I Legislative acts

REGULATIONS


DIRECTIVES


(1) Text with EEA relevance

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.
The titles of all other acts are printed in bold type and preceded by an asterisk.
I

(Legislative acts)

REGULATIONS

of 25 October 2011


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 74 and points (b) and (d) of Article 77(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

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 development of a forward-looking and comprehensive European migration policy, based on human rights, solidarity and responsibility, especially for those Member States facing specific and disproportionate pressures, remains a key policy objective for the Union.

(2) Union policy in the field of the external borders aims at an integrated border management ensuring a uniform and high level of control and surveillance, which is a necessary corollary to the free movement of persons within the Union and a fundamental component of an area of freedom, security and justice. To that end, the establishment of common rules on standards and procedures for the control and surveillance of the external borders is contemplated.

(3) The efficient implementation of the common rules on standards and procedures for the control and surveillance of the external borders calls for increased coordination of the operational cooperation between the Member States.

(4) Efficient management of the external borders through checks and surveillance contributes to combat illegal immigration and trafficking in human beings and to reduce the threats to the internal security, public policy, public health and international relations of the Member States.

(5) Border control at the external borders is in the interest not only of the Member State at whose external borders it is carried out, but also of all Member States which have abolished internal border controls.


(1) OJ C 44, 11.2.2011, p. 162.
A further enhancement of the role of the Agency is in line with the objective of the Union to develop a policy with a view to the gradual introduction of the concept of Integrated Border Management. The Agency should, within the limits of its mandate, support the Member States in implementing that concept as defined in the Council conclusions on Integrated Border Management of 4-5 December 2006.

The multiannual programme for an area of freedom, security and justice serving the citizen (the Stockholm Programme) adopted by the European Council on 10-11 December 2009 calls for a clarification and enhancement of the role of the Agency regarding the management of the external borders.

The mandate of the Agency should therefore be revised in order to strengthen in particular its operational capabilities while ensuring that all measures taken are proportionate to the objectives pursued, are effective and fully respect fundamental rights and the rights of refugees and asylum seekers, including in particular the prohibition of refoulement.

Current possibilities for providing effective assistance to the Member States regarding the operational aspects of external border management should be reinforced in terms of the available technical resources. The Agency should be able to plan with sufficient accuracy the coordination of joint operations or pilot projects.

Minimum levels of necessary technical equipment provided by the Agency and/or, on a compulsory basis, by the Member States on the basis of annual bilateral negotiations and agreements will largely contribute to a better planning and implementation of the envisaged operations coordinated by the Agency.

The Agency should manage lists of technical equipment owned either by the Member States or by the Agency and equipment co-owned by the Member States and the Agency, by setting up and keeping centralised records in a technical equipment pool. That pool should contain the minimum number of categories of technical equipment necessary to enable the Agency to conduct its activities.

To ensure effective operations, teams of border guards should be set up by the Agency. Member States should contribute to those teams with an appropriate number of skilled border guards and make them available for deployment, unless they are faced with exceptional situations substantially affecting the discharge of national tasks.

The Agency should be able to contribute to those teams with the border guards who are seconded by Member States to the Agency on a semi-permanent basis, who should be subject, in the exercise of their tasks and powers, to the same legal framework as the guest officers contributed directly to those teams by Member States. The Agency should adapt its internal rules on seconded national experts to allow for direct instructions by the host Member State to the border guards during joint operations and pilot projects.

A well-defined operational plan, including an evaluation and an obligation to report incidents, agreed prior to the start of joint operations or pilot projects amongst the Agency and the host Member State, in consultation with the participating Member States, will largely contribute to the objectives of this Regulation with a more harmonised modus operandi regarding the coordination of joint operations and pilot projects.

The incident reporting scheme should be used by the Agency to transmit to the relevant national public authorities and to its Management Board (the Management Board) any information concerning credible allegations of breaches of, in particular, Regulation (EC) No 2007/2004 or the Schengen Borders Code established by Regulation (EC) No 562/2006 of the European Parliament and of the Council (\(^\text{1}\)), including fundamental rights, during joint operations, pilot projects or rapid interventions.

Risk analysis has been demonstrated to be a key element for conducting operations at the external borders. Its quality should be improved by adding a method for assessing the capacity of Member States to face upcoming challenges, including present and future threats and pressures at the external borders. However, those assessments should be without prejudice to the Schengen evaluation mechanism.

The Agency should provide training, including on fundamental rights, access to international protection and access to asylum procedures, at European level, for instructors of the national border guards of Member States and additional training and seminars related to control and surveillance at the external borders and removal of third-country nationals illegally present in the Member States for officers of the competent national services. The Agency may organise training activities, including an exchange programme, in cooperation with Member States on their territory. Member States should integrate the results of the Agency’s work in that perspective in the national training programmes of their border guards.

The Agency should monitor and contribute to the developments in scientific research relevant to its field of activity and disseminate that information to the Commission and the Member States.

In most Member States, the operational aspects of the return of third-country nationals illegally present in the Member States fall within the competence of the authorities responsible for controlling the external borders. As there is a clear added value in performing those tasks at Union level, the Agency should, in full compliance with the return policy of the Union, accordingly ensure the coordination or the organisation of joint return operations of Member States and identify best practices on the acquisition of travel documents, and define a code of conduct to be followed during the removal of third-country nationals illegally present on the territories of the Member States. No Union financial means should be made available for activities or operations that are not carried out in conformity with the Charter of Fundamental Rights of the European Union (‘the Charter of Fundamental Rights’).

For the purpose of fulfilling its mission and to the extent required for the accomplishment of its tasks, the Agency may cooperate with Europol, the European Asylum Support Office, the European Union Agency for Fundamental Rights and other Union agencies and bodies, the competent authorities of third countries and the international organisations competent in matters covered by Regulation (EC) No 2007/2004 within the framework of working arrangements concluded in accordance with the relevant provisions of the Treaty on the Functioning of the European Union (TFEU). The Agency should facilitate operational cooperation between Member States and third countries within the framework of the external relations policy of the Union.

Cooperation with third countries regarding matters covered by Regulation (EC) No 2007/2004 is increasingly important. To establish a solid cooperation model with relevant third countries, the Agency should be able to launch and finance projects of technical assistance and to deploy liaison officers in third countries in cooperation with the competent authorities of those countries. The Agency should be able to invite observers from third countries to participate in its activities, after having provided the necessary training. Establishing cooperation with third countries is also relevant with regard to promoting Union standards of border management, including respect for fundamental rights and human dignity.

In order to ensure open and transparent employment conditions and equal treatment of staff, the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the European Union, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68, should apply to the staff and to the Executive Director of the Agency, including the rules of professional secrecy or other equivalent duties of confidentiality.

Furthermore, specific provisions should be adopted by the Management Board to allow national experts from Member States to be seconded to the Agency. Such provisions should, among others, specify that seconded national border guards to be deployed during joint operations, pilot projects or rapid interventions should be considered as guest officers with the corresponding tasks and powers.

Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data applies to the processing of personal data by the Agency. The European Data Protection Supervisor should therefore monitor the processing of personal data by the Agency and have the power to obtain from the Agency access to all information necessary for his or her enquiries.

In so far as the Member States are processing personal data, 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 applies in full.

When ensuring the operational management of IT systems, the Agency should follow European and international standards, including on data protection, taking into account the highest professional requirements.


This Regulation respects the fundamental rights and observes the principles recognised in particular by the TFEU and the Charter of Fundamental Rights, notably the right to human dignity, the prohibition of torture and of inhuman or degrading treatment or punishment, the right to liberty and security, the right to protection of personal data, the right to asylum, the principle of non-refoulement, the principle of non-discrimination, the rights of the child, and the right to an effective remedy. This Regulation should be applied by the Member States in accordance with those rights and principles. Any use of force should be in accordance with the national law of the host Member State, including the principles of necessity and proportionality.
(30) The implementation of this Regulation should not affect the rights or obligations of Member States under the United Nations Convention on the Law of the Sea, the International Convention for the Safety of Life at Sea, the International Convention on Maritime Search and Rescue or the Geneva Convention Relating to the Status of Refugees.

(31) Since the objective of this Regulation, namely to contribute to the creation of an integrated management of operational cooperation at the external borders of the Member States, 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 (TFEU). 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.

(32) As regards Iceland and Norway, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement concluded by the Council of the European Union and the Republic of Iceland and the Kingdom of Norway concerning the latter's association with the implementation, application and development of the Schengen acquis (1), which fall within the area referred to in Article 1, point A of Council Decision 1999/437/EC of 17 May 1999 on certain arrangements for the application of that Agreement (2). Consequently, the delegations of the Republic of Iceland and the Kingdom of Norway should participate as members of the Management Board, albeit with limited voting rights.

(33) As regards Switzerland, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Agreement between the European Union, the European Community and the Swiss Confederation on the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (3), which fall within the area referred to in Article 1, points A, B and G of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2008/146/EC (4). Consequently, the delegation of the Swiss Confederation should participate as member of the Management Board, albeit with limited voting rights.

(34) As regards Liechtenstein, this Regulation constitutes a development of the provisions of the Schengen acquis within the meaning of the Protocol between the European Union, the European Community, the Swiss Confederation and the Principality of Liechtenstein on the accession of the Principality of Liechtenstein to the Agreement between the European Union, the European Community and the Swiss Confederation's association with the implementation, application and development of the Schengen acquis (5) which fall within the area referred to in Article 1, points A, B and G of Decision 1999/437/EC read in conjunction with Article 3 of Council Decision 2011/350/EU (6). Consequently, the delegation of the Principality of Liechtenstein should participate as member of the Management Board, albeit with limited voting rights.

(35) In accordance with Articles 1 and 2 of the Protocol (No 22) on the position of Denmark, annexed to the TEU and the TFEU, Denmark is not taking part in the adoption of this Regulation and is not bound by it or subject to its application. Given that this Regulation builds upon the Schengen acquis, Denmark shall, in accordance with Article 4 of that Protocol, decide within a period of six months after the Council has decided on this Regulation whether it will implement it in its national law.

(36) This Regulation constitutes a development of the provisions of the Schengen acquis in which the United Kingdom does not take part, in accordance with Council Decision 2000/365/EC of 29 May 2000 concerning the request of the United Kingdom of Great Britain and Northern Ireland to take part in some of the provisions of the Schengen acquis (7); the United Kingdom is therefore not taking part in its adoption and is not bound by it or subject to its application.

(37) This Regulation constitutes a development of the provisions of the Schengen acquis in which Ireland does not take part, in accordance with Council Decision 2002/192/EC of 28 February 2002 concerning Ireland's request to take part in some of the provisions of the Schengen acquis (8); Ireland is therefore not taking part in its adoption and is not bound by it or subject to its application.

(38) The Agency should facilitate the organisation of operational actions in which the Member States may avail themselves of the expertise and facilities which Ireland and the United Kingdom may be willing to offer, in accordance with modalities to be decided on a case-by-case basis by the Management Board. To that end, representatives of Ireland and the United Kingdom should be invited to attend all the meetings of the Management Board in order to allow them to participate fully in the deliberations for the preparation of such operational actions.

[OJ L 176, 10.7.1999, p. 36.]
[OJ L 176, 10.7.1999, p. 31.]
[OJ L 160, 18.6.2011, p. 21.]
[OJ L 131, 1.6.2000, p. 43.]
[OJ L 64, 7.3.2002, p. 20.]
A controversy exists between the Kingdom of Spain and the United Kingdom on the demarcation of the borders of Gibraltar.

The suspension of the applicability of this Regulation to the borders of Gibraltar does not imply any change in the respective positions of the States concerned.

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments

Regulation (EC) No 2007/2004 is hereby amended as follows:

(1) in Article 1, paragraphs 2 and 3 are replaced by the following:

‘2. While considering that the responsibility for the control and surveillance of external borders lies with the Member States, the Agency, as a body of the Union as defined in Article 15 and in accordance with Article 19 of this Regulation, shall facilitate and render more effective the application of existing and future Union measures relating to the management of external borders, in particular the Schengen Borders Code established by Regulation (EC) No 562/2006 (*). It shall do so by ensuring the coordination of the actions of the Member States in the implementation of those measures, thereby contributing to an efficient, high and uniform level of control on persons and of surveillance of the external borders of the Member States.

The Agency shall fulfil its tasks in full compliance with the relevant Union law, including the Charter of Fundamental Rights of the European Union ("the Charter of Fundamental Rights"); the relevant international law, including the Convention Relating to the Status of Refugees done at Geneva on 28 July 1951 ("the Geneva Convention"); obligations related to access to international protection, in particular the principle of non-refoulement; and fundamental rights, and taking into account the reports of the Consultative Forum referred to in Article 26a of this Regulation.

3. The Agency shall also provide the Commission and the Member States with the necessary technical support and expertise in the management of the external borders and promote solidarity between Member States, especially those facing specific and disproportionate pressures.

(2) Article 1a is amended as follows:

(a) the following point is inserted:

‘1a. “European Border Guard Teams" means for the purpose of Article 3, Article 3b, Article 3c, Article 8 and Article 17, teams to be deployed during joint operations and pilot projects; for the purpose of Articles 8a to 8g, teams to be deployed for rapid border interventions ("rapid interventions") within the meaning of Regulation (EC) No 863/2007 (*), and for the purpose of points (ea) and (g) of Article 2(1) and Article 5, teams to be deployed during joint operations, pilot projects and rapid interventions:

(3) Article 2 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) points (c) and (d) are replaced by the following:

‘(c) carry out risk analyses, including the assessment of the capacity of Member States to face threats and pressures at the external borders;
(d) participate in the development of research relevant for the control and surveillance of external borders;

(ii) the following point is inserted:

'(da) assist Member States in circumstances requiring increased technical and operational assistance at the external borders, taking into account that some situations may involve humanitarian emergencies and rescue at sea;

(iii) point (e) is replaced by the following:

'(e) assist Member States in circumstances requiring increased technical and operational assistance at the external borders, especially those Member States facing specific and disproportionate pressures;

(iv) the following point is inserted:

'(ea) set up European Border Guard Teams that are to be deployed during joint operations, pilot projects and rapid interventions;

(v) points (f) and (g) are replaced by the following:

'(f) provide Member States with the necessary support, including, upon request, coordination or organisation of joint return operations;

(g) deploy border guards from the European Border Guard Teams to Member States in joint operations, pilot projects or in rapid interventions in accordance with Regulation (EC) No 863/2007;

(vi) the following points are added:

'(h) develop and operate, in accordance with Regulation (EC) No 45/2001, information systems that enable swift and reliable exchanges of information regarding emerging risks at the external borders, including the Information and Coordination Network established by Decision 2005/267/EC (');

(j) provide the necessary assistance to the development and operation of a European border surveillance system and, as appropriate, to the development of a common information sharing environment, including interoperability of systems.


(b) the following paragraph is inserted:

‘1a. In accordance with Union and international law, no person shall be disembarked in, or otherwise handed over to the authorities of, a country in contravention of the principle of non-refoulement, or from which there is a risk of expulsion or return to another country in contravention of that principle. The special needs of children, victims of trafficking, persons in need of medical assistance, persons in need of international protection and other vulnerable persons shall be addressed in accordance with Union and international law.’

(c) in paragraph 2 the last subparagraph is replaced by the following:

‘Member States shall report to the Agency on those operational matters at the external borders outside the framework of the Agency. The Executive Director of the Agency (“the Executive Director”) shall inform the Management Board of the Agency (“the Management Board”) on those matters on a regular basis and at least once a year.’

(4) the following Article is inserted:

‘Article 2a

Code of Conduct

The Agency shall draw up and further develop a Code of Conduct applicable to all operations coordinated by the Agency. The Code of Conduct shall lay down procedures intended to guarantee the principles of the rule of law and respect for fundamental rights with particular focus on unaccompanied minors and vulnerable persons, as well as on persons seeking international protection, applicable to all persons participating in the activities of the Agency.

The Agency shall develop the Code of Conduct in cooperation with the Consultative Forum referred to in Article 26a.’
Article 3 is replaced by the following:

‘Article 3

Joint operations and pilot projects at the external borders

1. The Agency shall evaluate, approve and coordinate proposals for joint operations and pilot projects made by Member States, including the requests of Member States related to circumstances requiring increased technical and operational assistance, especially in cases of specific and disproportionate pressures.

The Agency may itself initiate and carry out joint operations and pilot projects in cooperation with the Member States concerned and in agreement with the host Member States.

It may also decide to put its technical equipment at the disposal of Member States participating in the joint operations or pilot projects.

Joint operations and pilot projects should be preceded by a thorough risk analysis.

1a. The Agency may terminate, after informing the Member State concerned, joint operations and pilot projects if the conditions to conduct those joint operations or pilot projects are no longer fulfilled.

The Member States participating in a joint operation or pilot project may request the Agency to terminate that joint operation or pilot project.

The home Member State shall provide for appropriate disciplinary or other measures in accordance with its national law in case of violations of fundamental rights or international protection obligations in the course of a joint operation or pilot project.

The Executive Director shall suspend or terminate, in whole or in part, joint operations and pilot projects if he/she considers that such violations are of a serious nature or are likely to persist.

1b. The Agency shall constitute a pool of border guards called European Border Guard Teams in accordance with Article 3b, for possible deployment during joint operations and pilot projects referred to in paragraph 1. It shall decide on the deployment of human resources and technical equipment in accordance with Articles 3a and 7.

2. The Agency may operate through its specialised branches provided for in Article 16 for the practical organisation of joint operations and pilot projects.

3. The Agency shall evaluate the results of the joint operations and pilot projects and transmit the detailed evaluation reports within 60 days following the end of those operations and projects to the Management Board, together with the observations of the Fundamental Rights Officer referred to in Article 26a. The Agency shall make a comprehensive comparative analysis of those results with a view to enhancing the quality, coherence and effectiveness of future joint operations and pilot projects and include it in its general report provided for in point (b) of Article 20(2).

4. The Agency shall finance or co-finance the joint operations and pilot projects referred to in paragraph 1, with grants from its budget in accordance with the financial rules applicable to the Agency.

5. Paragraphs 1a and 4 shall apply also to rapid interventions.

(6) the following Articles are inserted:

‘Article 3a

Organisational aspects of joint operations and pilot projects

1. The Executive Director shall draw up an operational plan for the joint operations and pilot projects referred to in Article 3(1). The Executive Director and the host Member State, in consultation with the Member States participating in a joint operation or pilot project, shall agree on the operational plan detailing the organisational aspects in due time before the envisaged beginning of that joint operation or pilot project.

