regulation to the carrier; and/or

(b) that the national enforcement body or any other competent body designated by the Member State shall act as an appeal body for complaints not resolved under Article 24.

4. Member States that have chosen to exempt certain services pursuant to Article 2(4) shall ensure that a comparable mechanism of enforcement of passenger rights is in place.

*Article 26***Report on enforcement**

On 1 June ... (*) and every two years thereafter, the enforcement bodies designated pursuant to Article 25 shall publish a report on their activity in the previous two calendar years, containing in particular a description of actions taken in order to implement the provisions of this Regulation, details of sanctions applied and statistics on complaints and sanctions applied.

*Article 27***Cooperation between enforcement bodies**

National enforcement bodies referred to in Article 25(1) shall, whenever appropriate, exchange information on their work and decision-making principles and practice. The Commission shall support them in this task.

*Article 28***Penalties**

The Member States shall lay down rules on penalties applicable to infringements of the provisions of this Regulation and shall take all the measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall notify those rules and measures to the Commission by ... (**) and shall notify it without delay of any subsequent amendment affecting them.

(*) Two years following the date of application of this Regulation.

(**) Date of application of this Regulation.

CHAPTER VI

FINAL PROVISIONS

Article 29

Report

The Commission shall report to the European Parliament and to the Council by ... (*) on the operation and the effects of this Regulation. The report shall be accompanied where necessary by legislative proposals implementing in further detail the provisions of this Regulation, or amending it.

Article 30

Amendment to Regulation (EC) No 2006/2004

In the Annex to Regulation (EC) No 2006/2004 the following point shall be added:

‘19. Regulation (EU) No .../2009 of the European Parliament and of the Council of ... concerning the rights of passengers traveling by sea and inland waterway (*).

(*) OJ ...’

Article 31

Entry into force

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

It shall apply from ... (**).

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

Done at ...,

For the European Parliament
The President

...

For the Council
The President

...

(*) Three years after the date of application of this Regulation.

(**) 36 months after the date of publication of this Regulation.

ANNEX I

Right to reimbursement or re-routing for disabled persons and persons with reduced mobility as referred to in Article 8

1. Where reference is made to this Annex, disabled persons and persons with reduced mobility shall be offered the choice between:
 - (a) — reimbursement within seven days, paid in cash, by electronic bank transfer, bank orders or bank cheques of the full cost of the ticket at the price at which it was purchased, for the part or parts of the journey not made, and for the part or parts already made if the journey no longer serves any purpose in relation to the passenger's original travel plan, plus, where relevant,
 - a return service to the first point of departure, at the earliest opportunity; or
 - (b) re-routing to the final destination as set out in the transport contract, under comparable conditions, at the earliest opportunity; or
 - (c) re-routing to the final destination as set out in the transport contract, under comparable conditions, at a later date at the passenger's convenience, subject to availability of tickets.
 2. Paragraph 1(a) shall also apply to passengers whose journeys form part of a package, except for the right to reimbursement where such a right arises under Directive 90/314/EEC.
 3. When, in the case where a town, city or region is served by several ports, a carrier offers a passenger a journey to an alternative port to that for which the reservation was made, the carrier shall bear the cost of transferring the passenger from that alternative port either to that for which the reservation was made, or to another nearby destination agreed with the passenger.
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ANNEX II

Assistance in ports, including embarkation and disembarkation, as referred to in Articles 10 and 13

1. Assistance and arrangements necessary to enable disabled persons and persons with reduced mobility to:
 - communicate their arrival at a port terminal and their request for assistance,
 - move from an entry point to the check-in counter, if any, or to the ship,
 - check-in and register baggage, if necessary,
 - proceed from the check-in counter, if any, to the ship, through emigration and security points,
 - embark the ship, with the provision of lifts, wheelchairs or other assistance needed, as appropriate,
 - proceed from the ship door to their seats/area,
 - store and retrieve baggage on the ship,
 - proceed from their seats to the ship door,
 - disembark from the ship, with the provision of lifts, wheelchairs or other assistance needed, as appropriate,
 - retrieve baggage, if necessary, and proceed through immigration and customs points,
 - proceed from the baggage hall or the disembarkation point to a designated point of exit,
 - if required, make their way to the toilet facilities (if any).
 2. Where a disabled person or person with reduced mobility is assisted by an accompanying person, this person must, if requested, be allowed to provide the necessary assistance in the port and with embarking and disembarking.
 3. Handling of all necessary mobility equipment, including equipment such as electric wheelchairs.
 4. Temporary replacement of damaged or lost mobility equipment, albeit not necessarily on a like for like basis.
 5. Ground handling of recognised assistance dogs, when relevant.
 6. Communication in accessible formats of information needed to embark and disembark.
-

*ANNEX III***Assistance on board ships as referred to in Articles 10 and 13**

1. Carriage of recognised assistance dogs on board the ship, subject to national regulations.
 2. Carriage of medical equipment and of the mobility equipment necessary for the disabled person or person with reduced mobility, including electric wheelchairs.
 3. Communication of essential information concerning a route in accessible formats.
 4. Making all reasonable efforts to arrange seating to meet the needs of disabled persons or persons with reduced mobility on request and subject to safety requirements and availability.
 5. If required, assistance in moving to toilet facilities (if any).
 6. Where a disabled person or person with reduced mobility is assisted by an accompanying person, the carrier shall make all reasonable efforts to give such person a seat or a cabin next to the disabled person or person with reduced mobility.
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ANNEX IV

Disability-related training, including instructions, as referred to in Article 14**A. Disability-awareness training, including instructions**

Disability-awareness training, including instructions, includes:

- awareness of and appropriate responses to passengers with physical, sensory (hearing and visual), hidden or learning disabilities, including how to distinguish between the different abilities of persons whose mobility, orientation, or communication may be reduced;
- barriers faced by disabled persons and persons with reduced mobility, including attitudinal, environmental/physical and organisational barriers;
- recognised assistance dogs, including the role and the needs of an assistance dog;
- dealing with unexpected occurrences;
- interpersonal skills and methods of communication with hearing impaired people, visually impaired people, speech impaired people and people with a learning disability;
- general awareness of IMO guidelines relating to the Recommendation of the Design and Operation of passenger ships to respond to elderly and disabled persons' needs.

B. Disability-assistance training, including instructions

Disability-assistance training, including instructions, includes:

- how to help wheelchair users make transfers into and out of a wheelchair;
 - skills for providing assistance to disabled persons and persons with reduced mobility travelling with a recognised assistance dog, including the role and the needs of those dogs;
 - techniques for escorting visually impaired passengers and for the handling and carriage of recognised assistance dogs;
 - an understanding of the types of equipment which can assist disabled persons and persons with reduced mobility and a knowledge of how to carefully handle such equipment;
 - the use of boarding and debording assistance equipment used and knowledge of the appropriate boarding and debording assistance procedures that safeguard the safety and dignity of disabled persons and persons with reduced mobility;
 - understanding of the need for reliable and professional assistance. Also awareness of the potential of certain disabled persons and persons with reduced mobility to experience feelings of vulnerability during travel because of their dependence on the assistance provided;
 - a knowledge of first aid.
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STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

On 4 December 2008, the Commission presented the proposal for a Regulation of the European Parliament and the Council concerning the rights of passengers when travelling by sea and inland waterway and amending Regulation (EC) No 2006/2004 on cooperation between national authorities responsible for the enforcement of consumer protection laws ⁽¹⁾.

On 23 April 2009, the European Parliament voted its opinion at first reading ⁽²⁾.

On 9 October 2009, the Council reached a political agreement on the draft Regulation. Following legal/linguistic revision, the Council adopted its position at first reading on 11 March 2010, in accordance with the ordinary legislative procedure laid down in Article 294 of the Treaty on the Functioning of the European Union.

In carrying out its work, the Council took account of the opinion of the European Economic and Social Committee. The Committee of Regions declined to give an opinion.

II. ANALYSIS OF THE POSITION AT FIRST READING

1. General

The proposal for a Regulation of the European Parliament and the Council concerning the rights of passengers when travelling by sea and inland waterway forms part of the general objective of the EU to strengthen passenger rights, in particular the rights of disabled persons and persons with reduced mobility. Legislation of similar nature has already been adopted for passengers travelling by air ⁽³⁾ or by rail ⁽⁴⁾. The proposal contains, on the one hand, provisions on non-discriminatory access and assistance for disabled persons and persons with reduced mobility and, on the other hand, provisions on right to assistance, information and possibly compensation in the case of delays or cancellation for all categories of passengers.

Although the Council agrees with the Commission as regards the objective of the proposal, the Council's approach involved major adaptations of the original proposal. A number of the proposed provisions were not acceptable because they imposed too heavy administrative burdens and ensuing costs on carriers and national administrations, without bringing an added value for passengers that would outweigh these inconveniences. Others were redrafted with a view to simplifying and clarifying the Regulation.

Resulting from this approach, the Council's first-reading position modifies, to a large extent, the original Commission proposal by redrafting it and deleting several provisions of the text. This implies that all amendments introduced in the European Parliament's first-reading opinion related to these deleted provisions were not accepted by the Council.

2. Key policy issues

(i) *Scope of application*

Geographical scope

The Commission proposed that the Regulation should apply to passenger services and cruises between ports in the Member States or at ports in Member States.

⁽¹⁾ Doc. 11990/08.

⁽²⁾ A6-0209/2009.

⁽³⁾ Regulation (EC) No 261/2004 of the European Parliament and of the Council of 11 February 2004 establishing common rules on compensation and assistance to passengers in the event of denied boarding and of cancellation or long delay of flights, and repealing Regulation (EEC) No 295/91, OJ L 46, 17.2.2004, p. 1, and Regulation (EC) No 1107/2006 of the European Parliament and of the Council of 5 July 2006 concerning the rights of disabled persons and persons with reduced mobility when travelling by air, OJ L 204, 26.7.2006, p. 1.

⁽⁴⁾ Regulation (EC) No 1371/2007 of the European Parliament and of the Council of 23 October 2007 on rail passengers' rights and obligations, OJ L 315, 3.12.2007, p. 14.

The Council considers that the Commission proposal needs to be clarified in this respect, in order to avoid distortion of competition between intra-EU and extra-EU passenger services. The Council's first-reading position therefore fine-tunes the above provisions. It distinguishes between passenger services where the port of embarkation is situated in the territory of a Member State, on the one hand, and passenger services where the port of embarkation is situated outside the territory of a Member State, but the port of disembarkation is situated in the territory of a Member State, on the other. In the latter case, the Regulation will apply only if the service is operated by a Union carrier. However, the definition of Union carrier should be interpreted as broadly as possible in order to cover most passenger services between EU and non-EU ports. As for cruises, the Regulation will apply only to cruises where the port of embarkation is situated in the territory of a Member State.

Furthermore, the Council introduces a definition of 'territory of a Member State'.

Exemptions from the scope

The Commission original proposal covered in principle all passenger services, regardless of the number of passengers carried, the distance of the service, the purpose of the voyage, etc. The Commission had only foreseen a possibility for Member States to exempt services covered by public service contracts.

The Council considers it important to adapt these provisions to what is practically possible and necessary. It therefore introduces a certain number of exemptions where the provisions of the Regulation will not apply. The Council agrees to exclude from the scope passengers travelling with ships certified to carry up to 36 passengers, with ships with a crew of not more than three persons or with an overall passenger service of less than 500 meters one way. Furthermore, excursion and sightseeing trips (other than cruises) are also excluded.

In addition to this, the Member States may exempt, for a period of two years from the date of application of the Regulation, seagoing ships of less than 300 gross tons operated in domestic transport. If a Member State chooses to do so, it must however adequately ensure the rights of passengers under national law. Member States may also exempt passenger services covered by public service obligations, public service contracts or integrated services, provided that the rights of passengers are adequately guaranteed under national law.

The European Parliament followed in principle the Commission approach, but added a possibility for Member States to exempt urban and suburban services (amendment 10). The Council does not take this amendment into account, but the exemptions from the scope proposed by the Council will in practice mean that many services of that kind will be excluded.

(ii) *Rights of disabled persons and persons with reduced mobility*

The Council wholeheartedly supports the Commission's objective to ensure that disabled persons and persons with reduced mobility have non-discriminatory access to maritime and inland waterway transport. The Council therefore follows the Commission proposal closely, except for certain simplifications and clarifications.

Concerning the exceptions to the right of transport, the Commission had proposed that a disabled person could be denied transport with reference to safety requirements or the structure of the passenger ship. To this, the Council has added health requirements, in order to take into account cases where the medical state of the passenger is such, that his or her safe transport cannot be guaranteed.

In this respect, the European Parliament had proposed a deletion of any references to safety requirements (amendments 1, 26 and 29) and the addition of a reference to transportation in a safe, dignified and operationally feasible manner (amendment 27). As for this latter amendment, the Council integrated it into its first-reading position, except for the word 'dignified'. The Council considers that nobody, except the disabled person or person with reduced mobility, can decide what a dignified manner of transportation is and that such a decision should not be taken by the carrier.

According to the initial proposal, the carrier could require a disabled person or person with reduced mobility to be accompanied by another person who is capable of providing assistance. According to the Council's first-reading position, if the carrier makes such a request with respect to a passenger service, the accompanying person shall be carried free of charge.

As for the assistance to disabled persons and persons with reduced mobility, such assistance will be provided on the condition that the person concerned notifies the carrier or the terminal operator at the latest two working days in advance (the Commission had proposed 48 hours) and is present in the port or at a designated point at least 60 minutes before the embarkation or departure time. Furthermore, if the person has specific needs of accommodation or seating or for bringing medical equipment, the passenger should notify the carrier of such needs at the time of reservation, if the need is known at that time. This additional requirement, introduced by the Council, will allow for the carrier to cater for those specific needs and to give the best possible service to the person concerned.

Several of the European Parliament's amendments concerned information in formats accessible to disabled persons and persons with reduced mobility. These were taken on board by the Council. The same applies to the Parliament's amendments concerning changing from 'assistance animal' to 'assistance dog'.

(iii) *Obligations of carriers and terminal operators in the event of interrupted travel*

The Commission proposal provided for the right to information, assistance (including meals, refreshment and possibly hotel accommodation), re-routing and reimbursement as well as compensation of the ticket price for all passengers in case of delay and, in certain cases, cancellation of a passenger service or a cruise. However, compensation of the ticket price would not be paid when the delay or cancellation was caused by exceptional circumstances hindering the performance of the transport service.

The Council agrees with the principle that carriers and terminal operators should take care of their passengers, and it has extended this principle to include all cases of cancellations. Nevertheless, in certain cases it is not possible or reasonable to provide, for example, information on delays in an unmanned port. The Council's first-reading position therefore introduces the concept of port terminals, i.e. manned terminals in a port with certain facilities and staff (such as check in, ticket counters or lounges). Certain obligations of carriers and terminal operators only apply to passengers departing from such port terminals. This is the case of information and assistance and, to a certain extent, of re-routing and reimbursement.

Another consideration underlying the Council's first-reading position is that of maritime safety. In order to avoid that carriers, for economic reasons, set to sea or speed in weather conditions endangering the safe operation of the ship, an exemption has been introduced to the obligation of providing accommodation or compensation of the ticket price in such cases. Furthermore, the concepts of bad weather conditions and extraordinary circumstances are explained in a non-exhaustive manner in two recitals. Further exemptions to the right to assistance and compensation have been introduced when the passenger is informed of the cancellation or delay before buying the ticket or when the passenger causes the cancellation or delay. Finally, the carrier has been given the possibility to limit the cost for accommodation to 120 euro and to introduce a minimum threshold under which payments for compensation will not be paid (tickets costing 10 euro or less).

The European Parliament had suggested exemptions in case of force majeure (amendments 23 and 60) or if cancellation or delay is announced beforehand (amendment 59). The spirit of these amendments has been taken on board by the Council. Furthermore, the Parliament had proposed a limit for the cost of accommodation to twice the ticket price (amendment 53). The Council considers this to be too unfavourable for passengers and carriers in certain cases and finds the limitation to 120 euro more reasonable both for passengers and carriers.

(iv) *Complaint handling and national enforcement bodies*

The Commission proposal contained detailed rules on how carriers should handle complaints, in particular far-reaching legal consequences of not replying to complaints, and on the designation and responsibilities of national enforcement bodies.

The Council, though agreeing in principle with the proposal, in particular that carriers should reply to complaints from their customers, introduces more flexibility into the system in order to avoid any unforeseen consequences for the Member States' legal systems or administrative structures.

The European Parliament suggested that each Member State should designate only one national enforcement body (amendments 5, 6, 66, 67 and 68) and that the Member States, not the carriers, should set up an independent complaint handling mechanism (amendment 65). However, for the reasons of flexibility explained above, the Council does not consider it appropriate to limit the Member States' margin of manoeuvre in such a way. In addition, the Parliament proposed that the national enforcement bodies should be independent of all commercial interests (amendment 66). The Council's first-reading position specifies that these bodies should be independent of carriers, tour operators and terminal operators.

(v) *Date of application of the Regulation*

The Commission had proposed that the Regulation as a whole should apply from two years after publication, whereas certain provisions should apply already from one year after its publication.

The Council's first-reading position provides that the whole of the Regulation will apply from three years after its publication.

3. Other policy issues

The Council decides to simplify the title of the Regulation.

The Council decides to clarify the provisions on sub-contracting of certain obligations stemming from the Regulation by adding a general article on other performing parties.

The Council decides to delete the requirement for carriers to keep separate accounts for the cost of providing assistance to disabled persons and persons with reduced mobility in order to avoid unnecessary administrative burdens for, in particular, smaller carriers. In the same spirit, the Council decides to limit the obligation to set quality standard for such assistance to larger terminal operators and carriers, and to restrict the requirements of disability-related training and instructions to those categories of staff who actually need it.