The operational plan shall cover all aspects considered necessary for carrying out the joint operation or the pilot project, including the following:

(a) a description of the situation, with modus operandi and objectives of the deployment, including the operational aim;

(b) the foreseeable duration of the joint operation or pilot project;

(c) the geographical area where the joint operation or pilot project will take place;
(d) a description of the tasks and special instructions for the guest officers, including on permissible consultation of databases and permissible service weapons, ammunition and equipment in the host Member State;

(e) the composition of the teams of guest officers, as well as the deployment of other relevant staff;

(f) command and control provisions, including the names and ranks of the host Member State’s border guards responsible for cooperating with the guest officers and the Agency, in particular those of the border guards who are in command during the period of deployment, and the place of the guest officers in the chain of command;

(g) the technical equipment to be deployed during the joint operation or pilot project, including specific requirements such as conditions for use, requested crew, transport and other logistics, and financial provisions;

(h) detailed provisions on immediate incident reporting by the Agency to the Management Board and to relevant national public authorities;

(i) a reporting and evaluation scheme containing benchmarks for the evaluation report and final date of submission of the final evaluation report in accordance with Article 3(3);

(j) regarding sea operations, specific information on the application of the relevant jurisdiction and legislation in the geographical area where the joint operation or pilot project takes place, including references to international and Union law regarding interception, rescue at sea and disembarkation;

(k) modalities of cooperation with third countries, other Union agencies and bodies or international organisations.

2. Any amendments to or adaptations of the operational plan shall require the agreement of the Executive Director and the host Member State. A copy of the amended or adapted operational plan shall immediately be sent by the Agency to the participating Member States.

3. The Agency shall, as part of its coordinating tasks, ensure the operational implementation of all the organisational aspects, including the presence of a staff member of the Agency during the joint operations and pilot projects referred to in this Article.

Article 3b

Composition and deployment of European Border Guard Teams

1. On a proposal by the Executive Director, the Management Board shall decide by an absolute majority of its members with a right to vote on the profiles and the overall number of border guards to be made available for the European Border Guard Teams. The same procedure shall apply with regard to any subsequent changes in the profiles and the overall numbers. Member States shall contribute to the European Border Guard Teams via a national pool on the basis of the various defined profiles by nominating border guards corresponding to the required profiles.

2. The contribution by Member States as regards their border guards to specific joint operations and pilot projects for the following year shall be planned on the basis of annual bilateral negotiations and agreements between the Agency and Member States. In accordance with those agreements, Member States shall make the border guards available for deployment at the request of the Agency, unless they are faced with an exceptional situation substantially affecting the discharge of national tasks. Such a request shall be made at least 45 days before the intended deployment. The autonomy of the home Member State in relation to the selection of staff and the duration of their deployment shall remain unaffected.

3. The Agency shall also contribute to the European Border Guard Teams with competent border guards seconded by the Member States as national experts pursuant to Article 17(5). The contribution by Member States as regards the secondment of their border guards to the Agency for the following year shall be planned on the basis of annual bilateral negotiations and agreements between the Agency and Member States.

In accordance with those agreements, Member States shall make the border guards available for secondment, unless that would seriously affect the discharge of national tasks. In such situations Member States may recall their seconded border guards.

The maximum duration of such secondments shall not exceed six months in a 12-month period. The seconded border guards shall, for the purpose of this Regulation, be considered as guest officers and have the tasks and powers provided for in Article 10. The Member State having seconded the border guards in question shall be considered as the home Member State, as defined in point 3 of Article 1a, for the purpose of applying Articles 3c, 10 and 10b. Other staff employed by the Agency on a temporary basis who are not qualified to perform border control functions shall only be deployed during joint operations and pilot projects for coordination tasks.
4. Members of the European Border Guard Teams shall, in the performance of their tasks and in the exercise of their powers, fully respect fundamental rights, including access to asylum procedures, and human dignity. Any measures taken in the performance of their tasks and in the exercise of their powers shall be proportionate to the objectives pursued by such measures. While performing their tasks and exercising their powers, they shall not discriminate against persons on grounds of sex, racial or ethnic origin, religion or belief, disability, age or sexual orientation.

5. In accordance with Article 8g, the Agency shall nominate a coordinating officer for each joint operation or pilot project where members of the European Border Guard Teams will be deployed.

The role of the coordinating officer shall be to foster cooperation and coordination amongst host and participating Member States.

6. The Agency shall meet the costs incurred by the Member States in making their border guards available pursuant to paragraph 1 of this Article for the European Border Guard Teams in accordance with Article 8h.

7. The Agency shall inform the European Parliament on an annual basis of the number of border guards that each Member State has committed to the European Border Guard Teams in accordance with this Article.

Article 3c

Instructions to the European Border Guard Teams

1. During deployment of European Border Guard Teams, the host Member State shall issue instructions to the teams in accordance with the operational plan referred to in Article 3a(1).

2. The Agency, via its coordinating officer as referred to in Article 3b(5), may communicate its views on the instructions referred to in paragraph 1 to the host Member State. If it does so, the host Member State shall take those views into consideration.

3. In accordance with Article 8g, the host Member State shall give the coordinating officer all necessary assistance, including full access to the European Border Guard Teams at all times throughout the deployment.

4. Members of the European Border Guard Teams shall, while performing their tasks and exercising their powers, remain subject to the disciplinary measures of their home Member State.

(7) Article 4 is replaced by the following:

‘Article 4

Risk analysis

The Agency shall develop and apply a common integrated risk analysis model.

It shall prepare both general and tailored risk analyses to be submitted to the Council and the Commission.

For the purpose of risk analysis, the Agency may assess, after prior consultation with the Member States concerned, their capacity to face upcoming challenges, including present and future threats and pressures at the external borders of the Member States, especially for those Member States facing specific and disproportionate pressures. To that end, the Agency may assess the equipment and the resources of the Member States regarding border control. The assessment shall be based on information given by the Member States concerned, and on the reports and results of joint operations, pilot projects, rapid interventions and other activities of the Agency. Those assessments are without prejudice to the Schengen evaluation mechanism.

The results of those assessments shall be presented to the Management Board.

For the purposes of this Article, Member States shall provide the Agency with all necessary information regarding the situation and possible threats at the external borders.

The Agency shall incorporate the results of a common integrated risk analysis model in its development of the common core curricula for the training of border guards referred to in Article 5;’

(8) Article 5 is amended as follows:

(a) the first paragraph is replaced by the following:

The Agency shall provide border guards who are members of the European Border Guard Teams with advanced training relevant to their tasks and powers and shall conduct regular exercises with those border guards in accordance with the advanced training and exercise schedule referred to in the annual work programme of the Agency.
The Agency shall also take the necessary initiatives to ensure that all border guards and other personnel of the Member States who participate in the European Border Guard Teams, as well as the staff of the Agency, have received, prior to their participation in operational activities organised by the Agency, training in relevant Union and international law, including fundamental rights and access to international protection and guidelines for the purpose of identifying persons seeking protection and directing them towards the appropriate facilities.

The Agency shall establish and further develop common core curricula for the training of border guards and provide training at European level for instructors of the national border guards of Member States, including with regard to fundamental rights, access to international protection and relevant maritime law.

The Agency shall draw up the common core curricula after consulting the Consultative Forum referred to in Article 26a.

Member States shall integrate the common core curricula in the training of their national border guards.

(b) the following paragraph is inserted after the last paragraph:

The Agency shall establish an exchange programme enabling border guards participating in the European Border Guard Teams to acquire knowledge or specific know-how from experiences and good practices abroad by working with border guards in a Member State other than their own.

(9) Articles 6 and 7 are replaced by the following:

Article 6

Monitoring and contributing to research

The Agency shall proactively monitor and contribute to the developments in research relevant for the control and surveillance of the external borders and disseminate that information to the Commission and the Member States.

Article 7

Technical equipment

1. The Agency may acquire, itself or in co-ownership with a Member State, or lease technical equipment for external border control to be deployed during joint operations, pilot projects, rapid interventions, joint return operations or technical assistance projects in accordance with the financial rules applicable to the Agency. Any acquisition or leasing of equipment entailing significant costs to the Agency shall be preceded by a thorough needs and cost/benefit analysis. Any such expenditure shall be provided for in the Agency's budget as adopted by the Management Board in accordance with Article 29(9). Where the Agency acquires or leases major technical equipment, such as open sea and coastal patrol vessels or vehicles, the following conditions shall apply:

(a) in case of acquisition and co-ownership, the Agency shall agree formally with one Member State that the latter will provide for the registration of the equipment in accordance with the applicable legislation of that Member State;

(b) in case of leasing, the equipment shall be registered in a Member State.

On the basis of a model agreement drawn up by the Agency, the Member State of registration and the Agency shall agree on modalities ensuring the periods of full availability of the co-owned assets for the Agency, as well as on the terms of use of the equipment.

The Member State of registration or the supplier of technical equipment shall provide the necessary experts and technical crew to operate the technical equipment in a legally sound and safe manner.

2. The Agency shall set up and keep centralised records of equipment in a technical equipment pool composed of equipment owned either by the Member States or by the Agency and equipment co-owned by the Member States and the Agency for external border control purposes. The technical equipment pool shall contain a minimum number per type of technical equipment as referred to in paragraph 5 of this Article. The equipment listed in the technical equipment pool shall be deployed during the activities referred to in Articles 3, 8a and 9.

3. Member States shall contribute to the technical equipment pool referred to in paragraph 2. The contribution by Member States to the pool and deployment of the technical equipment for specific operations shall be planned on the basis of annual bilateral negotiations and agreements between the Agency and Member States. In accordance with those agreements and to the extent that it forms part of the minimum number of technical equipment for a given year, Member States shall make their technical equipment available for deployment at the request of the Agency, unless they are faced with an exceptional situation substantially affecting the discharge of national tasks. Such request shall be made at least 45 days before the intended deployment. The contributions to the technical equipment pool shall be reviewed annually.
4. The Agency shall manage the records of the technical equipment pool as follows:

(a) classification by type of equipment and by type of operation;
(b) classification by owner (Member State, Agency, other);
(c) overall numbers of required equipment;
(d) crew requirements if applicable;
(e) other information, such as registration details, transportation and maintenance requirements, national applicable export regimes, technical instructions, or other relevant information to handle the equipment correctly.

5. The Agency shall finance the deployment of the technical equipment which forms part of the minimum number of technical equipment provided by a given Member State for a given year. The deployment of technical equipment which does not form part of the minimum number of technical equipment shall be co-financed by the Agency up to a maximum of 100% of the eligible expenses, taking into account the particular circumstances of the Member States deploying such technical equipment.

On a proposal of the Executive Director, the Management Board shall decide, in accordance with Article 24, on a yearly basis, on the rules relating to technical equipment, including the required overall minimum numbers per type of technical equipment, the conditions for deployment and reimbursement of costs. For budgetary purposes that decision should be taken by the Management Board by 31 March each year.

The Agency shall propose the minimum number of technical equipment in accordance with its needs, notably in order to be able to carry out joint operations, pilot projects, rapid interventions and joint return operations, in accordance with its work programme for the year in question.

If the minimum number of technical equipment proves to be insufficient to carry out the operational plan agreed for joint operations, pilot projects, rapid interventions or joint return operations, the Agency shall revise it on the basis of justified needs and of an agreement with the Member States.

6. The Agency shall report on the composition and the deployment of equipment which is part of the technical equipment pool to the Management Board on a monthly basis. Where the minimum number of technical equipment referred to in paragraph 5 is not reached, the Executive Director shall inform the Management Board without delay. The Management Board shall take a decision on the prioritisation of the deployment of the technical equipment urgently and take the appropriate steps to remedy the identified shortcomings. It shall inform the Commission of the identified shortcomings and the steps taken. The Commission shall subsequently inform the European Parliament and the Council thereof, communicating as well its own assessment.

7. The Agency shall inform the European Parliament on an annual basis of the number of technical equipment that each Member State has committed to the technical equipment pool in accordance with this Article.

(10) Article 8 is amended as follows:

(a) paragraph 1 is replaced by the following:

1. Without prejudice to Article 78(3) of the Treaty on the Functioning of the European Union ("TFEU"), one or more Member States facing specific and disproportionate pressures and confronted with circumstances requiring increased technical and operational assistance when implementing their obligations with regard to control and surveillance of external borders may request the Agency for assistance. The Agency shall in accordance with Article 3 organise the appropriate technical and operational assistance for the requesting Member State(s).

(b) in paragraph 2, the following point is added:

(c) deploy border guards from the European Border Guard Teams.

(c) paragraph 3 is replaced by the following:

3. The Agency may acquire technical equipment for checks and surveillance of external borders to be used by its experts and within the framework of rapid interventions for their duration.

(11) Article 8a is replaced by the following:

‘Article 8a

Rapid interventions

At the request of a Member State faced with a situation of urgent and exceptional pressure, especially the arrival at points of the external borders of large numbers of third-country nationals trying to enter the territory of that Member State illegally, the Agency may deploy for a limited period one or more European Border Guard Teams ("team(s)") on the territory of the requesting Member State for the appropriate duration in accordance with Article 4 of Regulation (EC) No 863/2007.’
(12) in Article 8d, paragraph 5 is replaced by the following:

‘5. If the Executive Director decides to deploy one or more teams, the Agency together with the requesting Member State shall draw up an operational plan in accordance with Article 8e immediately, and in any event no later than five working days from the date of the decision.’;

(13) in Article 8e, paragraph 1 is amended as follows:

(a) points (e), (f) and (g) are replaced by the following:

‘(e) the composition of the teams, as well as the deployment of other relevant staff;

(f) command and control provisions, including the names and ranks of the border guards of the host Member State responsible for cooperating with the teams, in particular of those border guards who are in command of the teams during the period of deployment, and the place of the teams in the chain of command;

(g) the technical equipment to be deployed together with the teams, including specific requirements such as conditions for use, requested crew, transport and other logistics, and financial provisions;’;

(b) the following points are added:

‘(h) detailed provisions on immediate incident reporting by the Agency to the Management Board and to relevant national public authorities;

(i) a reporting and evaluation scheme containing benchmarks for the evaluation report and final date of submission of the final evaluation report in accordance with Article 3(3);

(j) regarding sea operations, specific information on the application of the relevant jurisdiction and legislation in the geographical area where the rapid intervention takes place, including references to international and Union law regarding interception, rescue at sea and disembarkation;

(k) modalities of cooperation with third countries, other Union agencies and bodies or international organisations;’;

(14) in Article 8h(1), the introductory part is replaced by the following:

‘1. The Agency shall fully meet the following costs incurred by Member States in making available their border guards for the purposes mentioned in Article 3(1b), Article 8a and Article 8c:’;

(15) Article 9 is replaced by the following:

‘Article 9

Return cooperation

1. Subject to the return policy of the Union, and in particular Directive 2008/115/EC of the European Parliament and of the Council of 16 December 2008 on common standards and procedures in Member States for returning illegally staying third-country nationals (\(^*\)), and without entering into the merits of return decisions, the Agency shall provide the necessary assistance, and at the request of the participating Member States ensure the coordination or the organisation of joint return operations of Member States, including through the chartering of aircraft for the purpose of such operations. The Agency shall finance or co-finance the operations and projects referred to in this paragraph with grants from its budget in accordance with the financial rules applicable to the Agency. The Agency may also use financial means of the Union available in the field of return. The Agency shall ensure that in its grant agreements with Member States any financial support is conditional upon the full respect for the Charter of Fundamental Rights.

1a. The Agency shall develop a Code of Conduct for the return of illegally present third-country nationals which shall apply during all joint return operations coordinated by the Agency, describing common standardised procedures which should simplify the organisation of joint return operations and assure return in a humane manner and with full respect for fundamental rights, in particular the principles of human dignity, prohibition of torture and of inhuman or degrading treatment or punishment, the right to liberty and security and the rights to the protection of personal data and non-discrimination.

1b. The Code of Conduct shall in particular pay attention to the obligation set out in Article 8(6) of Directive 2008/115/EC to provide for an effective forced-return monitoring system and to the Fundamental Rights Strategy referred to in Article 26a(1) of this Regulation. The monitoring of joint return operations should be carried out on the basis of objective and transparent criteria and cover the whole joint return operation from the pre-departure phase until the hand-over of the returnees in the country of return.'
1c. Member States shall regularly inform the Agency of their needs for assistance or coordination by the Agency. The Agency shall draw up a rolling operational plan to provide the requesting Member States with the necessary operational support, including technical equipment referred to in Article 7(1). The Management Board shall decide in accordance with Article 24 on a proposal of the Executive Director, on the content and modus operandi of the rolling operational plan.

2. The Agency shall cooperate with the competent authorities of the third countries referred to in Article 14 to identify best practices on the acquisition of travel documents and the return of illegally present third-country nationals.

3. Personal data referred to in paragraph 2 shall be further processed by the Agency only for the following purposes:

(a) the transmission, on a case-by-case basis, to Europol or other Union law enforcement agencies, subject to Article 13;

(b) the use for the preparation of risk analyses referred to in Article 4. In the result of the risk-analyses, data shall be depersonalised.

4. The personal data shall be deleted as soon as they have been transmitted to Europol or other Union agencies or used for the preparation of risk analyses referred to in Article 4. The term of storage shall in any event not exceed three months after the date of the collection of those data.

5. The processing of such personal data shall respect the principles of necessity and proportionality. The personal data shall not be used by the Agency for the purpose of investigations, which remain under the responsibility of the competent authorities of the Member States.

In particular, it shall be strictly limited to those personal data which are required for the purposes referred to in paragraph 3.

6. Without prejudice to Regulation (EC) No 1049/2001, onward transmission or other communication of such personal data processed by the Agency to third countries or other third parties shall be prohibited.

7. This Article shall be applied in accordance with the measures referred to in Article 11a.

Article 11d
Security rules on the protection of classified information and non-classified sensitive information


2. The Agency shall apply the security principles relating to the processing of non-classified sensitive information as set out in the Decision referred to in paragraph 1 of this Article and as implemented by the Commission. The Management Board shall establish measures for the application of those security principles.


(19) Articles 13 and 14 are replaced by the following:

‘Article 13
Cooperation with Union agencies and bodies and international organisations

The Agency may cooperate with Europol, the European Asylum Support Office, the European Union Agency for Fundamental Rights ("the Fundamental Rights Agency"), other Union agencies and bodies, and the international organisations competent in matters covered by this Regulation within the framework of working arrangements concluded with those bodies, in accordance with the relevant provisions of the TFEU and the provisions on the competence of those bodies. In every case the Agency shall inform the European Parliament of any such arrangements.

Onward transmission or other communication of personal data processed by the Agency to other Union agencies or bodies shall be subject to specific working arrangements regarding the exchange of personal data and subject to the prior approval of the European Data Protection Supervisor.

The Agency may also, with the agreement of the Member State(s) concerned, invite observers of Union agencies and bodies or international organisations to participate in its activities referred to in Articles 3, 4 and 5, to the extent that their presence is in accordance with the objectives of those activities, may contribute to the improvement of cooperation and the exchange of best practices, and does not affect the overall safety of those activities. The participation of those observers may take place only with the agreement of the host Member State regarding those activities referred to in Article 3. Detailed rules on the participation of observers shall be included in the operational plan referred to in Article 3a(1). Those observers shall receive the appropriate training from the Agency prior to their participation.