4. Other amendments adopted by the European Parliament

Further amendments not included in the Council's first-reading position concern:

- taking into account the needs of disabled persons and persons with reduced mobility in all cases when ports, terminals and passenger ships are designed or refurbished, without the qualification 'when necessary' (amendment 2);
- the provisions governing the embarkation of disabled persons and persons with reduced mobility without prejudice to the general provisions applicable to embarkation of passengers (amendment 3);
- the invitation to the Commission to propose clear rules for passengers' rights at points of transfer between land and sea or inland waterway transport (amendment 7);
- a horizontal legislative approach covering all means of transportation in the event of a future legislative initiative relating to passenger rights (amendment 8);

- the inclusion of psychosocial disability in the definition of a disabled person or person with reduced mobility (amendment 11);
- changes to the definition of ‘transport contract’ (amendment 14) and ‘ticket vendor’ (amendment 15);
- the proposed definitions of ‘accessible formats’ (amendment 18), ‘passenger’ (amendment 19), ‘arrival’ (amendment 20), ‘departure’ (amendment 21), ‘ticket price’ (amendment 22) and ‘force majeure’ (amendment 23);
- the access rules for carriage of disabled persons and persons with reduced mobility, which should be established under the supervision of the national enforcement bodies and that these rules should include accompanying persons and the accessibility of fitted assistive equipment (amendment 31);
- the written confirmation to be given for the provision of assistance to disabled persons and persons with reduced mobility (amendment 34);
- assistance adapted to the individual needs of disabled persons or persons with reduced mobility (amendment 35);
- the responsibility of the managing body of a port to ensure that the port is accessible to disabled persons or persons with reduced mobility (amendment 37);
- the possibility of agreeing on a shorter notification period for assistance between the assistance provider and the passenger (amendment 38);
- the need to ensure that the passenger receives a confirmation of the notification of his or her assistance needs (amendment 39);
- the obligation of the carrier to provide replacement equipment suitable to the needs of the passenger concerned when mobility equipment is damaged during the journey (amendment 50);
- in case of delay, a passenger should only be offered reimbursement of the ticket price if he or she decides not to travel with the carrier (amendment 54);
- any compensation awarded under the Regulation, which may be deducted from any additional compensation granted (amendment 61);
- the penalties applicable to infringements of the Regulation, which could include ordering the payment of compensation (amendment 70);
- amendments 71, 72 and 75 concerning the Annexes to the Regulation.

III. CONCLUSION

In establishing its position at first reading, the Council has taken full account of the proposal of the Commission and the European Parliament’s opinion at first reading. With respect to the amendments proposed by the European Parliament, the Council observes that a considerable number of amendments have – in spirit, partially or fully – already been included in its first-reading position.

POSITION (EU) No 6/2010 OF THE COUNCIL AT FIRST READING

with a view to the adoption of a Regulation of the European Parliament and of the Council on novel foods, amending Regulation (EC) No 1331/2008 and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001

Adopted by the Council on 15 March 2010

(Text with EEA relevance)

(2010/C 122 E/03)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Acting in accordance with the ordinary legislative procedure ⁽²⁾,

Whereas:

- (1) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, as well as to their social and economic interests. Differences between national laws, regulations and administrative provisions concerning the safety assessment and authorisation of novel foods may hinder their free movement, thereby creating unfair conditions of competition.
- (2) A high level of protection of human health should be assured in the pursuit of Union policies. Due attention should be given, where appropriate, to the protection of the environment and to animal welfare.
- (3) The Union's rules on novel foods were established by Regulation (EC) No 258/97 of the European Parliament

and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ⁽³⁾ and by Commission Regulation (EC) No 1852/2001 of 20 September 2001 laying down detailed rules for making certain information available to the public and for the protection of information submitted pursuant to European Parliament and Council Regulation (EC) No 258/97 ⁽⁴⁾. For the sake of clarity, Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 should be repealed and Regulation (EC) No 258/97 should be replaced by this Regulation. Commission Recommendation 97/618/EC of 29 July 1997 concerning the scientific aspects and the presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽⁵⁾ should therefore become obsolete as regards novel foods.

- (4) In order to ensure continuity with Regulation (EC) No 258/97, the absence of a use for human consumption to a significant degree within the Union before the date of application of Regulation (EC) No 258/97, namely 15 May 1997, should be kept as the criterion for a food to be considered as novel. A use within the Union refers to a use in the Member States irrespective of the date of their accession to the European Union.
- (5) 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 ⁽⁶⁾ applies. The existing definition of novel food should be clarified and updated by replacing the existing categories with a reference to the general definition of food in that Regulation.
- (6) It should also be clarified that a food is to be considered as novel when a production technology which was not previously used for food production in the Union is applied to that food. In particular, emerging technologies

⁽¹⁾ OJ C 224, 30.8.2008, p. 81.

⁽²⁾ Position of the European Parliament of 25 March 2009 (not yet published in the Official Journal) and Council Position at first reading of 15 March 2010, position of the European Parliament of ... (not yet published in the Official Journal).

⁽³⁾ OJ L 43, 14.2.1997, p. 1.

⁽⁴⁾ OJ L 253, 21.9.2001, p. 17.

⁽⁵⁾ OJ L 253, 16.9.1997, p. 1.

⁽⁶⁾ OJ L 31, 1.2.2002, p. 1.

in breeding and food production processes which have an impact on food, and thus might have an impact on food safety, should be covered by this Regulation. Novel food should therefore include foods derived from animals produced by non-traditional breeding techniques and from their offspring, foods derived from plants produced by non-traditional breeding techniques, foods produced by new production processes which might have an impact on food, and foods containing or consisting of engineered nanomaterials. Foods derived from new plant varieties or animal breeds produced by traditional breeding techniques should not be considered as novel foods. Furthermore, it should be clarified that foods from third countries which are novel in the Union can be considered as traditional only when they are derived from primary production as defined in Regulation (EC) No 178/2002, whether they are processed or unprocessed (e.g. fruit, jam, fruit juice). However, foods thus obtained should neither include foods produced from animals or plants to which a non-traditional breeding technique was applied or foods produced from the offspring of such animals, nor foods to which a new production process is applied.

- (7) However, in the light of the opinion of the European Group on Ethics in Science and New Technologies, established by Commission Decision of 16 December 1997, issued on 16 January 2008 and of the opinion of the European Food Safety Authority adopted on 15 July 2008, techniques for the cloning of animals, such as somatic cell nuclear transfer, have specific characteristics such that this Regulation cannot address all the issues of cloning. Therefore, food produced from animals obtained by using a cloning technique and from the offspring thereof should be subject to a report submitted by the Commission to the European Parliament and the Council, followed, if appropriate, by a legislative proposal. If specific legislation is adopted, the scope of this Regulation should be adapted accordingly.
- (8) Implementing measures should be adopted to provide for criteria to facilitate the assessment of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997. If, prior to that date, a food was used exclusively as, or in, a food supplement, as defined in Directive 2002/46/EC⁽¹⁾, it should be allowed to be placed on the market within the Union after that date for the same use without being considered a novel food. However, that use as, or in, a food supplement should not be taken into account for the assessment of whether the food was

used for human consumption to a significant degree within the Union before 15 May 1997. Therefore, uses of the food concerned other than in, or as, a food supplement should be authorised in accordance with this Regulation.

- (9) The use of engineered nanomaterials in food production might increase with the further development of technology. In order to ensure a high level of protection of human health, free movement of goods and legal certainty for manufacturers, it is necessary to develop a uniform definition for engineered nanomaterial at international level. The Union should endeavour to reach an agreement on a definition in appropriate international fora. Should such an agreement be reached, the definition of engineered nanomaterial in this Regulation should be adapted accordingly.
- (10) Food products produced from food ingredients that do not fall within the scope of this Regulation, in particular by changing the ingredients of the food, their composition or amount, should not be considered a novel food. However, modifications of a food ingredient, e.g. selective extracts or the use of other parts of a plant, that have so far not been used for human consumption within the Union, should still fall within the scope of this Regulation.
- (11) The provisions of 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⁽²⁾ should apply where, taking into account all its characteristics, a product may fall both within the definition of 'medicinal product' and within the definition of a product covered by other Union legislation. In this respect, a Member State, if it establishes in accordance with Directive 2001/83/EC that a product is a medicinal product, should be able to restrict the placing on the market of such product in accordance with Union law. Moreover, medicinal products are excluded from the definition of food as established by Regulation (EC) No 178/2002 and should not be subject to this Regulation.
- (12) Novel foods authorised under Regulation (EC) No 258/97 should maintain their novel food status but authorisation should be required for any new uses of such foods.

⁽¹⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽²⁾ OJ L 311, 28.11.2001, p. 67.

- (13) Foods which are intended for technological uses or which are genetically modified should not fall within the scope of this Regulation. Therefore, genetically modified food falling within the scope of Regulation (EC) No 1829/2003 ⁽¹⁾, food used solely as additives falling within the scope of Regulation (EC) No 1333/2008 ⁽²⁾, flavourings falling within the scope of Regulation (EC) No 1334/2008 ⁽³⁾, enzymes falling within the scope of Regulation (EC) No 1332/2008 ⁽⁴⁾ and extraction solvents falling within the scope of Directive 2009/32/EC ⁽⁵⁾ should not be covered by this Regulation.
- (14) The use of vitamins and minerals is governed by specific sectoral food laws. The vitamins and minerals falling within the scope of Directive 2002/46/EC, Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods ⁽⁶⁾ and Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (recast) ⁽⁷⁾ should therefore be excluded from the scope of this Regulation. However, those specific legal acts do not deal with cases where authorised vitamins and mineral substances are obtained by production methods or using new sources that were not taken into account when they were authorised. Therefore, pending the amendment of those specific legal acts, such vitamins and mineral substances should not be excluded from the scope of this Regulation when the production methods or new sources give rise to significant changes in the composition or structure of the vitamins or minerals which affect their nutritional value, how they are metabolised or the level of undesirable substances.
- (15) Novel foods, other than vitamins and minerals, intended for particular nutritional uses, for food fortification or as food supplements, should be assessed in conformity with this Regulation. They should also remain subject to the rules provided for in Directive 2002/46/EC, in Regulation (EC) No 1925/2006, in Directive 2009/39/EC, and in the specific Directives referred to in Directive 2009/39/EC and in Annex I thereto.
- (16) The determination of whether a food was used for human consumption to a significant degree within the Union before 15 May 1997 should be based on information submitted by food business operators and, where appropriate, supported by other information available in the Member States. When there is no or insufficient information available on human consumption before 15 May 1997, a simple and transparent procedure, involving the Commission, the Member States and any parties concerned, should be established for collecting that information.
- (17) Novel foods should be placed on the market within the Union only if they are safe and do not mislead the consumer. In addition, where the novel food is intended to replace another food, it should not differ from that food in a way that would be nutritionally disadvantageous for the consumer.
- (18) It is necessary to apply a harmonised centralised procedure for safety assessment and authorisation that is efficient, time-limited and transparent. With a view to further harmonising different procedures for the authorisation of food, the safety assessment of novel foods and their inclusion in the Union list should be carried out in accordance with the procedure laid down in Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings ⁽⁸⁾, which should be applicable whenever it is not specifically derogated from by this Regulation. Upon receipt of an application for authorisation of a product as a novel food, the Commission should assess the validity and applicability of the application. The authorisation of a novel food should also take into account other factors relevant to the matter under consideration, including ethical, environmental, animal welfare factors and the precautionary principle.
- (19) Criteria for the evaluation of the potential risks arising from novel foods should also be laid down. In order to ensure the harmonised scientific assessment of novel foods, such assessments should be carried out by the European Food Safety Authority ('the Authority').
- (20) At present, there is inadequate information on the risks associated with engineered nanomaterials. In order to better assess their safety the Commission, in cooperation with the Authority, should develop test methodologies which take into account specific characteristics of engineered nanomaterials.
- ⁽¹⁾ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).
- ⁽²⁾ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).
- ⁽³⁾ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods (OJ L 354, 31.12.2008, p. 34).
- ⁽⁴⁾ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (OJ L 354, 31.12.2008, p. 7).
- ⁽⁵⁾ 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 (recast) (OJ L 141, 6.6.2009, p. 3).
- ⁽⁶⁾ OJ L 404, 30.12.2006, p. 26.
- ⁽⁷⁾ OJ L 124, 20.5.2009, p. 21.
- ⁽⁸⁾ OJ L 354, 31.12.2008, p. 1.