Article 14
Facilitation of operational cooperation with third countries and cooperation with competent authorities of third countries

1. In matters covered by its activities and to the extent required for the fulfilment of its tasks, the Agency shall facilitate operational cooperation between Member States and third countries, within the framework of the external relations policy of the Union, including with regard to human rights.

The Agency and the Member States shall comply with norms and standards at least equivalent to those set by Union legislation also when cooperation with third countries takes place on the territory of those countries.
The establishment of cooperation with third countries shall serve to promote European border management standards, also covering respect for fundamental rights and human dignity.

2. The Agency may cooperate with the authorities of third countries competent in matters covered by this Regulation within the framework of working arrangements concluded with those authorities, in accordance with the relevant provisions of the TFEU. Those working arrangements shall be purely related to the management of operational cooperation.

3. The Agency may deploy its liaison officers, who should enjoy the highest possible protection to carry out their duties, in third countries. They shall form part of the local or regional cooperation networks of immigration liaison officers of the Member States set up pursuant to Council Regulation (EC) No 377/2004 of 19 February 2004 on the creation of an immigration liaison officers network (*). Liaison officers shall only be deployed to third countries in which border management practices comply with minimum human rights standards. Their deployment shall be approved by the Management Board. Within the framework of the external relations policy of the Union, priority for deployment should be given to those third countries, which on the basis of risk analysis constitute a country of origin or transit regarding illegal migration. On a reciprocal basis the Agency may receive liaison officers posted by those third countries also, for a limited period of time. The Management Board shall adopt, on a proposal of the Executive Director and in accordance with Article 24, the list of priorities on a yearly basis.

4. The tasks of the Agency's liaison officers shall include, in compliance with Union law and in accordance with fundamental rights, establishing and maintaining contacts with the competent authorities of the third country to which they are assigned with a view to contributing to the prevention of and fight against illegal immigration and the return of illegal migrants.

5. The Agency may benefit from Union funding in accordance with the provisions of the relevant instruments supporting the external relations policy of the Union. It may launch and finance technical assistance projects in third countries regarding matters covered by this Regulation.

6. The Agency may also, with the agreement of the Member State(s) concerned invite observers from third countries to participate in its activities referred to in Articles 3, 4 and 5, to the extent that their presence is in accordance with the objectives of those activities, may contribute to improving cooperation and the exchange of best practices, and does not affect the overall safety of those activities. The participation of those observers may take place only with the agreement of the Member State(s) concerned regarding the activities referred to in Articles 4 and 5 and only with the agreement of the host Member State regarding those referred to in Article 3. Detailed rules on the participation of observers shall be included in the operational plan referred to in Article 3a(1). Those observers shall receive the appropriate training from the Agency prior to their participation.

7. When concluding bilateral agreements with third countries as referred to in Article 2(2), Member States may include provisions concerning the role and competence of the Agency, in particular regarding the exercise of executive powers by members of the teams deployed by the Agency during the joint operations or pilot projects referred to in Article 3.

8. The activities referred to in paragraphs 2 and 3 of this Article shall be subject to receiving a prior opinion of the Commission, and the European Parliament shall be fully informed of those activities as soon as possible.

(*) OJ L 64, 2.3.2004, p. 1;
(22) Article 17 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. For the purpose of implementing Article 3b(5) only a staff member of the Agency subject to the Staff Regulations of Officials of the European Union or to Title II of the Conditions of employment of other servants of the European Union may be designated as coordinating officer in accordance with Article 8g. For the purpose of implementing Article 3b(3), only national experts seconded by a Member State to the Agency may be designated for attachment to the European Border Guard Teams. The Agency shall designate those national experts who shall be attached to the European Border Guard Teams in accordance with that Article.;

(b) the following paragraphs are added:

'4. The Management Board shall adopt the necessary implementing measures in agreement with the Commission pursuant to Article 110 of the Staff Regulations of Officials of the European Union.

5. The Management Board may adopt provisions to allow national experts from Member States to be seconded to the Agency. Those provisions shall take into account the requirements of Article 3b(3), in particular the fact that they are considered as guest officers and have the tasks and powers provided for in Article 10. They shall include provisions on the conditions of deployment.';

(23) Article 20 is amended as follows:

(a) paragraph 2 is amended as follows:

(i) point (h) is replaced by the following:

'(h) establish the organisational structure of the Agency and adopt the Agency's staff policy, in particular the multiannual staff policy plan. In accordance with the relevant provisions of the Commission Regulation (EC, Euratom) No 2343/2002 of 19 November 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities (*) the multiannual staff policy plan shall be submitted to the Commission and the budgetary authority after receiving a favourable opinion of the Commission;

(ii) the following point is added:

'(i) adopt the Agency's multiannual plan aiming at outlining the future long term strategy regarding the activities of the Agency.;

(b) paragraph 4 is replaced by the following:

'4. The Management Board may advise the Executive Director on any matter strictly related to the development of operational management of the external borders, including activities related to research provided for in Article 6.;

(24) Article 21 is amended as follows:

(a) in paragraph 1, the last sentence is replaced by the following:

'The terms of office shall be extendable.;

(b) paragraph 3 is replaced by the following:

'3. Countries associated with the implementation, application and development of the Schengen acquis shall participate in the Agency. They shall have one representative and one alternate each in the Management Board. Under the relevant provisions of their association agreements, arrangements have been developed that specify the nature and extent of, and the detailed rules for, the participation by those countries in the work of the Agency, including provisions on financial contributions and staff.;

(25) Article 25 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. The European Parliament or the Council may invite the Executive Director to report on the carrying out of his/her tasks, in particular on the implementation and monitoring of the Fundamental Rights Strategy, the general report of the Agency for the previous year, the work programme for the following year and the Agency's multiannual plan referred to in point (i) of Article 20(2).;

(b) in paragraph 3, the following point is added:

'(g) to ensure the implementation of the operational plans referred to in Articles 3a and 8c.;

(26) the following Article is inserted:

‘Article 26a

Fundamental Rights Strategy

1. The Agency shall draw up and further develop and implement its Fundamental Rights Strategy. The Agency shall put in place an effective mechanism to monitor the respect for fundamental rights in all the activities of the Agency.

2. A Consultative Forum shall be established by the Agency to assist the Executive Director and the Management Board in fundamental rights matters. The Agency shall invite the European Asylum Support Office, the Fundamental Rights Agency, the United Nations High Commissioner for Refugees and other relevant organisations to participate in the Consultative Forum. On a proposal by the Executive Director, the Management Board shall decide on the composition and the working methods of the Consultative Forum and the modalities of the transmission of information to the Consultative Forum.

The Consultative Forum shall be consulted on the further development and implementation of the Fundamental Rights Strategy, Code of Conduct and common core curricula.

The Consultative Forum shall prepare an annual report of its activities. That report shall be made publicly available.

3. A Fundamental Rights Officer shall be designated by the Management Board and shall have the necessary qualifications and experience in the field of fundamental rights. He/she shall be independent in the performance of his/her duties as a Fundamental Rights Officer and shall report directly to the Management Board and the Consultative Forum. He/she shall report on a regular basis and as such contribute to the mechanism for monitoring fundamental rights.

4. The Fundamental Rights Officer and the Consultative Forum shall have access to all information concerning respect for fundamental rights, in relation to all the activities of the Agency:’.

(27) in Article 33, the following paragraphs are inserted:


2b. The evaluation shall include a specific analysis on the way the Charter of Fundamental Rights was complied with in the application of this Regulation.

(*) OJ L 304, 22.11.2011, p. 1.’

Article 2

Entry into force

This Regulation shall enter into force on the 20th day following its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in the Member States in accordance with the Treaties.

Done at Strasbourg, 25 October 2011.

For the European Parliament
The President
J. BUZEK

For the Council
The President
M. DOWGIELEWICZ
of 25 October 2011


(Text with EEA relevance)

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) Article 169 of the Treaty on the Functioning of the European Union (TFEU) provides that the Union is to contribute to the attainment of a high level of consumer protection by the measures it adopts pursuant to Article 114 thereof.

(2) 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, and to their social and economic interests.

(3) In order to achieve a high level of health protection for consumers and to guarantee their right to information, it should be ensured that consumers are appropriately informed as regards the food they consume. Consumers' choices can be influenced by, inter alia, health, economic, environmental, social and ethical considerations.

(4) According to 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 (3) it is a general principle of food law to provide a basis for consumers to make informed choices in relation to food they consume and to prevent any practices that may mislead the consumer.

(5) Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market (4) covers certain aspects of the provision of information to consumers specifically to prevent misleading actions and omissions of information. The general principles on unfair commercial practices should be complemented by specific rules concerning the provision of food information to consumers.


(7) Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs (6) lays down rules on the content and presentation of nutrition information on prepacked foods. According to those rules, the inclusion of nutrition information is voluntary unless a nutrition-related claim is made concerning the food. The majority of the provisions laid down in that Directive date back to 1978 and should therefore be updated.

(8) The general labelling requirements are complemented by a number of provisions applicable to all foods in particular circumstances or to certain categories of foods. In addition, there are a number of specific rules which are applicable to specific foods.

(5) OJ L 109, 6.5.2000, p. 29.
(9) While the original objectives and the core components of the current labelling legislation are still valid, it is necessary to streamline it in order to ensure easier compliance and greater clarity for stakeholders and to modernise it in order to take account of new developments in the field of food information. This Regulation will both serve the interests of the internal market by simplifying the law, ensuring legal certainty and reducing administrative burden, and benefit citizens by requiring clear, comprehensible and legible labelling of foods.

(10) The general public has an interest in the relationship between diet and health and in the choice of an appropriate diet to suit individual needs. The Commission White Paper of 30 May 2007 on a Strategy for Europe on Nutrition, Overweight and Obesity related health issues (the "Commission White Paper") noted that nutrition labelling is one important method of informing consumers about the composition of foods and of helping them to make an informed choice. The Commission Communication of 13 March 2007 entitled "EU Consumer Policy strategy 2007-2013 — Empowering consumers, enhancing their welfare, effectively protecting them' underlined that allowing consumers to make an informed choice is essential both to effective competition and consumer welfare. Knowledge of the basic principles of nutrition and appropriate nutrition information on foods would contribute significantly towards enabling the consumer to make such an informed choice. Education and information campaigns are an important mechanism for improving consumer understanding of food information.

(11) In order to enhance legal certainty and ensure rationality and consistency of enforcement, it is appropriate to repeal Directives 90/496/EEC and 2000/13/EC and to replace them by a single regulation which ensures certainty for consumers and other stakeholders and reduces the administrative burden.


(13) It is necessary to set common definitions, principles, requirements and procedures so as to form a clear framework and a common basis for Union and national measures governing food information.

(14) In order to follow a comprehensive and evolutionary approach to the information provided to consumers relating to food they consume, there should be a broad definition of food information law covering rules of a general and specific nature as well as a broad definition of food information covering information provided also by other means than the label.

(15) Union rules should apply only to undertakings, the concept of which implies a certain continuity of activities and a certain degree of organisation. Operations such as the occasional handling and delivery of food, the serving of meals and the selling of food by private persons, for example at charity events, or at local community fairs and meetings, should not fall within the scope of this Regulation.

(16) Food information law should provide sufficient flexibility to be able to keep up to date with new information requirements of consumers and ensure a balance between the protection of the internal market and the differences in the perception of consumers in the Member States.

(17) The prime consideration for requiring mandatory food information should be to enable consumers to identify and make appropriate use of a food and to make choices that suit their individual dietary needs. With this aim, food business operators should facilitate the accessibility of that information to the visually impaired.

(18) In order to enable food information law to adapt to consumers' changing needs for information, any considerations about the need for mandatory food information should also take account of the widely demonstrated interest of the majority of consumers in the disclosure of certain information.

(19) New mandatory food information requirements should however only be established if and where necessary, in accordance with the principles of subsidiarity, proportionality and sustainability.

(2) OJ L 69, 16.3.1999, p. 22.
(4) OJ L 97, 1.4.2004, p. 44.
Food information law should prohibit the use of information that would mislead the consumer in particular as to the characteristics of the food, food effects or properties, or attribute medicinal properties to foods. To be effective, that prohibition should also apply to the advertising and presentation of foods.

In order to prevent a fragmentation of the rules concerning the responsibility of food business operators with respect to food information it is appropriate to clarify the responsibilities of food business operators in this area. That clarification should be in accordance with the responsibilities regarding the consumer referred to in Article 17 of Regulation (EC) No 178/2002.

A list should be drawn up of all mandatory information which should in principle be provided for all foods intended for the final consumer and mass caterers. That list should maintain the information that is already required under existing Union legislation given that it is generally considered as a valuable acquis in respect of consumer information.

In order to take account of changes and developments in the field of food information, provisions should be made to empower the Commission to enable certain particulars to be made available through alternative means. Consultation with stakeholders should facilitate timely and well-targeted changes of food information requirements.

When used in the production of foods and still present therein, certain ingredients or other substances or products (such as processing aids) can cause allergies or intolerances in some people, and some of those allergies or intolerances constitute a danger to the health of those concerned. It is important that information on the presence of food additives, processing aids and other substances or products with a scientifically proven allergenic or intolerance effect should be given to enable consumers, particularly those suffering from a food allergy or intolerance, to make informed choices which are safe for them.

In order to inform consumers of the presence of engineered nanomaterials in food, it is appropriate to provide for a definition of engineered nanomaterials. Taking into account the possibility of food containing or consisting of engineered nanomaterials being a novel food, the appropriate legislative framework for that definition should be considered in the context of the upcoming review of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (1). (1) OJ L 43, 14.2.1997, p. 1.

Food labels should be clear and understandable in order to assist consumers who want to make better-informed food and dietary choices. Studies show that easy legibility is an important element in maximising the possibility for labelled information to influence its audience and that illegible product information is one of the main causes of consumer dissatisfaction with food labels. Therefore, a comprehensive approach should be developed in order to take into account all aspects related to legibility, including font, colour and contrast.

In order to ensure the provision of food information, it is necessary to consider all ways of supplying food to consumers, including selling food by means of distance communication. Although it is clear that any food supplied through distance selling should meet the same information requirements as food sold in shops, it is necessary to clarify that in such cases the relevant mandatory food information should also be available before the purchase is concluded.

The technology used in the freezing of foods has developed significantly during recent decades and has become widely used both to improve the circulation of goods on the Union internal market, and to reduce food safety risks. However, the freezing and later defrosting of certain foods, especially meat and fishery products, limits their possible further use and may also have an effect on their safety, taste and physical quality. Conversely, for other products, especially butter, freezing has no such effects. Therefore, where a product has been defrosted, the final consumer should be appropriately informed of its condition.

The indication of the country of origin or of the place of provenance of a food should be provided whenever its absence is likely to mislead consumers as to the true country of origin or place of provenance of that product. In all cases, the indication of country of origin or place of provenance should be provided in a manner which does not deceive the consumer and on the basis of clearly defined criteria which ensure a level playing field for industry and improve consumers’ understanding of the information related to the country of origin or place of provenance of a food. Such criteria should not apply to indications related to the name or address of the food business operator.

In some cases, food business operators may want to indicate the origin of a food on a voluntary basis to draw consumers’ attention to the qualities of their product. Such indications should also comply with harmonised criteria.
The indication of origin is currently mandatory for beef and beef products (1) in the Union following the bovine spongiform encephalopathy crisis and it has created consumer expectations. The impact assessment of the Commission confirms that the origin of meat appears to be consumers’ prime concern. There are other meats widely consumed in the Union, such as swine, sheep, goat and poultry meat. It is therefore appropriate to impose a mandatory declaration of origin for those products. The specific origin requirements could differ from one type of meat to another according to the characteristics of the animal species. It is appropriate to provide for the establishment through implementing rules of mandatory requirements that could vary from one type of meat to another taking into account the principle of proportionality and the administrative burden for food business operators and enforcement authorities.

Mandatory origin provisions have been developed on the basis of vertical approaches for instance for honey (2), fruit and vegetables (3), fish (4), beef and beef products (5) and olive oil (6). There is a need to explore the possibility to extend mandatory origin labelling for other foods. It is therefore appropriate to request the Commission to prepare reports covering the following foods: types of meat other than beef, swine, sheep and poultry meat; milk; milk used as an ingredient in dairy products; meat used as an ingredient; unprocessed foods; single-ingredient products; and ingredients that represent more than 50 % of a food. Milk being one of the products for which an indication of origin is considered of particular interest, the Commission report on this product should be made available as soon as possible. Based on the conclusions of such reports, the Commission may submit proposals to modify the relevant Union provisions or may take new initiatives, where appropriate, on a sectoral basis.

The Union’s non-preferential rules of origin are laid down in Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (7) and its implementing provisions in Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code (8). Determination of the country of origin of foods will be based on those rules, which are well known to food business operators and administrations and should ease their implementation.

The nutrition declaration for a food concerns information on the presence of energy and certain nutrients in foods. The mandatory provision of nutrition information on packaging should assist nutrition actions as part of public health policies which could involve the provision of scientific recommendations for nutrition education for the public and support informed food choices.

To facilitate the comparison of products in different package sizes, it is appropriate to retain the requirement that the mandatory nutrition declaration should refer to 100 g or 100 ml amounts and, if appropriate, to allow additional portion-based declarations. Therefore, where food is prepacked and individual portions or consumption units are identified, a nutrition declaration per portion or per consumption unit, in addition to the expression per 100 g or per 100 ml, should be allowed. Furthermore, in order to provide comparable indications relating to portions or consumption units, the Commission should be empowered to adopt rules on the expression of the nutrition declaration per portion or per consumption unit for specific categories of food.

The Commission White Paper highlighted certain nutritional elements of importance to public health such as saturated fat, sugars or sodium. Therefore, it is appropriate that the requirements on the mandatory provision of nutrition information should take into account such elements.

Since one of the objectives pursued by this Regulation is to provide a basis to the final consumer for making informed choices, it is important to ensure in this respect that the final consumer easily understands the information provided on the labelling. Therefore it is appropriate to use on the labelling the term ‘salt’ instead of the corresponding term of the nutrient ‘sodium’.

In the interest of consistency and coherence of Union law the voluntary inclusion of nutrition or health claims on food labels should be in accordance with the 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 (9).

(39) To avoid unnecessary burdens on food business operators, it is appropriate to exempt from the mandatory provision of a nutrition declaration certain categories of foods that are unprocessed or for which nutrition information is not a determining factor for consumers’ purchasing decisions, or for which the packaging is too small to accommodate the mandatory labeling requirements, unless the obligation to provide such information is provided for under other Union rules.