- (21) In order to simplify procedures, applicants should be allowed to present a single application for foods regulated under different sectoral food laws. Regulation (EC) No 1331/2008 should therefore be amended accordingly. As a consequence of the entry into force of the Treaty of Lisbon on 1 December 2009, the European Union has replaced and succeeded the European Community, and the word 'Community' should be replaced by 'Union' throughout that Regulation.
- (22) If traditional foods from third countries are included in the list of traditional foods from third countries, they should be allowed to be placed on the market within the Union, under conditions that correspond to those for which the history of safe food use has been demonstrated. As regards the safety assessment and management of traditional food from third countries, their history of safe food use in their country of origin should be taken into account. The history of safe food use should not include non-food uses or uses not related to normal diets.
- (23) Where appropriate and based on the conclusions of the safety assessment, post-market monitoring requirements for the use of novel foods for human consumption should be introduced.
- (24) The inclusion of a novel food in the Union list of novel foods or in the list of traditional foods from third countries should be without prejudice to the possibility of evaluating the effects of the overall consumption of a substance which is added to, or used for the manufacture of that food, or of a comparable product in accordance with Regulation (EC) No 1925/2006.
- (25) Under specific circumstances, in order to stimulate research and development within the agri-food industry, and thus innovation, the newly developed scientific evidence and proprietary data provided in support of an application for inclusion of a novel food in the Union list should be protected. That data and information should not be used to the benefit of a subsequent applicant, during a limited period of time, without the agreement of the prior applicant. The protection of scientific data provided by one applicant should not prevent other applicants from seeking the inclusion in the Union list of novel foods on the basis of their own scientific data.
- (26) Novel foods are subject to the general labelling requirements laid down in Directive 2000/13/EC ⁽¹⁾
- and, where necessary, to the nutritional labelling requirements laid down in Directive 90/496/EEC ⁽²⁾. In certain cases it might be necessary to provide for additional labelling information, in particular regarding the description of the food, its source or its conditions of use. Therefore, when a novel food is included in the Union list or in the list of traditional foods from third countries, specific conditions of use or labelling obligations may be imposed, which might, *inter alia*, relate to any specific characteristic or food property, such as composition, nutritional value or nutritional effects and intended use of the food, or to ethical considerations or implications for the health of specific groups of the population.
- (27) Regulation (EC) No 1924/2006 ⁽³⁾ harmonises the provisions in the Member States which relate to nutrition and health claims. Therefore, claims regarding novel foods should only be made in accordance with that Regulation.
- (28) The European Group on Ethics in Science and New Technologies may be consulted, where appropriate, with a view to obtaining advice on ethical issues regarding the placing on the market within the Union of novel foods.
- (29) Novel foods placed on the market within the Union under Regulation (EC) No 258/97 should continue to be placed on the market. Novel foods authorised in accordance with Regulation (EC) No 258/97 should be included in the Union list of novel foods established by this Regulation. In addition, applications submitted under Regulation (EC) No 258/97 before the date of application of this Regulation should be transformed into an application under this Regulation where the initial assessment report provided for under Regulation (EC) No 258/97 has not yet been forwarded to the Commission, as well as in all cases where an additional assessment report is required in accordance with that Regulation. Other pending requests submitted under Article 4 of Regulation (EC) No 258/97 before the date of application of this Regulation should be processed under the provisions of Regulation (EC) No 258/97.
- (30) Regulation (EC) No 882/2004 ⁽⁴⁾ lays down general rules for the performance of official controls to verify compliance with food law. The Member States should be requested to carry out official controls in accordance with that Regulation, in order to enforce compliance with this Regulation.

⁽¹⁾ Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29).

⁽²⁾ Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs (OJ L 276, 6.10.1990, p. 40).

⁽³⁾ 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 (OJ L 404, 30.12.2006, p. 9).

⁽⁴⁾ 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).

(31) Requirements in respect of the hygiene of foodstuffs as laid down in Regulation (EC) No 852/2004 ⁽¹⁾ apply.

(32) Since the objective of this Regulation, namely laying down harmonised rules for the placing of novel foods on the market within the Union, cannot be sufficiently achieved by the Member States and can therefore be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(33) The Member States should lay down the rules on penalties applicable to infringements of the provisions of this Regulation and should take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

(34) The measures necessary for the implementation of this Regulation should be adopted in accordance with Articles 5 and 7 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽²⁾.

(35) In particular, the Commission should be empowered to clarify certain definitions in order to ensure a harmonised implementation of these provisions by the Member States on the basis of relevant criteria, including the definition of 'engineered nanomaterial', taking into account the technical and scientific developments, and the non-traditional animal breeding technique that includes techniques used for asexual reproduction of genetically identical animals not used for food production within the Union before 15 May 1997. Furthermore, the Commission should be empowered to adopt any appropriate transitional measures and to update the list of traditional foods from third countries and the Union list.

(36) In addition, the Commission should be empowered to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union in respect of the criteria according to which foods may be considered as having been used for human consumption to a significant degree within the Union before 15 May 1997. It is of particular importance that the Commission consult experts in the preparatory phase in accordance with the commitment of the Commission undertaken in the Communication of 9 December 2009 on the implementation of Article 290 of the Treaty on the Functioning of the European Union,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

INTRODUCTORY PROVISIONS

Article 1

Subject matter

This Regulation lays down harmonised rules for the placing of novel foods on the market within the Union with a view to ensuring a high level of protection of human health and consumers' interests, whilst ensuring the effective functioning of the internal market, taking into account, where appropriate, the protection of the environment and animal welfare.

Article 2

Scope

1. This Regulation shall apply to the placing of novel foods on the market within the Union.

2. This Regulation shall not apply to:

(a) foods when and in so far as they are used as:

(i) food additives falling within the scope of Regulation (EC) No 1333/2008;

(ii) food flavourings falling within the scope of Regulation (EC) No 1334/2008;

(iii) extraction solvents used in the production of foodstuffs and falling within the scope of Directive 2009/32/EC;

(iv) food enzymes falling within the scope of Regulation (EC) No 1332/2008;

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

⁽²⁾ OJ L 184, 17.7.1999, p. 23.

- (v) vitamins and minerals falling within the respective scope of Directive 2002/46/EC, Regulation (EC) No 1925/2006 or Directive 2009/39/EC, except for vitamin and mineral substances already authorised, which are obtained by production methods or using new sources that were not taken into account when they were authorised under specific legislation, where those production methods or new sources give rise to the significant changes referred to in point (iii) of Article 3(2)(a) of this Regulation;
- (b) foods falling within the scope of Regulation (EC) No 1829/2003.

Article 3

Definitions

1. For the purposes of this Regulation, the definitions laid down in Regulation (EC) No 178/2002 shall apply.

2. The following definitions shall also apply:

- (a) 'novel food' means food that was not used for human consumption to a significant degree within the Union before 15 May 1997, including:
- (i) food of animal origin, when a non-traditional breeding technique not used for food production within the Union before 15 May 1997 is applied to the animal, and food derived from the offspring of these animals;
- (ii) food of plant origin, when a non-traditional breeding technique not used for food production within the Union before 15 May 1997 is applied to the plant, if that non-traditional breeding technique applied to a plant gives rise to significant changes in the composition or structure of the food, which affect its nutritional value, how it is metabolised or the level of undesirable substances;
- (iii) food to which a new production process not used for food production within the Union before 15 May 1997 is applied, if that production process gives rise to significant changes in the composition or structure of the food which affect its nutritional value, how it is metabolised or the level of undesirable substances;
- (iv) food containing or consisting of engineered nano-materials;
- (v) traditional food from a third country; and

- (vi) food ingredients used exclusively in food supplements within the Union before 15 May 1997, if they are to be used in foods other than food supplements. However, if a food has been used exclusively as, or in, a food supplement prior that date, it may be placed on the market within the Union after that date for the same use without being considered a novel food;

- (b) 'offspring' means an animal produced by a traditional breeding technique, where at least one of its parents is an animal produced by a non-traditional breeding technique;

- (c) 'engineered nanomaterial' means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.