(40) Taking into account the specific nature of alcoholic beverages, it is appropriate to invite the Commission to analyse further the information requirements for those products. Therefore, the Commission should, taking into account the need to ensure coherence with other relevant Union policies, produce a report within 3 years of the entry into force of this Regulation concerning the application of the requirements to provide information on ingredients and nutrition information to alcoholic beverages. In addition, taking into account the resolution of the European Parliament of 5 September 2007 on an European Union strategy to support Member States in reducing alcohol-related harm (1), the opinion of the European Economic and Social Committee (2), the work of the Commission, and general public concern about alcohol-related harm especially to young and vulnerable consumers, the Commission, after consultation with stakeholders and the Member States, should consider the need for a definition of beverages such as ‘alcopops’, which are specifically targeted at young people. The Commission should also, if appropriate, propose specific requirements relating to alcoholic beverages in the context of this Regulation.

(41) To appeal to the average consumer and to serve the informative purpose for which it is introduced, and given the current level of knowledge on the subject of nutrition, the nutrition information provided should be simple and easily understood. To have the nutrition information partly in the principal field of vision, commonly known as the ‘front of pack’, and partly on another side on the pack, for instance the ‘back of pack’, might confuse consumers. Therefore, the nutrition declaration should be in the same field of vision. In addition, on a voluntary basis, the most important elements of the nutrition information may be repeated in the principal field of vision, in order to help consumers to easily see the essential nutrition information when purchasing foods. A free choice as to the information that could be repeated might confuse consumers. Therefore it is necessary to clarify which information may be repeated.

(42) In order to encourage food business operators to provide on a voluntary basis the information contained in the nutrition declaration for foods such as alcoholic beverages and non-prepacked foods that may be exempted from the nutrition declaration, the possibility should be given to declare only limited elements of the nutrition declaration. It is nevertheless appropriate to clearly establish the information that may be provided on a voluntary basis in order to avoid misleading the consumer by the free choice of the food business operator.

(43) There have been recent developments in the expression of the nutrition declaration, other than per 100 g, per 100 ml or per portion, or in its presentation, through the use of graphical forms or symbols, by some Member States and organisations in the food sector. Such additional forms of expression and presentation may help consumers to better understand the nutrition declaration. However, there is insufficient evidence across all the Union on how the average consumer understands and uses the alternative forms of expression or presentation of the information. Therefore, it is appropriate to allow for different forms of expression and presentation to be developed on the basis of criteria established in this Regulation and to invite the Commission to prepare a report regarding the use of those forms of expression and presentation, their effect on the internal market and the advisability of further harmonisation.

(44) In order to assist the Commission in producing that report, Member States should provide the Commission with the relevant information on the use of additional forms of expression and presentation of the nutrition declaration on the market in their territory. In order to do so, Member States should be empowered to request food business operators placing on the market in their territory foods bearing additional forms of expression or presentation to notify national authorities of the use of such additional forms and of the relevant justifications regarding the fulfilment of the requirements set out in this Regulation.

(45) It is desirable to ensure a certain level of consistency in the development of additional forms of expression and presentation of the nutrition declaration. It is therefore appropriate to promote the constant exchange and sharing of best practices and experience between Member States and with the Commission and to promote the participation of stakeholders in such exchanges.

(46) The declaration in the same field of vision of the amounts of nutritional elements and comparative indicators in an easily recognisable form to enable an assessment of the nutritional properties of a food should be considered in its entirety as part of the nutrition declaration and should not be treated as a group of individual claims.

(2) OJ C 77, 31.3.2009, p. 81.
Experience shows that in many cases voluntary food information is provided to the detriment of the clarity of the mandatory food information. Therefore, criteria should be provided to help food business operators and enforcement authorities to strike a balance between the provision of mandatory and voluntary food information.

Member States should retain the right, depending on local practical conditions and circumstances, to lay down rules in respect of the provision of information concerning non-prepacked foods. Although in such cases the consumer demand for other information is limited, information on potential allergens is considered very important. Evidence suggests that most food allergy incidents can be traced back to non-prepacked food. Therefore information on potential allergens should always be provided to the consumer.

As regards the matters specifically harmonised by this Regulation, Member States should not be able to adopt national provisions unless authorised by Union law. This Regulation should not prevent Member States from adopting national measures concerning matters not specifically harmonised by this Regulation. However, such national measures should not prohibit, impede or restrict the free movement of goods that are in conformity with this Regulation.

Union consumers show an increasing interest in the implementation of the Union animal welfare rules at the time of slaughter, including whether the animal was stunned before slaughter. In this respect, a study on the opportunity to provide consumers with the relevant information on the stunning of animals should be considered in the context of a future Union strategy for the protection and welfare of animals.

Food information rules should be able to adapt to a rapidly changing social, economic and technological environment.

Member States should carry out official controls in order to enforce compliance with this Regulation in accordance with 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 (1).


Irregular and frequent updating of food information requirements may impose considerable administrative burdens on food businesses, especially small and medium-sized enterprises. It is therefore appropriate to ensure that measures that may be adopted by the Commission in exercising the powers conferred by this Regulation apply on the same day in any calendar year following an appropriate transitional period. Derogations from this principle should be permitted in cases of urgency where the purpose of the measures concerned is the protection of human health.

In order to enable food business operators to adapt the labelling of their products to the new requirements introduced by this Regulation, it is important to provide for appropriate transitional periods for the application of this Regulation.

Given the substantial changes in the requirements related to nutrition labelling introduced by this Regulation, in particular changes in relation to the content of the nutrition declaration, it is appropriate to authorise food business operators to anticipate the application of this Regulation.

Since the objectives of this Regulation 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 those objectives.

The power to adopt delegated acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of, inter alia, the availability of certain mandatory particulars by means other than on the package or on the label, the list of foods not required to bear a list of ingredients, the re-examination of the list of substances or products causing allergies or intolerances, or the list of nutrients that may be declared on a voluntary basis. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to adopt implementing acts in relation to, inter alia, the modalities of expression of one or more particulars by means of pictograms or symbols instead of words or numbers, the manner of indicating the date of minimum durability, the manner of indicating the country of origin or place of provenance for meat, the precision of the declared values for the nutrition declaration, or the expression per portion or per consumption unit of the nutrition declaration. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers (1).

HAVE ADOPTED THIS REGULATION:

CHAPTER I
GENERAL PROVISIONS

Article 1
Subject matter and scope

1. This Regulation provides the basis for the assurance of a high level of consumer protection in relation to food information, taking into account the differences in the perception of consumers and their information needs whilst ensuring the smooth functioning of the internal market.

2. This Regulation establishes the general principles, requirements and responsibilities governing food information, and in particular food labelling. It lays down the means to guarantee the right of consumers to information and procedures for the provision of food information, taking into account the need to provide sufficient flexibility to respond to future developments and new information requirements.

3. This Regulation shall apply to food business operators at all stages of the food chain, where their activities concern the provision of food information to consumers. It shall apply to all foods intended for the final consumer, including foods delivered by mass caterers, and foods intended for supply to mass caterers.

This Regulation shall apply to catering services provided by transport undertakings when the departure takes place on the territories of the Member States to which the Treaties apply.

4. This Regulation shall apply without prejudice to labelling requirements provided for in specific Union provisions applicable to particular foods.

Article 2
Definitions

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

(a) the definitions of 'food', 'food law', 'food business', 'food business operator', 'retail', 'placing on the market' and 'final consumer' in Article 2 and in points (1), (2), (3), (7), (8) and (18) of Article 3 of Regulation (EC) No 178/2002;

(b) the definitions of 'processing', 'unprocessed products' and 'processed products' in points (m), (n) and (o) of Article 2(1) of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (2);

(c) the definition of 'food enzyme' in point (a) of Article 3(2) of Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes (3);

(d) the definitions of 'food additive', 'processing aid' and 'carrier' in points (a) and (b) of Article 3(2) of, and in point 5 of Annex I to, Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (4);

(e) the definition of 'flavourings' in point (a) of Article 3(2) of 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 (5);

(f) the definitions of 'meat', 'mechanically separated meat', 'meat preparations', 'fishery products' and 'meat products' in points 1.1, 1.14, 1.15, 3.1 and 7.1 of Annex I to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (6);

(g) the definition of 'advertising' in point (a) of Article 2 of Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (7).


2. The following definitions shall also apply:

(a) ‘food information’ means information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication;

(b) ‘food information law’ means the Union provisions governing the food information, and in particular labelling, including rules of a general nature applicable to all foods in particular circumstances or to certain categories of foods and rules which apply only to specific foods;

(c) ‘mandatory food information’ means the particulars that are required to be provided to the final consumer by Union provisions;

(d) ‘mass caterer’ means any establishment (including a vehicle or a fixed or mobile stall), such as restaurants, canteens, schools, hospitals and catering enterprises in which, in the course of a business, food is prepared to be ready for consumption by the final consumer;

(e) ‘prepacked food’ means any single item for presentation as such to the final consumer and to mass caterers, consisting of a food and the packaging into which it was put before being offered for sale, whether such packaging encloses the food completely or only partially, but in any event in such a way that the contents cannot be altered without opening or changing the packaging; ‘prepacked food’ does not cover foods packed on the sales premises at the consumer’s request or prepacked for direct sale;

(f) ‘ingredient’ means any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as ‘ingredients’;

(g) ‘place of provenance’ means any place where a food is indicated to come from, and that is not the ‘country of origin’ as determined in accordance with Articles 23 to 26 of Regulation (EEC) No 2913/92; the name, business name or address of the food business operator on the label shall not constitute an indication of the country of origin or place of provenance of food within the meaning of this Regulation;

(h) ‘compound ingredient’ means an ingredient that is itself the product of more than one ingredient;

(i) ‘label’ means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to the packaging or container of food;

(j) ‘labelling’ means any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food;

(k) ‘field of vision’ means all the surfaces of a package that can be read from a single viewing point;

(l) ‘principal field of vision’ means the field of vision of a package which is most likely to be seen at first glance by the consumer at the time of purchase and that enables the consumer to immediately identify a product in terms of its character or nature and, if applicable, its brand name. If a package has several identical principal fields of vision, the principal field of vision is the one chosen by the food business operator;

(m) ‘legibility’ means the physical appearance of information, by means of which the information is visually accessible to the general population and which is determined by various elements, inter alia, font size, letter spacing, spacing between lines, stroke width, type colour, typeface, width-height ratio of the letters, the surface of the material and significant contrast between the print and the background;

(n) ‘legal name’ means the name of a food prescribed in the Union provisions applicable to it or, in the absence of such Union provisions, the name provided for in the laws, regulations and administrative provisions applicable in the Member State in which the food is sold to the final consumer or to mass caterers;

(o) ‘customary name’ means a name which is accepted as the name of the food by consumers in the Member State in which that food is sold, without that name needing further explanation;

(p) ‘descriptive name’ means a name providing a description of the food, and if necessary of its use, which is sufficiently clear to enable consumers to know its true nature and distinguish it from other products with which it might be confused;

(q) ‘primary ingredient’ means an ingredient or ingredients of a food that represent more than 50 % of that food or which are usually associated with the name of the food by the consumer and for which in most cases a quantitative indication is required;
date of minimum durability of a food’ means the date until which the food retains its specific properties when properly stored;

‘nutrient’ means protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in point 1 of Part A of Annex XIII to this Regulation, and substances which belong to or are components of one of those categories;

‘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;

‘means of distance communication’ means any means which, without the simultaneous physical presence of the supplier and the consumer, may be used for the conclusion of a contract between those parties.

3. For the purposes of this Regulation the country of origin of a food shall refer to the origin of a food as determined in accordance with Articles 23 to 26 of Regulation (EEC) No 2913/92.

4. The specific definitions set out in Annex I shall also apply.

CHAPTER II

GENERAL PRINCIPLES ON FOOD INFORMATION

Article 3

General objectives

1. The provision of food information shall pursue a high level of protection of consumers’ health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social and ethical considerations.

2. Food information law shall aim to achieve in the Union the free movement of legally produced and marketed food, taking into account, where appropriate, the need to protect the legitimate interests of producers and to promote the production of quality products.

3. When food information law establishes new requirements, a transitional period after the entry into force of the new requirements shall be granted, except in duly justified cases. During such transitional period, foods bearing labels not complying with the new requirements may be placed on the market, and stocks of such foods that have been placed on the market before the end of the transitional period may continue to be sold until exhausted.

4. An open and transparent public consultation shall be conducted, including with stakeholders, directly or through representative bodies, during the preparation, evaluation and revision of food information law, except where the urgency of the matter does not allow it.

Article 4

Principles governing mandatory food information

1. Where mandatory food information is required by food information law, it shall concern information that falls, in particular, into one of the following categories:

(a) information on the identity and composition, properties or other characteristics of the food;

(b) information on the protection of consumers’ health and the safe use of a food. In particular, it shall concern information on:

(i) compositional attributes that may be harmful to the health of certain groups of consumers;

(ii) durability, storage and safe use;

(iii) the health impact, including the risks and consequences related to harmful and hazardous consumption of a food;

(c) information on nutritional characteristics so as to enable consumers, including those with special dietary requirements, to make informed choices.

2. When considering the need for mandatory food information and to enable consumers to make informed choices, account shall be taken of a widespread need on the part of the majority of consumers for certain information to which they attach significant value or of any generally accepted benefits to the consumer.
Article 5
Consultation of the European Food Safety Authority
Any Union measure in the field of food information law which is likely to have an effect on public health shall be adopted after consultation of the European Food Safety Authority ('the Authority').

CHAPTER III
GENERAL FOOD INFORMATION REQUIREMENTS AND RESPONSIBILITIES OF FOOD BUSINESS OPERATORS

Article 6
Basic requirement
Any food intended for supply to the final consumer or to mass caterers shall be accompanied by food information in accordance with this Regulation.

Article 7
Fair information practices
1. Food information shall not be misleading, particularly:

(a) as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production;

(b) by attributing to the food effects or properties which it does not possess;

(c) by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients;

(d) by suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient.

2. Food information shall be accurate, clear and easy to understand for the consumer.

3. Subject to derogations provided for by Union law applicable to natural mineral waters and foods for particular nutritional uses, food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor refer to such properties.

4. Paragraphs 1, 2 and 3 shall also apply to:

(a) advertising;

(b) the presentation of foods, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed.

Article 8
Responsibilities
1. The food business operator responsible for the food information shall be the operator under whose name or business name the food is marketed or, if that operator is not established in the Union, the importer into the Union market.

2. The food business operator responsible for the food information shall ensure the presence and accuracy of the food information in accordance with the applicable food information law and requirements of relevant national provisions.

3. Food business operators which do not affect food information shall not supply food which they know or presume, on the basis of the information in their possession as professionals, to be non-compliant with the applicable food information law and requirements of relevant national provisions.

4. Food business operators, within the businesses under their control, shall not modify the information accompanying a food if such modification would mislead the final consumer or otherwise reduce the level of consumer protection and the possibilities for the final consumer to make informed choices. Food business operators are responsible for any changes they make to food information accompanying a food.

5. Without prejudice to paragraphs 2 to 4, food business operators, within the businesses under their control, shall ensure compliance with the requirements of food information law and relevant national provisions which are relevant to their activities and shall verify that such requirements are met.

6. Food business operators, within the businesses under their control, shall ensure that information relating to non-prepacked food intended for the final consumer or for supply to mass caterers shall be transmitted to the food business operator receiving the food in order to enable, when required, the provision of mandatory food information to the final consumer.
7. In the following cases, food business operators, within the businesses under their control, shall ensure that the mandatory particulars required under Articles 9 and 10 shall appear on the prepackaging or on a label attached thereto, or on the commercial documents referring to the foods where it can be guaranteed that such documents either accompany the food to which they refer or were sent before or at the same time as delivery:

(a) where prepacked food is intended for the final consumer but marketed at a stage prior to sale to the final consumer and where sale to a mass caterer is not involved at that stage;

(b) where prepacked food is intended for supply to mass caterers for preparation, processing, splitting or cutting up.

Notwithstanding the first subparagraph, food business operators shall ensure that the particulars referred to in points (a), (f), (g) and (h) of Article 9(1) also appear on the external packaging in which the prepacked foods are presented for marketing.

8. Food business operators that supply to other food business operators food not intended for the final consumer or to mass caterers shall ensure that those other food business operators are provided with sufficient information to enable them, where appropriate, to meet their obligations under paragraph 2.

CHAPTER IV
MANDATORY FOOD INFORMATION

SECTION 1
Content and presentation

Article 9
List of mandatory particulars

1. In accordance with Articles 10 to 35 and subject to the exceptions contained in this Chapter, indication of the following particulars shall be mandatory:

(a) the name of the food;

(b) the list of ingredients;

(c) any ingredient or processing aid listed in Annex II or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form;

(d) the quantity of certain ingredients or categories of ingredients;

(e) the net quantity of the food;

(f) the date of minimum durability or the 'use by' date;

(g) any special storage conditions and/or conditions of use;

(h) the name or business name and address of the food business operator referred to in Article 8(1);

(i) the country of origin or place of provenance where provided for in Article 26;

(j) instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions;

(k) with respect to beverages containing more than 1.2 % by volume of alcohol, the actual alcoholic strength by volume;

(l) a nutrition declaration.

2. The particulars referred to in paragraph 1 shall be indicated with words and numbers. Without prejudice to Article 35, they may additionally be expressed by means of pictograms or symbols.

3. Where the Commission adopts delegated and implementing acts referred to in this Article, the particulars referred to in paragraph 1 may alternatively be expressed by means of pictograms or symbols instead of words or numbers.

In order to ensure that consumers benefit from other means of expression of mandatory food information than words and numbers, and provided that the same level of information as with words and numbers is ensured, the Commission, taking into account evidence of uniform consumer understanding, may establish, by means of delegated acts in accordance with Article 51, the criteria subject to which one or more particulars referred to in paragraph 1 may be expressed by pictograms or symbols instead of words or numbers.

4. For the purpose of ensuring the uniform implementation of paragraph 3 of this Article, the Commission may adopt implementing acts on the modalities of application of the criteria defined in accordance with paragraph 3 to express one or more particulars by means of pictograms or symbols instead of words or numbers. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2).

Article 10
Additional mandatory particulars for specific types or categories of foods

1. In addition to the particulars listed in Article 9(1), additional mandatory particulars for specific types or categories of foods are laid down in Annex III.
2. In order to ensure consumer information with respect to specific types or categories of foods and to take account of technical progress, scientific developments, the protection of consumers’ health or the safe use of a food, the Commission may amend Annex III by means of delegated acts, in accordance with Article 51.

Where, in the case of the emergence of a risk to consumers’ health, imperative grounds of urgency so require, the procedure provided for in Article 52 shall apply to delegated acts adopted pursuant to this Article.