Properties that are characteristic of the nanoscale include:

- (i) those related to the large specific surface area of the materials considered; and/or
- (ii) specific physico-chemical properties that are different from those of the non-nanoform of the same material;
- (d) 'traditional food from a third country' means novel food, other than the novel food under sub-points (i) to (iv) of point (a), derived from primary production, with a history of food use in any third country, such that the food in question has been and continues to be part of the customary diet for at least 25 years in a large part of the population of the country;
- (e) 'history of safe food use in a third country' means that the safety of the food in question is confirmed with compositional data and from experience of use and continued use for at least 25 years in the customary diet of a large part of the population of a country.

3. The Commission may adopt further criteria to clarify the definitions in sub-points (i) to (iv) of point (a), and in points (c), (d) and (e) of paragraph 2 of this Article in accordance with the regulatory procedure referred to in Article 19(2).

*Article 4***Procedure for determination of novel food status**

1. Food business operators shall verify the status of the food they intend to place on the market within the Union with respect to the scope of this Regulation.

2. In case of doubt, food business operators shall consult the relevant competent authority for novel foods as defined in Article 15 of Regulation (EC) No 1331/2008 on the status of the food in question. On request from the relevant competent authority, food business operators shall submit information concerning the extent to which the food in question was used for human consumption within the Union before 15 May 1997.

3. Where necessary, the competent authority may consult other competent authorities and the Commission concerning the extent to which a food was used for human consumption within the Union before 15 May 1997. Replies to any such consultation shall also be transmitted to the Commission. The Commission shall summarise the replies received and communicate the result of the consultation to all competent authorities.

4. The Commission may adopt implementing measures for paragraph 3 of this Article in accordance with the regulatory procedure referred to in Article 19(2).

*Article 5***Interpretation decisions**

Where necessary, it may be decided in accordance with the regulatory procedure referred to in Article 19(2) whether a type of food falls within the scope of this Regulation.

CHAPTER II

REQUIREMENTS FOR PLACING NOVEL FOODS ON THE MARKET WITHIN THE UNION*Article 6***Prohibition of non-compliant novel foods**

No person shall place on the market within the Union a novel food if it does not comply with this Regulation.

*Article 7***Lists of novel foods**

1. The Commission shall maintain a Union list of authorised novel foods other than traditional foods from third countries (hereinafter 'the Union list'), which shall be published in accordance with Article 2(1) of Regulation (EC) No 1331/2008.

2. The Commission shall establish and maintain a list of traditional foods from third countries authorised pursuant to Article 11(5) of this Regulation, which shall be published in the C series of the *Official Journal of the European Union*.

3. Only novel foods included in the Union list or in the list of traditional foods from third countries may be placed on the market within the Union.

*Article 8***General conditions for inclusion of novel foods in the lists**

A novel food may be included in the relevant list only if it meets the following conditions:

- (a) it does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer;
- (b) it does not mislead the consumer;
- (c) if it is intended to replace another food, it does not differ from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

*Article 9***Content of the Union list**

1. The Union list shall be updated in accordance with the procedure laid down in Regulation (EC) No 1331/2008 and, where applicable, in accordance with Article 16 of this Regulation.

2. The entry for a novel food in the Union list shall include a specification of the food, and, where appropriate, specify the conditions of use, additional specific labelling requirements to inform the final consumer, and/or a post-market monitoring requirement and, where applicable, the information referred to in Article 16(4).

*Article 10***Content of the list of traditional foods from third countries**

1. The list of traditional foods from third countries shall be updated in accordance with the procedure laid down in Article 11.

2. The entry for a traditional food from a third country in the list of traditional foods from third countries shall include a specification of the food, and, where appropriate, specify the conditions of use and/or additional specific labelling requirements to inform the final consumer.

*Article 11***Procedure for including a traditional food from a third country in the list**

1. By way of derogation from the procedure laid down in Article 9(1) of this Regulation, an interested party referred to in Article 3(1) of Regulation (EC) No 1331/2008, who intends to place on the market within the Union a traditional food from a third country, shall submit an application to the Commission.

The application shall include:

- (a) the name and description of the food,
- (b) its composition,
- (c) its country of origin,
- (d) documented data demonstrating the history of safe food use in any third country,
- (e) where applicable, the conditions of use and specific labelling requirements,
- (f) a summary of the content of the application.

The application shall be made in accordance with the implementing rules referred to in paragraph 7 of this Article.

2. The Commission shall forward the valid application referred to in paragraph 1 without delay to the Member States and the Authority.

3. Within six months of receipt of an application, the Authority shall give its opinion. Whenever the Authority seeks supplementary information from the interested party, it shall, after consulting the interested party, lay down a period within which that information shall be provided. The six-month time limit shall be automatically extended by this additional period. The supplementary information shall be made available to the Member States and the Commission by the Authority.

4. In order to prepare its opinion the Authority shall verify that:

- (a) the history of safe food use in any third country is substantiated by the quality of data submitted by the interested party; and

- (b) the composition of the food and, where applicable, the conditions of its use, do not pose a health risk to consumers in the Union.

The Authority shall forward its opinion to the Commission, the Member States and the interested party.

5. Within three months of the Authority giving its opinion, the Commission shall, in accordance with the regulatory procedure referred to in Article 19(2), update the list of traditional foods from third countries, taking account of the opinion of the Authority, any relevant provisions of Union law and any other legitimate factors relevant to the matter under consideration. The Commission shall inform the interested party accordingly. If the Commission decides not to proceed with an update of the list of traditional foods from third countries, it shall inform the interested party and the Member States accordingly, indicating the reasons for not considering the update justified.

6. At any stage of the procedure the interested party may withdraw its application.

7. By ... (*), the Commission shall adopt detailed rules for the implementation of this Article in accordance with the regulatory procedure referred to in Article 19(2).

*Article 12***Technical guidance**

Without prejudice to the implementing measures adopted under point (a) of Article 9(1) of Regulation (EC) No 1331/2008 and by ... (*), the Commission shall, where appropriate, in close cooperation with the Authority and after consultation with interested parties, make available technical guidance and tools to assist interested parties in preparing and submitting applications under this Regulation; in particular, food business operators, especially small and medium-sized enterprises.

*Article 13***Opinion of the Authority**

In assessing the safety of novel foods, where appropriate, the Authority shall, in particular:

- (a) consider whether the food is as safe as food from a comparable food category already existing on the market within the Union or as safe as the food that the novel food is intended to replace;

- (b) take into account the history of safe food use.

(*) 2 years after the entry into force of this Regulation.

Article 14

Special obligations on food business operators

1. The Commission may, for food safety reasons and following the opinion of the Authority, impose a requirement for post-market monitoring. The food business operator placing the food on the market within the Union shall be responsible for fulfilling the post-marketing requirements specified in the entry of the food concerned in the Union list of novel foods.

2. The producer shall forthwith inform the Commission of:

- (a) any new scientific or technical information which might influence the evaluation of the safety in use of the novel food;
- (b) any prohibition or restriction imposed by the competent authority of any third country in which the novel food is placed on the market.

Article 15

European Group on Ethics in Science and New Technologies

The Commission, on its own initiative or at the request of a Member State, may consult the European Group on Ethics in Science and New Technologies, with a view to obtaining its opinion on ethical questions relating to science and new technologies of major ethical importance.

The Commission shall make this opinion available to the public.

Article 16

Authorisation procedure in cases of data protection

1. On request by the applicant, supported by appropriate and verifiable information included in the application dossier, newly developed scientific evidence and/or scientific data supporting the application may not be used for the benefit of another application during a period of five years from the date of the inclusion of the novel food in the Union list without the agreement of the prior applicant. This protection shall be granted where:

- (a) newly developed scientific evidence and/or scientific data was designated as proprietary by the applicant at the time the first application was made (proprietary scientific data);
- (b) the prior applicant had exclusive right of reference to the proprietary scientific data at the time the first application was made; and

- (c) the novel food could not have been authorised without the submission of the proprietary scientific data by the prior applicant.

However, a prior applicant may agree with a subsequent applicant that such data and information may be used.

2. The Commission shall determine, in consultation with the applicant, which information should be granted the protection referred to in paragraph 1 and shall inform the applicant, the Authority and the Member States of its decision.

3. By way of derogation from Article 7(5) of Regulation (EC) No 1331/2008, the updating of the Union list with a novel food, other than traditional food from third countries, shall be decided in accordance with the regulatory procedure referred to in Article 19(2) of this Regulation in cases where proprietary scientific data are protected in accordance with this Article. In this case, the authorisation shall be granted for the period specified in paragraph 1 of this Article.

4. In the cases referred to in paragraph 3 of this Article, the entry of a novel food in the Union list shall indicate, in addition to the information referred to in Article 9(2) of this Regulation:

- (a) the date of entry of the novel food in the Union list;
- (b) the fact that the entry is based on proprietary newly developed scientific evidence and/or proprietary scientific data protected in accordance with this Article;
- (c) the name and address of the applicant;
- (d) the fact that the novel food is authorised for placing on the market within the Union only by the applicant specified in point (c), unless a subsequent applicant obtains authorisation for the food without reference to the proprietary scientific data designated as such by the prior applicant.

5. Before the expiry of the period referred to in paragraph 1 of this Article, the Commission shall update the Union list in accordance with the regulatory procedure referred to in Article 19(2) so that, provided that the authorised food still meets the conditions laid down in this Regulation, the specific indications referred to in paragraph 4 of this Article are no longer included.