**Article 11**

**Weights and measures**

Article 9 shall be without prejudice to more specific Union provisions regarding weights and measures.

**Article 12**

**Availability and placement of mandatory food information**

1. Mandatory food information shall be available and shall be easily accessible, in accordance with this Regulation, for all foods.

2. In the case of prepacked food, mandatory food information shall appear directly on the package or on a label attached thereto.

3. In order to ensure that consumers benefit from other means of provision of mandatory food information better adapted for certain mandatory particulars, and provided that the same level of information as by means of the package or the label is ensured, the Commission, taking into account evidence of uniform consumer understanding and of the wide use of these means by consumers, may establish, by means of delegated acts in accordance with Article 51, criteria subject to which certain mandatory particulars may be expressed by means other than on the package or on the label.

4. For the purposes of ensuring the uniform implementation of paragraph 3 of this Article, the Commission may adopt implementing acts on the modalities of application of the criteria referred to in paragraph 3 in order to express certain mandatory particulars by means other than on the package or on the label. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2).

5. In the case of non-prepacked food, the provisions of Article 44 shall apply.

**Article 13**

**Presentation of mandatory particulars**

1. Without prejudice to the national measures adopted under Article 44(2), mandatory food information shall be marked in a conspicuous place in such a way as to be easily visible, clearly legible and, where appropriate, indelible. It shall not in any way be hidden, obscured, detracted from or interrupted by any other written or pictorial matter or any other intervening material.

2. Without prejudice to specific Union provisions applicable to particular foods, when appearing on the package or on the label attached thereto, the mandatory particulars listed in Article 9(1) shall be printed on the package or on the label in such a way as to ensure clear legibility, in characters using a font size where the x-height, as defined in Annex IV, is equal to or greater than 1.2 mm.

3. In case of packaging or containers the largest surface of which has an area of less than 80 cm\(^2\), the x-height of the font size referred to in paragraph 2 shall be equal to or greater than 0.9 mm.

4. For the purpose of achieving the objectives of this Regulation, the Commission shall, by means of delegated acts in accordance with Article 51, establish rules for legibility.

For the same purpose as referred to in the first subparagraph, the Commission may, by means of delegated acts in accordance with Article 51, extend the requirements under paragraph 5 of this Article to additional mandatory particulars for specific types or categories of foods.

5. The particulars listed in points (a), (e) and (k) of Article 9(1) shall appear in the same field of vision.

6. Paragraph 5 of this Article shall not apply in the cases specified in Article 16(1) and (2).

**Article 14**

**Distance selling**

1. Without prejudice to the information requirements laid down in Article 9, in the case of prepacked foods offered for sale by means of distance communication:

(a) mandatory food information, except the particulars provided in point (f) of Article 9(1), shall be available before the purchase is concluded and shall appear on the material supporting the distance selling or be provided through other appropriate means clearly identified by the food business operator. When other appropriate means are used, the mandatory food information shall be provided without the food business operator charging consumers supplementary costs;

(b) all mandatory particulars shall be available at the moment of delivery.
2. In the case of non-prepacked foods offered for sale by means of distance communication, the particulars required under Article 44 shall be made available in accordance with paragraph 1 of this Article.

3. Point (a) of paragraph 1 shall not apply to foods offered for sale by means of automatic vending machines or automated commercial premises.

**Article 15**

**Language requirements**

1. Without prejudice to Article 9(3), mandatory food information shall appear in a language easily understood by the consumers of the Member States where a food is marketed.

2. Within their own territory, the Member States in which a food is marketed may stipulate that the particulars shall be given in one or more languages from among the official languages of the Union.

3. Paragraphs 1 and 2 shall not preclude the particulars from being indicated in several languages.

**Article 16**

**Omission of certain mandatory particulars**

1. In the case of glass bottles intended for reuse which are indelibly marked and which therefore bear no label, ring or collar only the particulars listed in points (a), (c), (e), (f) and (l) of Article 9(1) shall be mandatory.

2. In the case of packaging or containers the largest surface of which has an area of less than 10 cm² only the particulars listed in points (a), (c), (e) and (f) of Article 9(1) shall be mandatory on the package or on the label. The particulars referred to in point (b) of Article 9(1) shall be provided through other means or shall be made available at the request of the consumer.

3. Without prejudice to other Union provisions requiring a mandatory nutrition declaration, the declaration referred to in point (l) of Article 9(1) shall not be mandatory for the foods listed in Annex V.

4. Without prejudice to other Union provisions requiring a list of ingredients or a mandatory nutrition declaration, the particulars referred to in points (b) and (l) of Article 9(1) shall not be mandatory for beverages containing more than 1,2 % by volume of alcohol.

By 13 December 2014, the Commission shall produce a report concerning the application of Article 18 and Article 30(1) to the products referred to in this paragraph, and addressing whether alcoholic beverages should in future be covered, in particular, by the requirement to provide the information on the energy value, and the reasons justifying possible exemptions, taking into account the need to ensure coherence with other relevant Union policies. In this context, the Commission shall consider the need to propose a definition of ‘alcopops’.

The Commission shall accompany that report by a legislative proposal, if appropriate, determining the rules for a list of ingredients or a mandatory nutrition declaration for those products.

**SECTION 2**

**Detailed provisions on mandatory particulars**

**Article 17**

**Name of the food**

1. The name of the food shall be its legal name. In the absence of such a name, the name of the food shall be its customary name, or, if there is no customary name or the customary name is not used, a descriptive name of the food shall be provided.

2. The use in the Member State of marketing of the name of the food under which the product is legally manufactured and marketed in the Member State of production shall be allowed. However, where the application of the other provisions of this Regulation, in particular those set out in Article 9, would not enable consumers in the Member State of marketing to know the true nature of the food and to distinguish it from foods with which they could confuse it, the name of the food shall be accompanied by other descriptive information which shall appear in proximity to the name of the food.

3. In exceptional cases, the name of the food in the Member State of production shall not be used in the Member State of marketing when the food which it designates in the Member State of production is so different, as regards its composition or manufacture, from the food known under that name in the Member State of marketing that paragraph 2 is not sufficient to ensure, in the Member State of marketing, correct information for consumers.

4. The name of the food shall not be replaced with a name protected as intellectual property, brand name or fancy name.

5. Specific provisions on the name of the food and particulars that shall accompany it are laid down in Annex VI.

**Article 18**

**List of ingredients**

1. The list of ingredients shall be headed or preceded by a suitable heading which consists of or includes the word ‘ingredients’. It shall include all the ingredients of the food, in descending order of weight, as recorded at the time of their use in the manufacture of the food.
2. Ingredients shall be designated by their specific name, where applicable, in accordance with the rules laid down in Article 17 and in Annex VI.

3. All ingredients present in the form of engineered nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets.

4. Technical rules for applying paragraphs 1 and 2 of this Article are laid down in Annex VII.

5. For the purposes of achieving the objectives of this Regulation, the Commission shall, by means of delegated acts in accordance with Article 51, adjust and adapt the definition of engineered nanomaterials referred to in point (t) of Article 2(2) to technical and scientific progress or to definitions agreed at international level.

Article 19

Omission of the list of ingredients

1. The following foods shall not be required to bear a list of ingredients:

(a) fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated;

(b) carbonated water, the description of which indicates that it has been carbonated;

(c) fermentation vinegars derived exclusively from a single basic product, provided that no other ingredient has been added;

(d) cheese, butter, fermented milk and cream, to which no ingredient has been added other than lactic products, food enzymes and micro-organism cultures essential to manufacture, or in the case of cheese other than fresh cheese and processed cheese the salt needed for its manufacture;

(e) foods consisting of a single ingredient, where:

(i) the name of the food is identical to the ingredient name; or

(ii) the name of the food enables the nature of the ingredient to be clearly identified.

2. In order to take into account the relevance for the consumer of a list of ingredients for specific types or categories of foods, the Commission may, in exceptional cases, by means of delegated acts, in accordance with Article 51, supplement paragraph 1 of this Article, provided that omissions do not result in the final consumer or mass caterers being inadequately informed.

Article 20

Omission of constituents of food from the list of ingredients

Without prejudice to Article 21, the following constituents of a food shall not be required to be included in the list of ingredients:

(a) the constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions;

(b) food additives and food enzymes:

(i) whose presence in a given food is solely due to the fact that they were contained in one or more ingredients of that food, in accordance with the carry-over principle referred to in points (a) and (b) of Article 18(1) of Regulation (EC) No 1333/2008, provided that they serve no technological function in the finished product; or

(ii) which are used as processing aids;

(c) carriers and substances which are not food additives but are used in the same way and with the same purpose as carriers, and which are used in the quantities strictly necessary;

(d) substances which are not food additives but are used in the same way and with the same purpose as processing aids and are still present in the finished product, even if in an altered form;

(e) water:

(i) where the water is used during the manufacturing process solely for the reconstitution of an ingredient used in concentrated or dehydrated form; or

(ii) in the case of a liquid medium which is not normally consumed.

Article 21

Labelling of certain substances or products causing allergies or intolerances

1. Without prejudice to the rules adopted under Article 44(2), the particulars referred to in point (c) of Article 9(1) shall meet the following requirements:

(a) they shall be indicated in the list of ingredients in accordance with the rules laid down in Article 18(1), with a clear reference to the name of the substance or product as listed in Annex II; and
In the absence of a list of ingredients, the indication of the particulars referred to in point (c) of Article 9(1) shall comprise the word 'contains' followed by the name of the substance or product as listed in Annex II.

Where several ingredients or processing aids of a food originate from a single substance or product listed in Annex II, the labelling shall make it clear for each ingredient or processing aid concerned.

The indication of the particulars referred to in point (c) of Article 9(1) shall not be required in cases where the name of the food clearly refers to the substance or product concerned.

2. In order to ensure better information for consumers and to take account of the most recent scientific progress and technical knowledge, the Commission shall systematically re-examine and, where necessary, update the list in Annex II by means of delegated acts, in accordance with Article 51. Where, in the case of the emergence of a risk to consumers' health, imperative grounds of urgency so require, the procedure provided for in Article 52 shall apply to delegated acts adopted pursuant to this Article.

Article 22
Quantitative indication of ingredients

1. The indication of the quantity of an ingredient or category of ingredients used in the manufacture or preparation of a food shall be required where the ingredient or category of ingredients concerned:

(a) appears in the name of the food or is usually associated with that name by the consumer;

(b) is emphasised on the labelling in words, pictures or graphics; or

(c) is essential to characterise a food and to distinguish it from products with which it might be confused because of its name or appearance.

2. Technical rules for applying paragraph 1, including specific cases where the quantitative indication shall not be required in respect of certain ingredients, are laid down in Annex VIII.

Article 23
Net quantity

1. The net quantity of a food shall be expressed using litres, centilitres, millilitres, kilograms or grams, as appropriate:

(a) in units of volume in the case of liquid products;

(b) in units of mass in the case of other products.

2. In order to ensure a better understanding by the consumer of the food information on the labelling, the Commission may establish for certain specified foods, by means of delegated acts, in accordance with Article 51, a manner for the expression of the net quantity other than the one laid down in paragraph 1 of this Article.

3. Technical rules for applying paragraph 1, including specific cases where the indication of the net quantity shall not be required, are laid down in Annex IX.

Article 24
Minimum durability date, ‘use by’ date and date of freezing

1. In the case of foods which, from a microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the ‘use by’ date. After the ‘use by’ date a food shall be deemed to be unsafe in accordance with Article 14(2) to (5) of Regulation (EC) No 178/2002.

2. The appropriate date shall be expressed in accordance with Annex X.

3. In order to ensure a uniform application of the manner of indicating the date of minimum durability referred to in point 1(c) of Annex X, the Commission may adopt implementing acts setting out rules in this regard. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2).

Article 25
Storage conditions or conditions of use

1. In cases where foods require special storage conditions and/or conditions of use, those conditions shall be indicated.

2. To enable appropriate storage or use of the food after opening the package, the storage conditions and/or time limit for consumption shall be indicated, where appropriate.
Article 26

Country of origin or place of provenance

1. This Article shall apply without prejudice to labelling requirements provided for in specific Union provisions, in particular Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialties guaranteed (1) and Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (2).

2. Indication of the country of origin or place of provenance shall be mandatory:

(a) where failure to indicate this might mislead the consumer as to the true country of origin or place of provenance of the food, in particular if the information accompanying the food or the label as a whole would otherwise imply that the food has a different country of origin or place of provenance;

(b) for meat falling within the Combined Nomenclature (CN) codes listed in Annex XI. The application of this point shall be subject to the adoption of implementing acts referred to in paragraph 8.

3. Where the country of origin or the place of provenance of a food is given and where it is not the same as that of its primary ingredient:

(a) the country of origin or place of provenance of the primary ingredient in question shall also be given; or

(b) the country of origin or place of provenance of the primary ingredient shall be indicated as being different to that of the food.

The application of this paragraph shall be subject to the adoption of the implementing acts referred to in paragraph 8.

4. Within 5 years from the date of application of point (b) of paragraph 2, the Commission shall submit a report to the European Parliament and the Council to evaluate the mandatory indication of the country of origin or place of provenance for products referred to in that point.

5. By 13 December 2014, the Commission shall submit reports to the European Parliament and the Council regarding the mandatory indication of the country of origin or place of provenance for the following foods:

(a) types of meat other than beef and those referred to in point (b) of paragraph 2;

(b) milk;

(c) milk used as an ingredient in dairy products;

(d) unprocessed foods;

(e) single ingredient products;

(f) ingredients that represent more than 50 % of a food.

6. By 13 December 2013, the Commission shall submit a report to the European Parliament and the Council regarding the mandatory indication of the country of origin or place of provenance for meat used as an ingredient.

7. The reports referred to in paragraphs 5 and 6 shall take into account the need for the consumer to be informed, the feasibility of providing the mandatory indication of the country of origin or place of provenance and an analysis of the costs and benefits of the introduction of such measures, including the legal impact on the internal market and the impact on international trade.

The Commission may accompany those reports with proposals to modify the relevant Union provisions.

8. By 13 December 2013, following impact assessments, the Commission shall adopt implementing acts concerning the application of point (b) of paragraph 2 of this Article and the application of paragraph 3 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2).

9. In the case of foods referred to in point (b) of paragraph 2, in point (a) of paragraph 5 and in paragraph 6, the reports and the impact assessments under this Article shall consider, inter alia, the options for the modalities of expressing the country of origin or place of provenance of those foods, in particular with respect to each of the following determining points in the life of the animal:

(a) place of birth;

(b) place of rearing;

(c) place of slaughter.

Article 27

Instructions for use

1. The instructions for use of a food shall be indicated in such a way as to enable appropriate use to be made of the food.
2. The Commission may adopt implementing acts setting out detailed rules concerning the implementation of paragraph 1 for certain foods. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2).

Article 28

Alcoholic strength

1. The rules concerning indication of the alcoholic strength by volume shall, in the case of products classified in CN code 2204, be those laid down in the specific Union provisions applicable to such products.

2. The actual alcoholic strength by volume of beverages containing more than 1.2 % by volume of alcohol other than those referred to in paragraph 1 shall be indicated in accordance with Annex XII.

SECTION 3

Nutrition declaration

Article 29

Relationship with other legislation

1. This Section shall not apply to foods falling within the scope of the following legislation:


2. This Section shall apply without prejudice to Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (3) and specific Directives as referred to in Article 4(1) of that Directive.

Article 30

Content

1. The mandatory nutrition declaration shall include the following:

(a) energy value; and

(b) the amounts of fat, saturates, carbohydrate, sugars, protein and salt.

Where appropriate, a statement indicating that the salt content is exclusively due to the presence of naturally occurring sodium may appear in close proximity to the nutrition declaration.

2. The content of the mandatory nutrition declaration referred to in paragraph 1 may be supplemented with an indication of the amounts of one or more of the following:

(a) mono-unsaturates;

(b) polyunsaturates;

(c) polyols;

(d) starch;

(e) fibre;

(f) any of the vitamins or minerals listed in point 1 of Part A of Annex XIII, and present in significant amounts as defined in point 2 of Part A of Annex XIII.

3. Where the labelling of a prepacked food provides the mandatory nutrition declaration referred to in paragraph 1, the following information may be repeated thereon:

(a) the energy value; or

(b) the energy value together with the amounts of fat, saturates, sugars, and salt.

4. By way of derogation from Article 36(1), where the labelling of the products referred to in Article 16(4) provides a nutrition declaration, the content of the declaration may be limited to the energy value only.

5. Without prejudice to Article 44 and by way of derogation from Article 36(1), where the labelling of the products referred to in Article 44(1) provides a nutrition declaration, the content of that declaration may be limited only to:

(a) the energy value; or

(b) the energy value together with the amounts of fat, saturates, sugars, and salt.

6. In order to take account of the relevance of particulars referred to in paragraphs 2 to 5 of this Article for the information of consumers, the Commission may, by means of delegated acts, in accordance with Article 51, amend the lists in paragraphs 2 to 5 of this Article, by adding or removing particulars.

7. By 13 December 2014, the Commission, taking into account scientific evidence and experience acquired in Member States, shall submit a report on the presence of trans fats in foods and in the overall diet of the Union population. The aim of the report shall be to assess the impact of appropriate means that could enable consumers to make healthier food and overall dietary choices or that could promote the provision of healthier food options to consumers, including, among others, the provision of information on trans fats to consumers or restrictions on their use. The Commission shall accompany this report with a legislative proposal, if appropriate.

Article 31
Calculation
1. The energy value shall be calculated using the conversion factors listed in Annex XIV.

2. The Commission may adopt, by means of delegated acts, in accordance with Article 51, conversion factors for the vitamins and minerals referred to in point 1 of Part A of Annex XIII, in order to calculate more precisely the content of such vitamins and minerals in foods. Those conversion factors shall be added to Annex XIV.

3. The energy value and the amounts of nutrients referred to in Article 30(1) to (5) shall be those of the food as sold. Where appropriate, the information may relate to the food after preparation, provided that sufficiently detailed preparation instructions are given and the information relates to the food as prepared for consumption.

4. The declared values shall, according to the individual case, be average values based on:

(a) the manufacturer’s analysis of the food;

(b) a calculation from the known or actual average values of the ingredients used; or

(c) a calculation from generally established and accepted data.

The Commission may adopt implementing acts setting out detailed rules for the uniform implementation of this paragraph with regard to the precision of the declared values such as the differences between the declared values and those established in the course of official checks. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2).

Article 32
Expression per 100 g or per 100 ml
1. The energy value and the amount of nutrients referred to in Article 30(1) to (5) shall be expressed per 100 g or per 100 ml.

2. When provided, the declaration on vitamins and minerals shall, in addition to the form of expression referred to in paragraph 2, be expressed as a percentage of the reference intakes set out in point 1 of Part A of Annex XIII in relation to per 100 g or per 100 ml.

3. In addition to the form of expression referred to in paragraph 2 of this Article, the energy value and the amounts of nutrients referred to in Article 30(1), (3), (4) and (5) may be expressed, as appropriate, as a percentage of the reference intakes set out in Part B of Annex XIII in relation to per 100 g or per 100 ml.

4. Where information is provided pursuant to paragraph 4, the following additional statement shall be indicated in close proximity to it: ‘Reference intake of an average adult (8 400 kJ/ 2 000 kcal)’.

Article 33
Expression on a per portion basis or per consumption unit
1. In the following cases, the energy value and the amounts of nutrients referred to in Article 30(1) to (5) may be expressed per portion and/or per consumption unit, easily recognisable by the consumer, provided that the portion or the unit used is quantified on the label and that the number of portions or units contained in the package is stated:

(a) in addition to the form of expression per 100 g or per 100 ml referred to in Article 32(2);

(b) in addition to the form of expression per 100 g or per 100 ml referred to in Article 32(3) regarding the amounts of vitamins and minerals;

(c) in addition to or instead of the form of expression per 100 g or per 100 ml referred to in Article 32(4).

2. By way of derogation from Article 32(2), in the cases referred to in point (b) of Article 30(3) the amount of nutrients and/or the percentage of the reference intakes set out in Part B of Annex XIII may be expressed on the basis of per portion or per consumption unit alone.

When the amounts of nutrients are expressed on the basis of per portion or per consumption unit alone in accordance with the first subparagraph, the energy value shall be expressed per 100 g or per 100 ml and on the basis of per portion or per consumption unit.
3. By way of derogation from Article 32(2), in the cases referred to in Article 30(5) the energy value and the amount of nutrients and/or the percentage of the reference intakes set out in Part B of Annex XIII may be expressed on the basis of per portion or per consumption unit alone.

4. The portion or unit used shall be indicated in close proximity to the nutrition declaration.

5. In order to ensure the uniform implementation of the expression of the nutrition declaration per portion or per unit of consumption and to provide for a uniform basis of comparison for the consumer, the Commission shall, taking into account actual consumption behaviour of consumers as well as dietary recommendations, adopt, by means of implementing acts, rules on the expression per portion or per consumption unit for specific categories of foods. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2).

Article 34

Presentation

1. The particulars referred to in Article 30(1) and (2) shall be included in the same field of vision. They shall be presented together in a clear format and, where appropriate, in the order of presentation provided for in Annex XV.

2. The particulars referred to in Article 30(1) and (2) shall be presented, if space permits, in tabular format with the numbers aligned. Where space does not permit, the declaration shall appear in linear format.

3. The particulars referred to in Article 30(3) shall be presented:

(a) in the principal field of vision; and

(b) using a font size in accordance with Article 13(2).

The particulars referred to in Article 30(3) may be presented in a format different from that specified in paragraph 2 of this Article.

4. The particulars referred to in Article 30(4) and (5) may be presented in a format different from that specified in paragraph 2 of this Article.

5. In cases where the energy value or the amount of nutrient(s) in a product is negligible, the information on those elements may be replaced by a statement such as ‘Contains negligible amounts of …’ and shall be indicated in close proximity to the nutrition declaration when present.

In order to ensure the uniform implementation of this paragraph, the Commission may adopt implementing acts regarding the energy value and amounts of nutrients referred to in Article 30(1) to (5) which can be regarded as negligible. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2).

6. In order to ensure a uniform application of the manner of presenting the nutrition declaration under the formats referred to in paragraphs 1 to 4 of this Article, the Commission may adopt implementing acts in this regard. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2).

Additional forms of expression and presentation

1. In addition to the forms of expression referred to in Article 32(2) and (4) and Article 33 and to the presentation referred to in Article 34(2), the energy value and the amount of nutrients referred to in Article 30(1) to (5) may be given by other forms of expression and/or presented using graphical forms or symbols in addition to words or numbers provided that the following requirements are met:

(a) they are based on sound and scientifically valid consumer research and do not mislead the consumer as referred to in Article 7;

(b) their development is the result of consultation with a wide range of stakeholder groups;

(c) they aim to facilitate consumer understanding of the contribution or importance of the food to the energy and nutrient content of a diet;

(d) they are supported by scientifically valid evidence of understanding of such forms of expression or presentation by the average consumer;

(e) in the case of other forms of expression, they are based either on the harmonised reference intakes set out in Annex XIII, or in their absence, on generally accepted scientific advice on intakes for energy or nutrients;

(f) they are objective and non-discriminatory; and

(g) their application does not create obstacles to the free movement of goods.

2. Member States may recommend to food business operators the use of one or more additional forms of expression or presentation of the nutrition declaration that they consider as best fulfilling the requirements laid down in points (a) to (g) of paragraph 1. Member States shall provide the Commission with the details of such additional forms of expression and presentation.
3. Member States shall ensure an appropriate monitoring of additional forms of expression or presentation of the nutrition declaration that are present on the market in their territory.

To facilitate the monitoring of the use of such additional forms of expression or presentation, Member States may require food business operators placing on the market in their territory foods bearing such information to notify the competent authority of the use of an additional form of expression or presentation and to provide them with the relevant justifications regarding the fulfilment of the requirements laid down in paragraphs 1 to (g) of paragraph 1. In such cases, information on the discontinuation of the use of such additional forms of expression or presentation may also be required.

4. The Commission shall facilitate and organise the exchange of information between Member States, itself and stakeholders on matters relating to the use of any additional forms of expression or presentation of the nutrition declaration.

5. By 13 December 2017, in the light of the experience gained, the Commission shall submit a report to the European Parliament and the Council on the use of additional forms of expression and presentation, on their effect on the internal market and on the advisability of further harmonisation of those forms of expression and presentation. For this purpose, Member States shall provide the Commission with relevant information concerning the use of such additional forms of expression or presentation on the market in their territory. The Commission may accompany this report with proposals to modify the relevant Union provisions.

6. In order to ensure the uniform application of this Article, the Commission shall adopt implementing acts setting out detailed rules concerning the implementation of paragraphs 1, 3 and 4 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2).

CHAPTER V

VOLUNTARY FOOD INFORMATION

Article 36

Applicable requirements

1. Where food information referred to in Articles 9 and 10 is provided on a voluntary basis, such information shall comply with the requirements laid down in Sections 2 and 3 of Chapter IV.

2. Food information provided on a voluntary basis shall meet the following requirements:

(a) it shall not mislead the consumer, as referred to in Article 7;

(b) it shall not be ambiguous or confusing for the consumer; and

(c) it shall, where appropriate, be based on the relevant scientific data.

3. The Commission shall adopt implementing acts on the application of the requirements referred to in paragraph 2 of this Article to the following voluntary food information:

(a) information on the possible and unintentional presence in food of substances or products causing allergies or intolerances;

(b) information related to suitability of a food for vegetarians or vegans; and

(c) the indication of reference intakes for specific population groups in addition to the reference intakes set out in Annex XIII.

Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 48(2).

4. In order to ensure that consumers are appropriately informed, where voluntary food information is provided by food business operators on a divergent basis which might mislead or confuse the consumer, the Commission may, by means of delegated acts, in accordance with Article 51, provide for additional cases of provision of voluntary food information to the ones referred to in paragraph 3 of this Article.

Article 37

Presentation

Voluntary food information shall not be displayed to the detriment of the space available for mandatory food information.

CHAPTER VI

NATIONAL MEASURES

Article 38

National measures

1. As regards the matters specifically harmonised by this Regulation, Member States may not adopt or maintain national measures unless authorised by Union law. Those national measures shall not give rise to obstacles to free movement of goods, including discrimination as regards foods from other Member States.

2. Without prejudice to Article 39, Member States may adopt national measures concerning matters not specifically harmonised by this Regulation provided that they do not prohibit, impede or restrict the free movement of goods that are in conformity with this Regulation.
Article 39

**National measures on additional mandatory particulars**

1. In addition to the mandatory particulars referred to in Article 9(1) and in Article 10, Member States may, in accordance with the procedure laid down in Article 45, adopt measures requiring additional mandatory particulars for specific types or categories of foods, justified on grounds of at least one of the following:

(a) the protection of public health;

(b) the protection of consumers;

(c) the prevention of fraud;

(d) the protection of industrial and commercial property rights, indications of provenance, registered designations of origin and the prevention of unfair competition.

2. By means of paragraph 1, Member States may introduce measures concerning the mandatory indication of the country of origin or place of provenance of foods only where there is a proven link between certain qualities of the food and its origin or provenance. When notifying such measures to the Commission, Member States shall provide evidence that the majority of consumers attach significant value to the provision of that information.

Article 40

**Milk and milk products**

Member States may adopt measures derogating from Article 9(1) and Article 10(1) in the case of milk and milk products presented in glass bottles intended for reuse.

They shall communicate to the Commission the text of those measures without delay.

Article 41

**Alcoholic beverages**

Member States may, pending the adoption of the Union provisions referred to in Article 16(4), maintain national measures as regards the listing of ingredients in the case of beverages containing more than 1,2 % by volume of alcohol.

Article 42

**Expression of the net quantity**

In the absence of Union provisions referred to in Article 23(2) concerning the expression of net quantity for specified foods in a different manner to that provided for in Article 23(1), Member States may maintain national measures adopted before 12 December 2011.

By 13 December 2014, Member States shall inform the Commission about such measures. The Commission shall bring them to the attention of the other Member States.

Article 43

**Voluntary indication of reference intakes for specific population groups**

Pending the adoption of the Union provisions referred to in point (c) of Article 36(3), Member States may adopt national measures on the voluntary indication of reference intakes for specific population groups.

Member States shall communicate to the Commission the text of those measures without delay.

Article 44

**National measures for non-prepacked food**

1. Where foods are offered for sale to the final consumer or to mass caterers without prepackaging, or where foods are packed on the sales premises at the consumer’s request or prepacked for direct sale:

(a) the provision of the particulars specified in point (c) of Article 9(1) is mandatory;

(b) the provision of other particulars referred to in Articles 9 and 10 is not mandatory unless Member States adopt national measures requiring the provision of some or all of those particulars or elements of those particulars.

2. Member States may adopt national measures concerning the means through which the particulars or elements of those particulars specified in paragraph 1 are to be made available and, where appropriate, their form of expression and presentation.

3. Member States shall communicate to the Commission the text of the measures referred to in point (b) of paragraph 1 and in paragraph 2 without delay.

Article 45

**Notification procedure**

1. When reference is made to this Article, the Member State which deems it necessary to adopt new food information legislation shall notify in advance the Commission and the other Member States of the measures envisaged and give the reasons justifying them.
2. The Commission shall consult the Standing Committee on the Food Chain and Animal Health set up by Article 58(1) of Regulation (EC) No 178/2002 if it considers such consultation to be useful or if a Member State so requests. In that case, the Commission shall ensure that this process is transparent for all stakeholders.

3. The Member State which deems it necessary to adopt new food information legislation may take the envisaged measures only 3 months after the notification referred to in paragraph 1, provided that it has not received a negative opinion from the Commission.

4. If the Commission's opinion is negative, and before the expiry of the period referred to in paragraph 3 of this Article, the Commission shall initiate the examination procedure referred to in Article 48(2) in order to determine whether the envisaged measures may be implemented subject, if necessary, to the appropriate modifications.


CHAPTER VII
IMPLEMENTING, AMENDING AND FINAL PROVISIONS

Article 46
Amendments to the Annexes

In order to take into account technical progress, scientific developments, consumers' health, or consumers' need for information, and subject to the provisions of Article 10(2) and Article 21(2) relating to the amendments to Annexes II and III, the Commission may, by means of delegated acts in accordance with Article 51, amend the Annexes to this Regulation.

Article 47
Transitional period for and date of application of implementing measures or delegated acts

1. Without prejudice to paragraph 2 of this Article, in exercising the powers conferred by this Regulation to adopt measures by means of implementing acts in accordance with the examination procedure referred to in Article 48(2) or by means of delegated acts in accordance with Article 51 the Commission shall:

(a) establish an appropriate transitional period for application of the new measures, during which foods bearing labels not complying with the new measures may be placed on the market and after which stocks of such foods that have been placed on the market before the end of the transitional period may continue to be sold until exhausted; and

(b) ensure that those measures apply as from 1 April in any calendar year.

2. Paragraph 1 shall not apply in cases of urgency where the purpose of the measures referred to in that paragraph is the protection of human health.

Article 48
Committee

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health established by Article 58(1) of Regulation (EC) No 178/2002. That Committee is a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 49
Amendments to Regulation (EC) No 1924/2006

The first and second paragraphs of Article 7 of Regulation (EC) No 1924/2006 are replaced by the following:

'Nutrition labelling of products on which a nutrition and/or health claim is made shall be mandatory, with the exception of generic advertising. The information to be provided shall consist of that specified in Article 30(1) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (*) Where a nutrition and/or health claim is made for a nutrient referred to in Article 30(2) of Regulation (EU) No 1169/2011 the amount of that nutrient shall be declared in accordance with Articles 31 to 34 of that Regulation.

The amount(s) of the substance(s) to which a nutrition or health claim relates that does not appear in the nutrition labelling shall be stated in the same field of vision as the nutrition labelling and be expressed in accordance with Articles 31 to 34 of that Regulation.

The units of measurement used to express the amount of the substance shall be appropriate for the individual substances concerned.'

(*) OJ L 304, 22.11.2011, p. 18'.

Article 50

Amendments to Regulation (EC) No 1925/2006

Paragraph 3 of Article 7 of Regulation (EC) No 1925/2006 is replaced by the following:

‘3. Nutrition labelling of products to which vitamins and minerals have been added and which are covered by this Regulation shall be compulsory. The information to be provided shall consist of that specified in Article 30(1) of Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers (*) and of the total amounts present of the vitamins and minerals when added to the food.

(*) OJ L 304, 22.11.2011, p. 18’.

Article 51

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 9(3), Article 10(2), Article 12(3), Article 13(4), Article 18(5), Article 19(2), Article 21(2), Article 23(2), Article 30(6), Article 31(2), Article 36(4) and Article 46 shall be conferred on the Commission for a period of 5 years after 12 December 2011. The Commission shall draw up a report in respect of the delegation of power not later than 9 months before the end of the 5-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than 3 months before the end of each period.

3. The delegation of power referred to in Article 9(3), Article 10(2), Article 12(3), Article 13(4), Article 18(5), Article 19(2), Article 21(2), Article 23(2), Article 30(6), Article 31(2), Article 36(4) and Article 46 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or on a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

5. A delegated act adopted pursuant to Article 9(3), Article 10(2), Article 12(3), Article 13(4), Article 18(5), Article 19(2), Article 21(2), Article 23(2), Article 30(6), Article 31(2), Article 36(4) and Article 46 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of 2 months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by 2 months at the initiative of the European Parliament or of the Council.

Article 52

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 51(5). In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or by the Council.

Article 53

Repeal


2. References to the repealed acts shall be construed as references to this Regulation.

Article 54

Transitional measures

1. Foods placed on the market or labelled prior to 13 December 2014 which do not comply with the requirements of this Regulation may be marketed until the stocks of the foods are exhausted.

Foods placed on the market or labelled prior to 13 December 2016 which do not comply with the requirement laid down in point (l) of Article 9(1) may be marketed until the stocks of the foods are exhausted.

Foods placed on the market or labelled prior to 1 January 2014 which do not comply with the requirements laid down in Part B of Annex VI may be marketed until the stocks of the foods are exhausted.
2. Between 13 December 2014 and 13 December 2016, where the nutrition declaration is provided on a voluntary basis, it shall comply with Articles 30 to 35.


**Article 55**

**Entry into force and date of application**

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union.*

It shall apply from 13 December 2014, with the exception of point (l) of Article 9(1), which shall apply from 13 December 2016, and Part B of Annex VI, which shall apply from 1 January 2014.

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

Done at Strasbourg, 25 October 2011.

For the European Parliament
The President
J. BUZEK

For the Council
The President
M. DOWGIELEWICZ

ANNEX I

SPECIFIC DEFINITIONS
As referred to in Article 2(4)

1. ‘nutrition declaration’ or ‘nutrition labelling’ means information stating the:

(a) energy value; or

(b) energy value and one or more of the following nutrients only:
— fat (saturates, mono-unsaturates, polyunsaturates),
— carbohydrate (sugars, polyols, starch),
— salt,
— fibre,
— protein,
— any of the vitamins or minerals listed in point 1 of Part A of Annex XIII, and present in significant amounts as defined in point 2 of Part A of Annex XIII,

2. ‘fat’ means total lipids, and includes phospholipids;

3. ‘saturates’ means fatty acids without double bond;

4. ‘trans fat’ means fatty acids with at least one non-conjugated (namely interrupted by at least one methylene group) carbon-carbon double bond in the trans configuration;

5. ‘mono-unsaturates’ means fatty acids with one cis double bond;

6. ‘polyunsaturates’ means fatty acids with two or more cis, cis-methylene interrupted double bonds;

7. ‘carbohydrate’ means any carbohydrate which is metabolised by humans, and includes polyols;

8. ‘sugars’ means all monosaccharides and disaccharides present in food, but excludes polyols;

9. ‘polyols’ means alcohols containing more than two hydroxyl groups;

10. ‘protein’ means the protein content calculated using the formula: protein = total Kjeldahl nitrogen × 6,25;

11. ‘salt’ means the salt equivalent content calculated using the formula: salt = sodium × 2,5;

12. ‘fibre’ means carbohydrate polymers with three or more monomeric units, which are neither digested nor absorbed in the human small intestine and belong to the following categories:
— edible carbohydrate polymers naturally occurring in the food as consumed,
— edible carbohydrate polymers which have been obtained from food raw material by physical, enzymatic or chemical means and which have a beneficial physiological effect demonstrated by generally accepted scientific evidence,
— edible synthetic carbohydrate polymers which have a beneficial physiological effect demonstrated by generally accepted scientific evidence,

13. ‘average value’ means the value which best represents the amount of the nutrient which a given food contains, and reflects allowances for seasonal variability, patterns of consumption and other factors which may cause the actual value to vary.
ANNEX II

SUBSTANCES OR PRODUCTS CAUSING ALLERGIES OR INTOLERANCES

1. Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof, except:
   (a) wheat based glucose syrups including dextrose (1);
   (b) wheat based maltodextrins (1);
   (c) glucose syrups based on barley;
   (d) cereals used for making alcoholic distillates including ethyl alcohol of agricultural origin;

2. Crustaceans and products thereof;

3. Eggs and products thereof;

4. Fish and products thereof, except:
   (a) fish gelatine used as carrier for vitamin or carotenoid preparations;
   (b) fish gelatine or Isinglass used as fining agent in beer and wine;