Article 17

Information to the public

The Commission shall make available to the public:

- (a) the Union list referred to in Article 7(1) and the list of traditional foods from third countries referred to in Article 7(2), on a single dedicated page of the Commission website;
- (b) the summaries of the applications submitted under this Regulation;
- (c) the findings of the consultations referred to in Article 4(3).

The Commission may adopt the implementing measures for this Article, including arrangements for making public the outcome of the consultations under point (c) of the first paragraph of this Article, in accordance with the regulatory procedure referred to in Article 19(2).

CHAPTER III

GENERAL PROVISIONS

Article 18

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by ... (*) and shall notify it without delay of any subsequent amendment affecting them.

Article 19

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health, set up by Article 58 of Regulation (EC) No 178/2002.
2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

(*) 24 months after the date of entry into force of this Regulation.

Article 20

Delegated acts

For the purposes of achieving the objectives of this Regulation as set out in Article 1, the Commission shall, no later than ... (*), adopt further criteria for assessing whether a food was used for human consumption to a significant degree within the Union before 15 May 1997, as referred to in point (a) of Article 3(2), by means of delegated acts in accordance with Article 21 and subject to the conditions of Articles 22 and 23.

Article 21

Exercise of the delegation

1. The power to adopt the delegated acts referred to in Article 20 shall be conferred on the Commission for a period of five years following the entry into force of this Regulation. The Commission shall make a report in respect of the delegated powers at the latest six months before the end of the five-year period. The delegation of power shall be automatically extended for periods of an identical duration, unless the European Parliament or the Council revokes it in accordance with Article 22.

2. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

3. The power to adopt delegated acts are conferred on the Commission subject to the conditions laid down in Articles 22 and 23.

Article 22

Revocation of the delegation

1. The delegation of power referred to in Article 20 may be revoked at any time by the European Parliament or by the Council.
2. The institution which has commenced an internal procedure for deciding whether to revoke the delegation of power shall inform the other institution and the Commission at the latest one month before the final decision is taken, stating the delegated powers which could be subject to revocation and the reasons for a revocation.
3. The decision of revocation shall put an end to the delegation of the powers specified in that decision. It shall take effect immediately or at a later date specified therein. It shall not affect the validity of the delegated acts already in force. It shall be published in the *Official Journal of the European Union*.

*Article 23***Objections to delegated acts**

1. The European Parliament or the Council may object to the delegated act within a period of three months from the date of notification.

2. If, on expiry of that period, neither the European Parliament nor the Council has objected to the delegated act, or if, before that date, the European Parliament and the Council have both informed the Commission that they have decided not to raise objections, the delegated act shall enter into force on the date stated therein.

3. If the European Parliament or the Council objects to the delegated act, it shall not enter into force. The institution which objects shall state the reasons for objecting to the delegated act.

*Article 24***Review**

1. By ... (*) and in the light of experience gained, the Commission shall submit to the European Parliament and to the Council a report on the implementation of this Regulation and in particular of Articles 3, 11 and 16, accompanied, where appropriate, by any legislative proposals.

2. By ... (**), the Commission shall submit to the European Parliament and to the Council a report on all aspects of food produced from animals obtained by using a cloning technique and from their offspring, followed, where appropriate, by any legislative proposals.

3. The reports and any proposals shall be made accessible to the public.

CHAPTER IV

TRANSITIONAL AND FINAL PROVISIONS*Article 25***Repeal**

Regulation (EC) No 258/97 and Regulation (EC) No 1852/2001 shall be repealed with effect from ... (***), except with respect to those pending requests governed by Article 27 of this Regulation.

(*) 5 years after the entry into force of this Regulation.

(**) 1 year after the entry into force of this Regulation.

(***) 24 months after the entry into force of this Regulation.

*Article 26***Establishment of the Union list**

No later than ... (***) the Commission shall establish the Union list by entering novel foods authorised and/or notified under Articles 4, 5 and 7 of Regulation (EC) No 258/97 in the Union list, including any existing authorisation conditions, as appropriate.

*Article 27***Transitional measures**

1. Any request for placing a novel food on the market within the Union submitted to a Member State under Article 4 of Regulation (EC) No 258/97 before ... (***) shall be transformed into an application under this Regulation if an initial assessment report provided for under Article 6(3) of Regulation (EC) No 258/97 has not yet been forwarded to the Commission, and in cases where the additional assessment report is required in accordance with Article 6(3) or (4) of Regulation (EC) No 258/97.

Other pending requests submitted under Article 4 of Regulation (EC) No 258/97 before ... (***) shall be processed under the provisions of that Regulation.

2. The Commission may, in accordance with the regulatory procedure referred to in Article 19(2), adopt appropriate transitional measures for the application of paragraph 1 of this Article.

*Article 28***Amendments to Regulation (EC) No 1331/2008**

Regulation (EC) No 1331/2008 is hereby amended as follows:

1. The title is replaced by the following:

‘Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes, food flavourings and novel foods’.

2. In Article 1, paragraphs 1 and 2 are replaced by the following:

‘1. This Regulation lays down a common procedure for the assessment and authorisation (hereinafter referred to as the “common procedure”) of food additives, food enzymes, food flavourings and source materials of food flavourings and of food ingredients with flavouring properties used or intended for use in or on foodstuffs and novel foods (hereinafter referred to as the “substances or products”) which contributes to the free movement of food within the Union and to a high level of protection of human health and to a high level of consumer protection, including the protection of consumer interests. This Regulation shall not

apply to smoke flavourings falling within the scope of 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 (*).

2. The common procedure shall lay down the procedural arrangements for updating the lists of substances and products the marketing of which is authorised in the Union pursuant to Regulation (EC) No 1333/2008, Regulation (EC) No 1332/2008, Regulation (EC) No 1334/2008 and Regulation (EU) No .../2010 of the European Parliament and of the Council of ... on novel foods (**) (hereinafter referred to as the “sectoral food laws”).

(*) OJ L 309, 26.11.2003, p. 1.

(**) OJ L ... ’.

3. In Article 1(3), Article 2(1) and (2), Article 9(2), Article 12(1) and Article 13 the words ‘substance’ and ‘substances’ are replaced by ‘substance or product’ or ‘substances or products’ as appropriate.

4. The title of Article 2 is replaced by the following:

‘Union list of substances or products’.

5. The following paragraph is added to Article 4:

‘3. A single application relating to a substance or product may be made to update the different Union lists regulated under the different sectoral food laws in so far as the application complies with the requirements of each of the sectoral food laws.’.

6. The following sentence is inserted at the beginning of Article 6(1):

‘In the case of scientific grounds for safety concerns, additional information concerning risk assessment shall be identified and requested from the applicant.’.

7. In Article 7, paragraphs 4, 5 and 6 are replaced by the following:

‘4. The measures, designed to amend non-essential elements of each sectoral food law, with the exception of

novel foods, relating to the removal of a substance from the Union list, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(3).

5. On grounds of efficiency, the measures designed to amend non-essential elements of each sectoral food law, with the exception of novel foods, inter alia, by supplementing it, relating to the addition of a substance to the Union list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of the substance on the Union list, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 14(4).

6. With exception of novel foods and on imperative grounds of urgency, the Commission may use the urgency procedure referred to in Article 14(5) for the removal of a substance from the Union list and for adding, removing or changing conditions, specifications or restrictions associated with the presence of a substance on the Union list.

7. The measures relating to the removal, the adding of a product covered by the Regulation on novel foods to the Union list and/or for adding, removing or changing conditions, specifications or restrictions associated with the presence of such product on the Union list shall be adopted in accordance with the regulatory procedure referred to in Article 14(2).’.

8. The term ‘Community’ shall be replaced by ‘Union’.

Article 29

Entry into force

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

It shall apply from ... (*).

However, Articles 26, 27 and 28 shall apply from ... (**). Furthermore, by way of derogation from the second paragraph of this Article and by way of derogation from the second paragraph of Article 16 of Regulation (EC) No 1331/2008, applications may be made in accordance with this Regulation as from ... (**) for the authorisation of food referred to in point (iv) of Article 3(2)(a) of this Regulation, where such food is already on the market within the Union at that date.

(*) 24 months after the entry into force of this Regulation.

(**) Date of entry into force of this Regulation.

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

Done at ...,

For the European Parliament
The President

...

For the Council
The President

...

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

On 15 January 2008, the Commission submitted a proposal⁽¹⁾ for a Regulation on novel foods and amending Regulation (EC) No 1331/2008 of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings. The proposal was based on Article 95 of the Treaty establishing the European Community.

Acting in accordance with Article 251 of the Treaty establishing the European Community, the European Parliament adopted its first reading Opinion on 25 March 2009⁽²⁾.

The Economic and Social Committee adopted its opinion on 29 May 2008⁽³⁾.

In accordance with Article 294(5) of the Treaty on the Functioning of the European Union (TFEU), the Council adopted its position at first reading by unanimity on 15 March 2010.

II. OBJECTIVE OF THE PROPOSED REGULATION

The Commission announced already in the White Paper on Food Safety adopted on 12 January 2000⁽⁴⁾ its intentions to examine the application of the novel food legislation and to make the necessary adaptations to the existing Regulation (EC) No 258/97 on novel foods and novel food ingredients.

The proposal aims at updating and clarifying the regulatory framework for authorisation and placing on the market of novel foods while ensuring food safety, protection of human health and consumer interests and the effective functioning of the internal market. It repeals the current Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001.

The proposal keeps the date of 15 May 1997 as the threshold date for determination of the novelty of the food and clarifies that the novel food definitions include foods to which new technologies are applied or foods originating from plants or animals to which non-traditional breeding techniques are applied.

The Commission proposed that the placing on the market of novel foods would be subject to a centralised procedure at the Community level in accordance with Regulation (EC) No 1331/2008 establishing the common authorisation procedure that would replace the current system of risk assessment by national authorities. The risk assessment would be carried out by the European Food Safety Authority (EFSA). The inclusion of a novel food in the Community list of novel foods would be considered by the Commission on the basis of the opinion from EFSA. The Commission would be assisted by the Standing Committee on the Food Chain and Animal Health (SCFCAH). The final decision to update the list of novel foods would be made by the Commission via the comitology with scrutiny procedure.

The applicant-linked authorisation would be replaced and the simplified procedure abolished by authorisation decisions addressed to the Community as a general rule. Protection of data could be granted in justified cases concerning newly developed scientific evidence and proprietary data in order to support innovation in the agri-food industry.

The proposal introduced a definition of 'traditional food from a third country', as a category of novel food that should be subject to notification if no reasoned safety objections are presented by EFSA or Member States.

Already authorised novel foods would continue to be marketed and included in the Community list of novel foods.

⁽¹⁾ 5431/08.

⁽²⁾ 7990/09.

⁽³⁾ OJ C 224, 30.8.2008, p. 81.

⁽⁴⁾ 5761/00, COM(1999) 719 final.

III. ANALYSIS OF THE COUNCIL POSITION

1. *Introductory remarks*

The Council position reflects the result of the examination of the Commission's proposal by the Council. The Council introduced several changes in the text, some of them inspired by the amendments proposed by the European Parliament.

The Commission has accepted all the changes introduced by the Council to its proposal, except the introduction of the definition of offspring of cloned animals in Article 3(2)(b) and the inclusion of offspring in Article 3(2)(a)(i).

2. *The amendments of the European Parliament*

In its plenary vote on 25 March 2009, the European Parliament adopted 76 amendments to the proposal ⁽¹⁾. The Council incorporated in its common position 30 amendments, of which 20 in full (amendments 7, 15, 16, 20, 35, 41, 42, 44, 45, 53, 63, 65, 67, 68, 69, 76, 77, 88, 89, 93), 5 in part (amendments 1, 30, 40, 91, 92) and 5 in principle (amendments 3, 6, 11, 25, 64).

2.1. *The main modifications introduced by the Council in the proposal, with reference to EP amendments* ⁽²⁾

- (a) Objectives of the Regulation (Article 1 and recitals 1 and 2) — the Council added the protection of the environment and animal welfare. This partly covers amendments 1 and 30 and reflects the spirit of amendment 3.
- (b) Scope (Article 2(2)(a)(v) and recitals 13 and 14) — the Council clarified that, pending the respective amendments to Regulation (EC) No 1925/2006, Directive 2002/46/EC and Directive 89/398/EEC, those vitamins and minerals obtained from new sources or using a production process, which were not taken into account at the moment of their authorisation and which give rise to significant changes in the composition or structure of food which affect its nutritional value, metabolism or level of undesirable substances should be within the scope of the novel food Regulation. This is in line with the first part of amendment 91.
- (c) Definition of novel foods (Article 3 and recitals 6, 8, 10, 11) — the basic criterion for assessing the novelty of the food remains whether it has been used for human consumption to a significant degree within the Union before 15 May 1997. In order to provide legal clarity, the Council agreed that further criteria for assessing human consumption to a significant degree within the Union before 15 May 1997 must be developed before the date of application of the Regulation. The adoption of these criteria has been delegated to the Commission according to Article 290 TFEU. This was coupled with delaying the date of application until 24 months after the date of entry into force.

In order to ensure better clarity, the following changes of definition have been made:

- a distinction has been made between food of animal and food of plant origin. Food of plant origin falls under the scope of this Regulation only if a non-traditional breeding technique applied to the plant gives rise to significant changes in the composition or structure of the food;
- addition of the definition of 'offspring' and 'engineered nanomaterial' (see also points (d) and (e) below);
- ingredients used in food supplements before 15 May 1997 fall under the definition, and consequently require authorisation, only if they are to be used in foods other than food supplements;
- definition of the 'traditional food from a third country' cover food that is derived only from primary production and for which the history of safe food use has been proven in any third country for a continuous period of 25 years in the customary diet of a large part of the population;

⁽¹⁾ 7990/09 (P6_TA(2009)0171)

⁽²⁾ The numbering of recitals and Articles refers to the text of the Council position at first reading.

- it has been noted that the level of harmonisation for medicinal products makes it possible that a Member State may, if it establishes in accordance with Directive 2001/83/EC that a substance is a medicinal product, restrict the placing on the market of such product in accordance with Union law, even if the same product has been authorized as a novel food under the present Regulation.

The Council also agreed that the Commission may, through the regulatory comitology procedure, adopt further criteria to clarify definitions in sub-points (i) to (iv) of point (a) and points (c), (d) and (e) of Article 3(2) in order to ensure their harmonised implementation by the Member States.

These changes cover amendment **15, 16, 35, 63** and most of amendment **92**.

- (d) Food produced from animals obtained by non-traditional breeding techniques and their offspring (Article 3(2)(a)(i) and recitals 6 and 7) — the Council agreed that foods produced from animals obtained by non-traditional breeding techniques (e.g. cloning) and their offspring shall fall within the scope of the Regulation. At the same time, the Council is of the opinion that this Regulation cannot adequately manage all aspects of cloning and that the Commission should study the subject further. To this end, the Commission shall forward, within one year from the date of entry into force of this Regulation, to the European Parliament and the Council a report on all aspect of food production from cloned animals and their offspring, followed, if appropriate, by legislative proposal (Article 20(2)). This is in line with amendment **93**. The Council considered that it was necessary to keep food produced from cloned animals within the scope of the proposed Regulation until any specific legislation has been proposed by the Commission and adopted. This solution avoids a legal vacuum that would be created by excluding such a food from the Regulation as proposed by the European Parliament in the absence of any legislation regulating food production from cloned animals.

- (e) Nanomaterials — the Council recognized the need for systematic safety evaluation and authorisation of foods containing or consisting of engineered nanomaterials irrespective of any changes that the nanomaterials might cause in the properties of such foods. Therefore, the Council made clear that such foods are considered to be novel (Article 3(2)(a)(iv)) and added the definition of 'engineered nanomaterial' (Article 3(2)(c)). The Council thus closed the gap that might have been created if the use of nanotechnologies would have not given rise to significant changes in the composition or structure of the food as defined by Article 3(2)(a)(iii), but the food would have still contained engineered nanomaterials. Recital 9 highlights the need for an internationally agreed definition of nanomaterial. If a different definition is agreed at international level, the adaptation of the definition in this Regulation would be done through the ordinary legislative procedure. The Commission expressed its reservation as it argued that this adaptation should have been delegated to the Commission according to Article 290 TFEU. The Council thus accepted a part of amendment **92**.

The Council followed the thrust of amendments **6** and **11** on the necessity to have appropriate risk assessment methods for engineered nanomaterials, which is reflected in recital 20.

- (f) Determination of the status of food (Article 4 and recital 16) — the Council agreed that the determination of the status of food to be placed on the Union market with respect to the definition of novel food would be a responsibility of food business operators, who must consult their national authority in case of doubt.
- (g) Authorisation of novel foods (Article 9 and recital 18) — the Council agreed that the authorisation of novel foods should be carried out according to the Regulation (EC) No 1331/2008, unless there is provision for a specific derogation in the present Regulation. The Council clarified that ethical, environmental, animal welfare factors and the precautionary principle should be taken into account in authorisation of novel foods. These factors should be considered on a case-by-case basis according to the content of the application. This covers amendment **20**.

- (h) Authorisation of traditional foods from third countries (Article 11 and recital 22) — the Council did not accept the 'notification procedure' as proposed by the Commission. In order to ensure food safety, any authorisation should be based on the EFSA opinion and subsequent authorisation adopted by the Commission through the regulatory comitology procedure. The EFSA evaluation should primarily focus on the evidence of safe food use and the information on the composition of traditional food. In order to speed up the procedure, shorter deadlines should apply — 6 months for EFSA opinion and 3 months for the draft measure submitted by the Commission to SCFCAH. A separate list of authorised traditional foods from third countries would be established (Article 7(2)). The new Council approach nevertheless covers amendments **65** and **68**.
- (i) Technical guidance (Article 12) — the Commission must before the date of application of the Regulation (i.e. 2 years after its entry into force) make available technical guidance and tools to interested parties, in particular food business operators and SMEs. It is self-evident that the Commission Recommendation 97/618/EC will be applicable until the repeal of the of Regulation (EC) No 258/1997. This is in line with amendment **69**.
- (j) European Group on Ethics in Science and new Technologies — EGE (Article 15 and recital 28) — an additional provision was added on the possibility for the Commission to consult the EGE, on its initiative or at the request of a Member State, on ethical issues concerning the novel foods. This corresponds to amendment **76**. If consulted, its opinion will be taken into account at the risk management stage.
- (k) Data protection (Article 16 and recital 25) — in order to promote innovation in industry, the need for the protection of new scientific evidence and/or proprietary scientific data for the period of 5 years was accepted by the Council. Such protected data cannot be used for the benefit of another application without the agreement of the prior applicant and the authorisation is limited to the prior applicant during the period of 5 years unless a subsequent applicant obtains authorisation without reference to that proprietary data. This fully covers amendment **77**. Though amendment **25** was not accepted as such, its spirit is covered by Article 16.
- (l) Information to the public (Article 17) — summaries of applications, findings of any consultations for determination of the status of food and lists of authorised novel foods must be made available to the public, in the latter case on the single dedicated web page. This is in line with amendments **41**, **53** and **67**, part of amendment **40** and covers in principle amendment **64**.
- (m) Transitional measures (Article 23 and recital 29) — pending application submitted according to Article 4 of the Regulation (EC) No 258/97 shall be processed under that Regulation only if the initial assessment report has been provided under Article 6(3) and neither additional assessment was required, nor were any objections raised by Member States. This is in line with amendments **88** and **89**.