5. Peanuts and products thereof;

6. Soybeans and products thereof, except:
   (a) fully refined soybean oil and fat (1);
   (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, and natural D-alpha tocopherol succinate from soybean sources;
   (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources;
   (d) plant stanol ester produced from vegetable oil sterols from soybean sources;

7. Milk and products thereof (including lactose), except:
   (a) whey used for making alcoholic distillates including ethyl alcohol of agricultural origin;
   (b) lactitol;

8. Nuts, namely: almonds (Amygdalus communis L.), hazelnuts (Corylus avellana), walnuts (Juglans regia), cashews (Anacardium occidentale), pecan nuts (Carya illinoinensis (Wangenh.) K. Koch), Brazil nuts (Bertholletia excelsa), pistachio nuts (Pistacia vera), macadamia or Queensland nuts (Macadamia ternifolia), and products thereof, except for nuts used for making alcoholic distillates including ethyl alcohol of agricultural origin;

9. Celery and products thereof;

10. Mustard and products thereof;

11. Sesame seeds and products thereof;

12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre in terms of the total SO₂ which are to be calculated for products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers;

13. Lupin and products thereof;


(1) And the products thereof, in so far as the process that they have undergone is not likely to increase the level of allergenicity assessed by the Authority for the relevant product from which they originated.
FOODS FOR WHICH THE LABELLING MUST INCLUDE ONE OR MORE ADDITIONAL PARTICULARS

<table>
<thead>
<tr>
<th>TYPE OR CATEGORY OF FOOD</th>
<th>PARTICULARS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Foods packaged in certain gases</td>
<td></td>
</tr>
<tr>
<td>1.1. Foods whose durability has been extended by means of packaging gases authorised pursuant to Regulation (EC) No 1333/2008.</td>
<td>'packaged in a protective atmosphere'.</td>
</tr>
<tr>
<td>2. Foods containing sweeteners</td>
<td></td>
</tr>
<tr>
<td>2.1. Foods containing a sweetener or sweeteners authorised pursuant to Regulation (EC) No 1333/2008.</td>
<td>'with sweetener(s)' this statement shall accompany the name of the food.</td>
</tr>
<tr>
<td>2.2. Foods containing both an added sugar or sugars and a sweetener or sweeteners authorised pursuant to Regulation (EC) No 1333/2008.</td>
<td>'with sugar(s) and sweetener(s)' this statement shall accompany the name of the food.</td>
</tr>
</tbody>
</table>
| 2.3. Foods containing aspartame/aspartame-acesulfame salt authorised pursuant to Regulation EC) No 1333/2008. | 'contains aspartame (a source of phenylalanine)' shall appear on the label in cases where aspartame/aspartame-acesulfame salt is designated in the list of ingredients only by reference to the E number.  
'contains a source of phenylalanine' shall appear on the label in cases where aspartame/aspartame-acesulfame salt is designated in the list of ingredients by its specific name. |
<p>| 2.4. Foods containing more than 10 % added polyols authorised pursuant to Regulation (EC) No 1333/2008. | 'excessive consumption may produce laxative effects'.                                         |
| 3. Foods containing glycyrrhizinic acid or its ammonium salt                                                                         |
| 3.1. Confectionery or beverages containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant Glycyrrhiza glabra, at concentration of 100 mg/kg or 10 mg/l or above. | 'contains liquorice' shall be added immediately after the list of ingredients, unless the term 'liquorice' is already included in the list of ingredients or in the name of the food. In the absence of a list of ingredients, the statement shall accompany the name of the food. |
| 3.2. Confectionary containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant Glycyrrhiza glabra at concentrations of 4 g/kg or above. | 'contains liquorice – people suffering from hypertension should avoid excessive consumption' shall be added immediately after the list of ingredients. In the absence of a list of ingredients, the statement shall accompany the name of the food. |
| 3.3. Beverages containing glycyrrhizinic acid or its ammonium salt due to the addition of the substance(s) as such or the liquorice plant Glycyrrhiza glabra at concentrations of 50 mg/l or above, or of 300 mg/l or above in the case of beverages containing more than 1,2 % by volume of alcohol ('). | 'contains liquorice – people suffering from hypertension should avoid excessive consumption' shall be added immediately after the list of ingredients. In the absence of a list of ingredients, the statement shall accompany the name of the food. |</p>
<table>
<thead>
<tr>
<th>TYPE OR CATEGORY OF FOOD</th>
<th>PARTICULARS</th>
</tr>
</thead>
</table>

### 4. Beverages with high caffeine content or foods with added caffeine

<table>
<thead>
<tr>
<th>4.1. Beverages, with the exception of those based on coffee, tea or coffee or tea extract where the name of the food includes the term ‘coffee’ or ‘tea’, which:</th>
<th>'High caffeine content. Not recommended for children or pregnant or breast-feeding women' in the same field of vision as the name of the beverage, followed by a reference in brackets and in accordance with Article 13(1) of this Regulation to the caffeine content expressed in mg per 100 ml.</th>
</tr>
</thead>
<tbody>
<tr>
<td>— are intended for consumption without modification and contain caffeine, from whatever source, in a proportion in excess of 150 mg/l, or,</td>
<td></td>
</tr>
<tr>
<td>— are in concentrated or dried form and after reconstitution contain caffeine, from whatever source, in a proportion in excess of 150 mg/l,</td>
<td></td>
</tr>
</tbody>
</table>

| 4.2. Foods other than beverages, where caffeine is added with a physiological purpose. | 'Contains caffeine. Not recommended for children or pregnant women' in the same field of vision as the name of the food, followed by a reference in brackets and in accordance with Article 13(1) of this Regulation to the caffeine content expressed in mg per 100 g/ml. In the case of food supplements, the caffeine content shall be expressed per portion as recommended for daily consumption on the labelling. |

### 5. Foods with added phytosterols, phytosterol esters, phytostanols or phytostanol esters

<table>
<thead>
<tr>
<th>5.1. Foods or food ingredients with added phytosterols, phytosterol esters, phytostanols or phytostanol esters.</th>
<th>(1) ‘with added plant sterols’ or ‘with added plant stanols’ in the same field of vision as the name of the food;</th>
</tr>
</thead>
<tbody>
<tr>
<td>(2) the amount of added phytosterols, phytosterol esters, phytostanols or phytostanol esters content (expressed in % or as g of free plant sterols/plant stanols per 100 g or 100 ml of the food) shall be stated in the list of ingredients;</td>
<td></td>
</tr>
<tr>
<td>(3) a statement that the food is intended exclusively for people who want to lower their blood cholesterol level;</td>
<td></td>
</tr>
<tr>
<td>(4) a statement that patients on cholesterol lowering medication should only consume the product under medical supervision;</td>
<td></td>
</tr>
<tr>
<td>(5) an easily visible statement that the food may not be nutritionally appropriate for pregnant or breastfeeding women and children under the age of 5 years;</td>
<td></td>
</tr>
<tr>
<td>(6) advice that the food is to be used as part of a balanced and varied diet, including regular consumption of fruit and vegetables to help maintain carotenoid levels;</td>
<td></td>
</tr>
<tr>
<td>(7) in the same field of vision as the statement required under point (3) above, a statement that the consumption of more than 3 g/day of added plant sterols/plant stanols should be avoided;</td>
<td></td>
</tr>
<tr>
<td>(8) a definition of a portion of the food or food ingredient concerned (preferably in g or ml) with the amount of the plant sterol/plant stanol that each portion contains.</td>
<td></td>
</tr>
</tbody>
</table>

### 6. Frozen meat, frozen meat preparations and frozen unprocessed fishery products

| 6.1. Frozen meat, frozen meat preparations and frozen unprocessed fishery products. | the date of freezing or the date of first freezing in cases where the product has been frozen more than once, in accordance with point (3) of Annex X. |

(1) The level shall apply to the products as proposed ready for consumption or as reconstituted according to the instructions of the manufacturers.
ANNEX IV

DEFINITION OF x-HEIGHT

x-HEIGHT

Legend

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Ascender line</td>
</tr>
<tr>
<td>2</td>
<td>Cap line</td>
</tr>
<tr>
<td>3</td>
<td>Mean line</td>
</tr>
<tr>
<td>4</td>
<td>Baseline</td>
</tr>
<tr>
<td>5</td>
<td>Descender line</td>
</tr>
<tr>
<td>6</td>
<td>x-height</td>
</tr>
<tr>
<td>7</td>
<td>Font size</td>
</tr>
</tbody>
</table>

Appendix
ANNEX V

FOODS WHICH ARE EXEMPTED FROM THE REQUIREMENT OF THE MANDATORY NUTRITION DECLARATION

1. Unprocessed products that comprise a single ingredient or category of ingredients;

2. Processed products which the only processing they have been subjected to is maturing and that comprise a single ingredient or category of ingredients;

3. Waters intended for human consumption, including those where the only added ingredients are carbon dioxide and/or flavourings;

4. A herb, a spice or mixtures thereof;

5. Salt and salt substitutes;

6. Table top sweeteners;


8. Herbal and fruit infusions, tea, decaffeinated tea, instant or soluble tea or tea extract, decaffeinated instant or soluble tea or tea extract, which do not contain other added ingredients than flavourings which do not modify the nutritional value of the tea;

9. Fermented vinegars and substitutes for vinegar, including those where the only added ingredients are flavourings;

10. Flavourings;

11. Food additives;

12. Processing aids;

13. Food enzymes;

14. Gelatine;

15. Jam setting compounds;

16. Yeast;

17. Chewing-gums;

18. Food in packaging or containers the largest surface of which has an area of less than 25 cm²;

19. Food, including handcrafted food, directly supplied by the manufacturer of small quantities of products to the final consumer or to local retail establishments directly supplying the final consumer.

ANNEX VI

NAME OF THE FOOD AND SPECIFIC ACCOMPANYING PARTICULARS

PART A — MANDATORY PARTICULARS ACCOMPANYING THE NAME OF THE FOOD

1. The name of the food shall include or be accompanied by particulars as to the physical condition of the food or the specific treatment which it has undergone (for example, powdered, refrozen, freeze-dried, quick-frozen, concentrated, smoked) in all cases where omission of such information could mislead the purchaser.

2. In the case of foods that have been frozen before sale and which are sold defrosted, the name of the food shall be accompanied by the designation ‘defrosted’.

This requirement shall not apply to the following:

(a) ingredients present in the final product;
(b) foods for which freezing is a technologically necessary step of the production process;
(c) foods for which the defrosting has no negative impact on the safety or quality of the food.

This point shall apply without prejudice to point 1.

3. Foods treated with ionising radiation shall bear one of the following indications:


4. In the case of foods in which a component or ingredient that consumers expect to be normally used or naturally present has been substituted with a different component or ingredient, the labelling shall bear — in addition to the list of ingredients — a clear indication of the component or the ingredient that has been used for the partial or whole substitution:

(a) in close proximity to the name of the product; and
(b) using a font size which has an x-height of at least 75 % of the x-height of the name of the product and which is not smaller than the minimum font size required in Article 13(2) of this Regulation.

5. In the case of meat products, meat preparations and fishery products containing added proteins as such, including hydrolysed proteins, of a different animal origin, the name of the food shall bear an indication of the presence of those proteins and of their origin.

6. In the case of meat products and meat preparations which have the appearance of a cut, joint, slice, portion or carcase of meat, the name of the food shall include an indication of the presence of added water if the added water makes up more than 5 % of the weight of the finished product. The same rules shall apply in the case of fishery products and prepared fishery products which have the appearance of a cut, joint, slice, portion, filet or of a whole fishery product.

7. Meat products, meat preparations and fishery products which may give the impression that they are made of a whole piece of meat or fish, but actually consist of different pieces combined together by other ingredients, including food additives and food enzymes or by other means, shall bear the following indication:

in Bulgarian: ‘формовано месо’ and ‘формована риба’;

in Spanish: ‘combinado de piezas de carne’ and ‘combinado de piezas de pescado’;

in Czech: ‘ze spojovaných kousků masa’ and ‘ze spojovaných kousků rybího masa’;

in Danish: ‘Sammensat af stykker af kød’ and ‘Sammensat af stykker af fisk’;

in German: ‘aus Fleischstücken zusammengefügt’ and ‘aus Fischstücken zusammengefügt’;

in Estonian: ‘liidetud liha’ and ‘liidetud kala’;

in Greek: ‘μορφοποιημένο κρέας’ and ‘μορφοποιημένο ψάρι’;

in English: ‘formed meat’ and ‘formed fish’;

in French: ‘viande reconstituée’ and ‘poisson reconstitué’;

in Irish: ‘píosaí feola ceangailte’ and ‘píosaí éisc ceangailte’;

in Italian: ‘carne ricomposta’ and ‘pesce ricomposto’;

in Latvian: ‘formēta gaļa’ and ‘formēta zīvs’;

in Lithuanian: ‘sudarytas (-a) iš mėsos gabalų’ and ‘sudarytas (-a) iš žuvies gabalų’;

in Hungarian: ‘darabokból újraformázott hús’ and ‘darabokból újraformázott hal’;

in Maltese: ‘laħam rikostitwit’ and ‘ħut rikostitwit’;

in Dutch: ‘samengesteld uit stukjes vlees’ and ‘samengesteld uit stukjes vis’;

in Polish: ‘z połączonych kawałków mięsa’ and ‘z połączonych kawałków ryby’;

in Portuguese: ‘carne reconstituída’ and ‘peixe reconstituído’;

in Slovak: ‘spájané alebo formované mäso’ and ‘spájané alebo formované ryby’;

in Slovenian: ‘sestavljeno, iz koščkov oblikovano meso’ and ‘sestavljene, iz koščkov oblikovane ribe’;

in Finnish: ‘paloista yhdistetty liha’ and ‘paloista yhdistetty kala’;

in Swedish: ‘sammanfogade bitar av kött’ and ‘sammanfogade bitar av fisk’.

PART B — SPECIFIC REQUIREMENTS CONCERNING THE DESIGNATION OF ‘MINCED MEAT’

1. Composition criteria checked on the basis of a daily average:

<table>
<thead>
<tr>
<th></th>
<th>Fat content</th>
<th>Collagen/meat protein ratio (¹)</th>
</tr>
</thead>
<tbody>
<tr>
<td>— lean minced meat,</td>
<td>≤ 7 %</td>
<td>≤ 12 %</td>
</tr>
<tr>
<td>— minced pure beef,</td>
<td>≤ 20 %</td>
<td>≤ 15 %</td>
</tr>
<tr>
<td>— minced meat containing pigmeat,</td>
<td>≤ 30 %</td>
<td>≤ 18 %</td>
</tr>
<tr>
<td>— minced meat of other species,</td>
<td>≤ 25 %</td>
<td>≤ 15 %</td>
</tr>
</tbody>
</table>

(¹) The collagen/meat protein ratio is expressed as the percentage of collagen in meat protein. The collagen content means the hydroxyproline content multiplied by a factor of 8.

2. In addition to the requirements laid down in Chapter IV of Section V of Annex III to Regulation (EC) No 853/2004, the following expressions shall appear on the labelling:

— ‘percentage of fat content under …’;

— ‘collagen/meat protein ratio under …’,
3. The Member States may allow the placing on their national market of minced meat which does not comply with the criteria laid down in point 1 of this Part under a national mark that cannot be confused with the marks provided for in Article 5(1) of Regulation (EC) No 853/2004.

PART C — SPECIFIC REQUIREMENTS CONCERNING THE DESIGNATION OF SAUSAGE CASINGS

If a sausage casing is not edible, this must be indicated.
## ANNEX VII

### INDICATION AND DESIGNATION OF INGREDIENTS

**PART A — SPECIFIC PROVISIONS CONCERNING THE INDICATION OF INGREDIENTS BY DESCENDING ORDER OF WEIGHT**

<table>
<thead>
<tr>
<th>Category of ingredient</th>
<th>Provision concerning indication by weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Added water and volatile products</td>
<td>Shall be listed in order of their weight in the finished product. The amount of water added as an ingredient in a food shall be calculated by deducting from the total amount of the finished product the total amount of the other ingredients used. This amount shall not be required to be taken into consideration if it does not exceed 5 % by weight of the finished product. This derogation does not apply to meat, meat preparations, unprocessed fishery products and unprocessed bivalve molluscs</td>
</tr>
<tr>
<td>2. Ingredients used in concentrated or dehydrated form and reconstituted at the time of manufacture</td>
<td>May be listed in order of weight as recorded before their concentration or dehydration</td>
</tr>
<tr>
<td>3. Ingredients used in concentrated or dehydrated foods, which are intended to be reconstituted by the addition of water</td>
<td>May be listed in order of proportion in the reconstituted product provided that the list of ingredients is accompanied by an expression, such as ‘ingredients of the reconstituted product’, or ‘ingredients of the ready-to-use product’</td>
</tr>
<tr>
<td>4. Fruit, vegetables or mushrooms, none of which significantly predominates in terms of weight and which are used in proportions that are likely to vary, used in a mixture as ingredients of a food</td>
<td>May be grouped together in the list of ingredients under the designation ‘fruit’, ‘vegetables’ or ‘mushrooms’ followed by the phrase ‘in varying proportions’, immediately followed by a list of the fruit, vegetables or mushrooms present. In such cases, the mixture shall be included in the list of ingredients in accordance with Article 18(1), on the basis of the total weight of the fruit, vegetables or mushrooms present</td>
</tr>
<tr>
<td>5. Mixtures of spices or herbs, where none significantly predominates in proportion by weight</td>
<td>May be listed in different order provided that that list of ingredients is accompanied by an expression such as ‘in variable proportion’</td>
</tr>
<tr>
<td>6. Ingredients constituting less than 2 % of the finished product</td>
<td>May be listed in a different order after the other ingredients</td>
</tr>
<tr>
<td>7. Ingredients, which are similar or mutually substitutable, likely to be used in the manufacture or preparation of a food without altering its composition, its nature or its perceived value, and in so far as they constitute less than 2 % of the finished product</td>
<td>May be referred to in the list of ingredients by means of the statement ‘contains … and/or …’, where at least one of no more than two ingredients is present in the finished product. This provision shall not apply to food additives or to ingredients listed in Part C of this Annex, and to substances or products listed in Annex II causing allergies or intolerances</td>
</tr>
<tr>
<td>8. Refined oils of vegetable origin</td>
<td>May be grouped together in the list of ingredients under the designation ‘vegetable oils’ followed immediately by a list of indications of specific vegetable origin, and may be followed by the phrase ‘in varying proportions’. If grouped together, vegetable oils shall be included in the list of ingredients in accordance with Article 18(1), on the basis of the total weight of the vegetable oils present. The expression ‘fully hydrogenated’ or ‘partly hydrogenated’, as appropriate, must accompany the indication of a hydrogenated oil</td>
</tr>
</tbody>
</table>
### PART B — DESIGNATION OF CERTAIN INGREDIENTS BY THE NAME OF A CATEGORY RATHER THAN A SPECIFIC NAME

Without prejudice to Article 21, ingredients which belong to one of the categories of foods listed below and are constituents of another food may be designated by the name of that category rather than the specific name.