In addition to the amendments mentioned above, the common position incorporates amendments **7**, **42**, **44**, **45**, which are of technical/editorial nature and aim at improving the clarity of the text.

Given the entry into force of the Treaty on the Functioning of the European Union on the 1 December 2009, the Council had to adapt the regulatory procedure with scrutiny related provisions of the Commission's proposal to the TFEU. The Council agreed that the following provisions should confer implementing powers on the Commission (Article 291(2) TFEU):

- Article 3(4): the adoption of further criteria to clarify definitions in sub-points (i) to (iv) of point (a) and points (c), (d) and (e) of Article 3(2) that may be adopted;
- Article 11(5): the update of the list of traditional foods from third countries;
- Article 16(5): the update of the Union list in case of data protection before the expiry of the 5 years period for data protection;

- Article 27 (2): the transitional measures for the application of Article 27(1) that may be adopted;
- Article 9: the update of the Union list of novel foods. The Regulation (EC) 1331/2008 would need to be amended for that purpose (see Article 28 of the Council position).

As already mentioned in point c) above, the Council agreed that the adoption of criteria for assessing whether a food has been used for human consumption to a significant degree within the Union before 15 May 1997 by the date of application of this regulation (i.e. 24 months after the entry into force) should be delegated to the Commission according to Article 290 TFEU.

2.2. The European Parliament's amendments not accepted

The Council did not accept 46 amendments listed on the following grounds:

- (i) Amd **2**: high level of protection of human health and consumers' interests in relation to food and effective functioning of the internal market are two main goals of Union law on foodstuffs (Article 1 of Regulation (EC) No 178/2002). These two aspects are covered by recitals 1 and 2.
- (ii) Amd **9**: as explained in point (c) above, the basic criterion for assessing the novelty of the food remains its use for human consumption to a significant degree within the Union before 15 May 1997. Modified primary molecular structure, micro-organisms, fungi, algae, new strains of micro-organisms and concentrates of substances still fall under this definition and do not need to be listed separately
- (iii) Amd **22**: EFSA cooperates with Member States when preparing its opinions and may use a network as provided for by Article 36 of Regulation (EC) No 178/2002 and Commission Regulation (EC) No 2230/2004.
- (iv) Animal testing (amds **21**, **87**) — the issue of animal testing, in particular avoidance of testing on vertebrate animals and sharing of testing results, does not fall under the scope of this Regulation. According to Article 9(2) of the Regulation (EC) No 1331/2008 (Common authorisation procedure), EFSA shall present a proposal concerning the data required for risk assessment of novel foods and these should recognise the need to avoid unnecessary animal testing.
- (v) Prohibition of food production, placing on the market and imports of cloned animals and their offspring (amds **5**, **10**, **12**, **14**, **91** (**point 2(ba)**), **92** (**point 2(a)(ii)** and **2(ca)**), **51** (**second part**) — the Council cannot agree with the immediate exclusion of food obtained from cloned animals and their offspring from the scope of the Regulation (see point d) above). It should also be noted that the Commission has a right of initiative in proposing EU legislation and cannot be obliged to make a legislative proposal by a legislative act.
- (vi) Nanomaterials
 - (a) amd **13**: does not fall under the scope of novel foods Regulation; Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food applies.
 - (b) amd **90**: systematic specific labelling of ingredients in the form of nanomaterials is excessive; there is a requirement to consider specific labelling requirements on a case-by-case basis according to Article 9(2).
 - (c) amd **50**: in case of doubt concerning the safety of foods containing nanomaterials the precautionary principle would apply. In addition, the date of application of the Regulation has been prolonged to 24 months, thus leaving additional time for the development of risk assessment methods for engineered nanomaterials.
- (vii) Determination of the status of food (amd **18** and part of amd **40**): the amendments are not compatible with the approach agreed by the Council (see point (d) above).

- (viii) Additional criteria for risk assessment by EFSA
 - (d) **amd 70**: reference to Article 6 (Article 8 in the Common position) is not appropriate as it concerns conditions to be considered at risk management stage, not risk assessment conducted by EFSA.
 - (e) **amd 71**: interferes with EFSA internal procedures; in assessing safety of food, EFSA may consider also other aspects than harmful or toxic effects to human health.
 - (f) **amd 74**: does not belong to the risk assessment stage; the opinion of the European Group on Ethics in Science and New Technologies (EGE) could be sought at the request of a Member State and would then be considered at the risk management stage.
- (ix) Additional conditions for authorisation of novel foods (risk management)
 - (g) **amd 23**: ethical aspects may be considered at the risk management stage; assessment by European Environment Agency (EEA) is not applicable.
 - (h) **amd 43**: not necessary, aspects covered by this amendment are taken into account by EFSA at the risk assessment stage.
 - (i) **amd 47**: not applicable; it is neither necessary nor possible to ask a opinion of the EEA for every application for novel food authorisation.
 - (j) **amd 48**: the opinion of EGE cannot be requested for every application for novel food authorisation. If it is requested as provided for in Article 15, it will be taken into account at the risk management stage.
 - (k) **amd 49**: aspects covered by this amendment are taken into account by EFSA at risk assessment stage and may be covered by conditions of use and additional specific labelling requirements according to Article 9(2).
- (x) Precautionary principle (**amds 1(second part), 19, 52**) — the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002 is always applicable. There is a reference to this principle in recital 18. Therefore, there is no need to repeat it in other recitals and as an additional condition for authorisations.
- (xi) Additional specifications for the entry of novel food in the Union list:
 - (l) **amd 54**: all points raised are already covered by the Regulation, except point (f), which is not clear as monitoring requirements and inspections according to Regulation (EC) No 882/2004 on official controls are two different issues.
 - (m) **amd 57**: according to Article 9(2), the presence of undesirable substances in the novel food is already controlled by specifications of the food and limitation of exposure to substances present in novel foods will be covered under 'conditions of use' and may be introduced following the EFSA opinion.
- (xii) Post-marketing monitoring (**amd 55 and 75**) — systematic post market monitoring and revision of authorisations after five years for all novel foods placed on the market is disproportionate. It would place an administrative burden on food business operators and authorities of Member States. Article 14 provides for a possibility to impose post market monitoring on a case-by-case basis. Producers are obliged to inform the Commission of any new scientific or technical information which might influence the safety evaluation in use of novel food already placed on Union market.
- (xiii) Labelling of novel food (**amd 60 and 62**) — the systematic labelling of all novel foods (**amd 62**) is disproportionate and would create an administrative burden. Specific labelling requirements are possible according to Article 9(2). Labelling of products from animals fed with genetically modified feeding stuff (**amd 60**) does not fall under the scope of this Regulation (Regulation (EC) No 1829/2003 is clearly excluded).

- (xiv) Traditional foods from third countries (amds **28**, **64** and **66**): the Council agreed a different procedure for authorisation of these foods than that proposed by the Commission (see point (h) above).
- (xv) Consultation of the EGE (amd **29**): the Council wording of recital 28 better correspond to the content of Article 15 concerning consultations of the EGE (see point (j) above).
- (xvi) Alignment of deadlines for authorisation of health claim and novel food in the case of data protection (amd **27**, **80**) — such an alignment may be desirable, but would be difficult to ensure in practice as evaluations proceed according to different time schedules and the two decisions are taken separately.
- (xvii) Amd **61**: updates of the Union list in the case of data protection are to be decided in accordance with the regulatory procedure as these are individual authorisations and not measures of general scope.
- (xviii) Amd **56** and **91** (subparagraph (2a)): authorisation of food additives, food enzymes and food flavourings, to which a new production process is applied, which gives rise to significant changes is already covered by sectoral legislation on additives (Art. 12 and Recital 11 of Regulation (EC) No 1333/2008), enzymes (Art. 14 and Recital 12 of Regulation (EC) No 1332/2008) and flavourings (Art. 19 of Regulation (EC) No 1334/2008). The common authorization procedure applies to such authorizations.
- (xix) Amd **78**: the Council did not consider the issue of research projects financed from EU and/or public sources.
- (xx) Amd **81**: Regulation (EC) No 882/2004 on official controls to ensure compliance with feed and food law (including novel foods Regulation) is applicable and does not need to be repeated.
- (xxi) Amd **82**: the Council agreed to postpone the date of application of the Regulation until 24 months after the date of its publication. The same deadline was given to Member States to notify provisions concerning penalties.
- (xxii) Amd **83**: Not necessary; duplication of provisions applicable according to the Articles 53 and 54 of Regulation (EC) No 178/2002.

The Council did not accept amds **8** and **85** as they are unclear and amds **4**, **17**, **51** (**first part**), whose content is self-evident and they do not bring any added value.

IV. CONCLUSIONS

The Council believes that its position at first reading represents a balance of concerns and interests that would respect the objectives of the Regulation. It looks forward to constructive discussions with the European Parliament with a view to the early adoption of the Regulation ensuring a high level of human health and consumer protection.

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