<table>
<thead>
<tr>
<th>Definition of category of food</th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Refined oils of animal origin</td>
<td>'Oil', together with either the adjective 'animal', or the indication of specific animal origin. The expression 'fully hydrogenated' or 'partly hydrogenated', as appropriate, must accompany the indication of a hydrogenated oil</td>
</tr>
<tr>
<td>2. Refined fats of animal origin</td>
<td>'Fat', together with either the adjective 'animal' or the indication of specific animal origin. The expression 'fully hydrogenated' or 'partly hydrogenated', as appropriate, must accompany the indication of a hydrogenated fat</td>
</tr>
<tr>
<td>3. Mixtures of flour obtained from two or more cereal species</td>
<td>'Flour', followed by a list of the cereals from which it has been obtained, in descending order by weight</td>
</tr>
<tr>
<td>4. Starches, and starches modified by physical means or by enzymes</td>
<td>'Starch'</td>
</tr>
<tr>
<td>5. All species of fish where the fish constitutes an ingredient of another food and provided that the name and presentation of such food does not refer to a specific species of fish</td>
<td>'Fish'</td>
</tr>
<tr>
<td>6. All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another food and provided that the name and presentation of such food does not refer to a specific type of cheese</td>
<td>'Cheese'</td>
</tr>
<tr>
<td>7. All spices not exceeding 2 % by weight of the food</td>
<td>'Spice(s)' or 'mixed spices'</td>
</tr>
<tr>
<td>8. All herbs or parts of herbs not exceeding 2 % by weight of the food</td>
<td>'Herb(s)' or 'mixed herbs'</td>
</tr>
<tr>
<td>9. All types of gum preparations used in the manufacture of gum base for chewing gum</td>
<td>'Gum base'</td>
</tr>
<tr>
<td>10. All types of crumbed baked cereal products</td>
<td>'Crumbs' or 'rusks' as appropriate</td>
</tr>
</tbody>
</table>
Definition of category of food

<table>
<thead>
<tr>
<th></th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.</td>
<td>All types of sucrose</td>
</tr>
<tr>
<td>12.</td>
<td>Anhydrous dextrose or dextrose monohydrate</td>
</tr>
<tr>
<td>13.</td>
<td>Glucose syrup and anhydrous glucose syrup</td>
</tr>
<tr>
<td>14.</td>
<td>All types of milk protein (caseins, caseinates and whey proteins) and mixtures thereof</td>
</tr>
<tr>
<td>15.</td>
<td>Press, expeller or refined cocoa butter</td>
</tr>
<tr>
<td>16.</td>
<td>All types of wine as covered by Annex Xib to Regulation (EC) No 1234/2007 (1)</td>
</tr>
<tr>
<td>17.</td>
<td>Skeletal muscles of mammalian and bird species recognised as fit for human consumption with naturally included or adherent tissue, where the total fat and connective tissue content does not exceed the values indicated below and where the meat constitutes an ingredient of another food. Maximum fat and connective tissue contents for ingredients designated by the term ‘… meat’</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Fat content</th>
<th>Collagen/meat protein ratio (3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammals (other than rabbits and porcines) and mixtures of species with mammals predominating.</td>
<td>25 %</td>
<td>25 %</td>
</tr>
<tr>
<td>Porcines</td>
<td>30 %</td>
<td>25 %</td>
</tr>
<tr>
<td>Birds and rabbits</td>
<td>15 %</td>
<td>10 %</td>
</tr>
</tbody>
</table>

(1) The collagen/meat protein ratio is expressed as the percentage of collagen in meat protein. The collagen content means the hydroxyproline content multiplied by a factor of 8.

If these maximum limits are exceeded, but all other criteria for the definition of ‘meat’ are satisfied, the ‘… meat’ content must be adjusted downwards accordingly and the list of ingredients must mention, in addition to the term ‘… meat’, the presence of fat and/or connective tissue.

The products covered by the definition of ‘mechanically separated meat’ are excluded from this definition.

<table>
<thead>
<tr>
<th></th>
<th>Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>18.</td>
<td>All types of products covered by the definition of ‘mechanically separated meat’</td>
</tr>
</tbody>
</table>


(2) The diaphragm and the masseters are part of the skeletal muscles, while the heart, tongue, the muscles of the head (other than the masseters), the muscles of the carpus, the tarsus and the tail are excluded.

(3) For labelling in English, this designation may be replaced by the generic name of the ingredient for the animal species concerned.
PART C — DESIGNATION OF CERTAIN INGREDIENTS BY THE NAME OF THEIR CATEGORY FOLLOWED BY THEIR
SPECIFIC NAME OR E NUMBER

Without prejudice to Article 21, food additives and food enzymes other than those specified in point (b) of Article 20 belonging to one of the categories listed in this Part must be designated by the name of that category, followed by their specific name or, if appropriate, E number. If an ingredient belongs to more than one of the categories, the category appropriate to the principal function in the case of the food in question shall be indicated.

<table>
<thead>
<tr>
<th>Acid</th>
<th>Foaming agent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acidity regulator</td>
<td>Gelling agent</td>
</tr>
<tr>
<td>Anti-caking agent</td>
<td>Glazing agent</td>
</tr>
<tr>
<td>Anti-foaming agent</td>
<td>Humectant</td>
</tr>
<tr>
<td>Antioxidant</td>
<td>Modified starch ((^1))</td>
</tr>
<tr>
<td>Bulking agent</td>
<td>Preservative</td>
</tr>
<tr>
<td>Colour</td>
<td>Propellant gas</td>
</tr>
<tr>
<td>Emulsifier</td>
<td>Raising agent</td>
</tr>
<tr>
<td>Emulsifying salts ((^1))</td>
<td>Sequestrant</td>
</tr>
<tr>
<td>Firming agent</td>
<td>Stabiliser</td>
</tr>
<tr>
<td>Flavour enhancer</td>
<td>Sweetener</td>
</tr>
<tr>
<td>Flour treatment agent</td>
<td>Thickener</td>
</tr>
</tbody>
</table>

(\(^1\)) Only for processed cheeses and products based on processed cheeses.
(\(^2\)) The specific name or E number shall not be required to be indicated.

PART D — DESIGNATION OF FLAVOURINGS IN THE LIST OF INGREDIENTS

1. Flavourings shall be designated either by the terms:

— ‘flavouring(s)’ or by a more specific name or description of the flavouring if the flavouring component contains flavourings as defined in points (b), (c), (d), (e), (f), (g) and (h) of Article 3(2) of Regulation (EC) No 1334/2008,

— ‘smoke flavouring(s)’, or ‘smoke flavouring(s) produced from food(s) or food category or source(s)’ (e.g. ‘smoke flavouring produced from beech’), if the flavouring component contains flavourings as defined in point (f) of Article 3(2) of Regulation (EC) No 1334/2008 and imparts a smoky flavour to the food.

2. The term ‘natural’ for the description of flavourings shall be used in accordance with Article 16 of Regulation (EC) No 1334/2008.

3. Quinine and/or caffeine used as a flavouring in the production or preparation of a food shall be mentioned by name in the list of ingredients immediately after the term ‘flavouring(s)’.

PART E — DESIGNATION OF COMPOUND INGREDIENTS

1. A compound ingredient may be included in the list of ingredients, under its own designation in so far as this is laid down by law or established by custom, in terms of its overall weight, and immediately followed by a list of its ingredients.

2. Without prejudice to Article 21, the list of ingredients for compound ingredients shall not be compulsory:

(a) where the composition of the compound ingredient is defined in current Union provisions, and in so far as the compound ingredient constitutes less than 2 % of the finished product; however, this provision shall not apply to food additives, subject to points (a) to (d) of Article 20;

(b) for compound ingredients consisting of mixtures of spices and/or herbs that constitute less than 2 % of the finished product, with the exception of food additives, subject to points (a) to (d) of Article 20; or

(c) where the compound ingredient is a food for which a list of ingredients is not required under Union provisions.
ANNEX VIII

QUANTITATIVE INDICATION OF INGREDIENTS

1. The quantitative indication shall not be required:

(a) in respect of an ingredient or category of ingredients:

(i) the drained net weight of which is indicated in accordance with point 5 of Annex IX;

(ii) the quantities of which must already appear on the labelling under Union provisions;

(iii) which is used in small quantities for the purposes of flavouring; or

(iv) which, while appearing in the name of the food, is not such as to govern the choice of the consumer in the country of marketing because the variation in quantity is not essential to characterise the food or does not distinguish it from similar foods;

(b) where specific Union provisions stipulate precisely the quantity of an ingredient or of a category of ingredients without providing for the indication thereof on the labelling; or

(c) in the cases referred to in points 4 and 5 of Part A of Annex VII.

2. Points (a) and (b) of Article 22(1) shall not apply in the case of:

(a) any ingredient or category of ingredients covered by the indication ‘with sweetener(s)’ or ‘with sugar(s) and sweetener(s)’ if that indication accompanies the name of the food, pursuant Annex III; or

(b) any added vitamin and mineral if that substance is subject to a nutrition declaration.

3. The indication of quantity of an ingredient or category of ingredients shall:

(a) be expressed as a percentage, which shall correspond to the quantity of the ingredient or ingredients at the time of its/their use; and

(b) appear either in or immediately next to the name of the food or in the list of ingredients in connection with the ingredient or category of ingredients in question.

4. By way of derogation from point 3:

(a) where foods have lost moisture following heat treatment or other treatment, the quantity shall be expressed as a percentage which shall correspond to the quantity of the ingredient(s) used, related to the finished product, unless that quantity or the total quantity of all the ingredients indicated on the labelling exceeds 100%, in which case the quantity shall be indicated on the basis of the weight of the ingredient(s) used to prepare 100 g of finished product;

(b) the quantity of volatile ingredients shall be indicated on the basis of their proportion by weight in the finished product;

(c) the quantity of ingredients used in concentrated or dehydrated form and reconstituted during manufacture may be indicated on the basis of their proportion by weight as recorded before their concentration or dehydration;

(d) in the case of concentrated or dehydrated foods which are intended to be reconstituted by the addition of water, the quantity of the ingredients may be indicated on the basis of their proportion by weight in the reconstituted product.
ANNEX IX

NET QUANTITY DECLARATION

1. The net quantity declaration shall not be mandatory in the case of foods:

(a) which are subject to considerable losses in their volume or mass and which are sold by number or weighed in the presence of the purchaser;

(b) the net quantity of which is less than 5 g or 5 ml; however, this provision shall not apply to spices and herbs;

(c) normally sold by number, provided that the number of items can clearly be seen and easily counted from the outside or, if not, is indicated on the labelling.

2. Where the indication of a certain type of quantity (such as the nominal quantity, minimum quantity, or average quantity) is required by Union provisions or, where there are none, by national provisions, this quantity shall be regarded as the net quantity for the purposes of this Regulation.

3. Where a prepacked item consists of two or more individual prepacked items containing the same quantity of the same product, the net quantity shall be indicated by mentioning the net quantity contained in each individual package and the total number of such packages. The indication of those particulars shall not, however, be mandatory where the total number of individual packages can be clearly seen and easily counted from the outside and where at least one indication of the net quantity contained in each individual package can be clearly seen from the outside.

4. Where a prepacked item consists of two or more individual packages which are not regarded as units of sale, the net quantity shall be given by indicating the total net quantity and the total number of individual packages.

5. Where a solid food is presented in a liquid medium, the drained net weight of the food shall also be indicated. Where the food has been glazed, the declared net weight of the food shall be exclusive of the glaze.

For the purposes of this point, ‘liquid medium’ shall mean the following products, possibly in mixtures and also where frozen or quick-frozen, provided that the liquid is merely an adjunct to the essential elements of that preparation and is thus not a decisive factor for the purchase: water, aqueous solutions of salts, brine, aqueous solutions of food acids, vinegar, aqueous solutions of sugars, aqueous solutions of other sweetening substances, fruit or vegetable juices in the case of fruit or vegetables.
ANNEX X

DATE OF MINIMUM DURABILITY, ‘USE BY’ DATE AND DATE OF FREEZING

1. The date of minimum durability shall be indicated as follows:

(a) the date shall be preceded by the words:

— ‘Best before …’ when the date includes an indication of the day,
— ‘Best before end …’ in other cases,

(b) the words referred to in point (a) shall be accompanied by:

— either the date itself, or,
— a reference to where the date is given on the labelling,

If need be, these particulars shall be followed by a description of the storage conditions which must be observed if
the product is to keep for the specified period;

(c) the date shall consist of the day, the month and possibly, the year, in that order and in uncoded form.

However, in the case of foods:

— which will not keep for more than 3 months, an indication of the day and the month shall be sufficient,
— which will keep for more than 3 months but not more than 18 months, an indication of the month and year
  shall be sufficient,
— which will keep for more than 18 months, an indication of the year shall be sufficient,

(d) subject to Union provisions imposing other types of date indication, an indication of the date of minimum
durability shall not be required for:

— fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated; this
derogation shall not apply to sprouting seeds and similar products such as legume sprouts,
— wines, liqueur wines, sparkling wines, aromatised wines, and similar products obtained from fruit other than
  grapes, and beverages falling within CN code 2206 00 obtained from grapes or grape musts,
— beverages containing 10 % or more by volume of alcohol,
— bakers’ or pastry cooks’ wares which, given the nature of their content, are normally consumed within 24
  hours of their manufacture,
— vinegar,
— cooking salt,
— solid sugar,
— confectionery products consisting almost solely of flavoured and/or coloured sugars,
— chewing gums and similar chewing products,
2. The 'use by' date shall be indicated as follows:

(a) it shall be preceded by the words 'use by ...';

(b) the words in point (a) shall be accompanied by:
   — either the date itself, or,
   — a reference to where the date is given on the labelling.

Those particulars shall be followed by a description of the storage conditions which must be observed;

(c) the date shall consist of the day, the month and, possibly, the year, in that order and in uncoded form;

(d) the 'use by' date shall be indicated on each individual prepacked portion.

3. The date of freezing or the date of first freezing as referred to in point 6 of Annex III shall be indicated as follows:

(a) it shall be preceded by the words 'Frozen on ...';

(b) the words referred to in point (a) shall be accompanied by:
   — the date itself, or,
   — a reference to where the date is given on the labelling,

(c) the date shall consist of the day, the month and the year, in that order and in uncoded form.
ANNEX XI

TYPES OF MEAT FOR WHICH THE INDICATION OF THE COUNTRY OF ORIGIN OR PLACE OF PROVENANCE IS MANDATORY

<table>
<thead>
<tr>
<th>CN codes (Combined Nomenclature 2010)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0203</td>
<td>Meat of swine, fresh, chilled or frozen</td>
</tr>
<tr>
<td>0204</td>
<td>Meat of sheep or goats, fresh, chilled or frozen</td>
</tr>
<tr>
<td>Ex 0207</td>
<td>Meat of the poultry of heading 0105, fresh, chilled or frozen</td>
</tr>
</tbody>
</table>
ANNEX XII

ALCOHOLIC STRENGTH

The actual alcoholic strength by volume of beverages containing more than 1.2 % by volume of alcohol shall be indicated by a figure to not more than one decimal place. It shall be followed by the symbol ‘% vol.’ and may be preceded by the word ‘alcohol’ or the abbreviation ‘alc’.

The alcoholic strength shall be determined at 20 °C.

Positive and negative allowed tolerances in respect of the indication of the alcoholic strength by volume and expressed in absolute values shall be as listed in the following table. They shall apply without prejudice to the tolerances deriving from the method of analysis used for determining the alcoholic strength.

<table>
<thead>
<tr>
<th>Description of beverage</th>
<th>Positive or negative tolerance</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Beers of CN code 2203 00 having an alcoholic strength not exceeding 5,5 % vol.;</td>
<td>0.5 % vol.</td>
</tr>
<tr>
<td>still beverages falling within CN code 2206 00 obtained from grapes</td>
<td></td>
</tr>
<tr>
<td>2. Beers having an alcoholic strength exceeding 5,5 % vol.;</td>
<td>1 % vol.</td>
</tr>
<tr>
<td>sparkling beverages falling within CN code 2206 00 obtained from grapes, ciders,</td>
<td></td>
</tr>
<tr>
<td>perries, fruit wines and the like, obtained from fruit other than grapes,</td>
<td></td>
</tr>
<tr>
<td>whether or not semi-sparkling or sparkling; mead</td>
<td></td>
</tr>
<tr>
<td>3. Beverages containing macerated fruit or parts of plants</td>
<td>1.5 % vol.</td>
</tr>
<tr>
<td>4. Any other beverages containing more than 1.2 % by volume of alcohol</td>
<td>0.3 % vol.</td>
</tr>
</tbody>
</table>
ANNEX XIII

REFERENCE INTAKES

PART A — DAILY REFERENCE INTAKES FOR VITAMINS AND MINERALS (ADULTS)

1. Vitamins and minerals which may be declared and their nutrient reference values (NRVs)

<table>
<thead>
<tr>
<th>Vitamin/mineral</th>
<th>Reference intake</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A (μg)</td>
<td>800</td>
</tr>
<tr>
<td>Vitamin D (μg)</td>
<td>5</td>
</tr>
<tr>
<td>Vitamin E (mg)</td>
<td>12</td>
</tr>
<tr>
<td>Vitamin K (μg)</td>
<td>75</td>
</tr>
<tr>
<td>Vitamin C (mg)</td>
<td>80</td>
</tr>
<tr>
<td>Thiamin (mg)</td>
<td>1.1</td>
</tr>
<tr>
<td>Riboflavin (mg)</td>
<td>1.4</td>
</tr>
<tr>
<td>Niacin (mg)</td>
<td>16</td>
</tr>
<tr>
<td>Vitamin B6 (mg)</td>
<td>1.4</td>
</tr>
<tr>
<td>Folic acid (μg)</td>
<td>200</td>
</tr>
<tr>
<td>Vitamin B12 (μg)</td>
<td>2.5</td>
</tr>
<tr>
<td>Biotin (μg)</td>
<td>50</td>
</tr>
<tr>
<td>Pantothenic acid (mg)</td>
<td>6</td>
</tr>
<tr>
<td>Potassium (mg)</td>
<td>2 000</td>
</tr>
<tr>
<td>Chloride (mg)</td>
<td>800</td>
</tr>
<tr>
<td>Calcium (mg)</td>
<td>800</td>
</tr>
<tr>
<td>Phosphorus (mg)</td>
<td>700</td>
</tr>
<tr>
<td>Magnesium (mg)</td>
<td>375</td>
</tr>
<tr>
<td>Iron (mg)</td>
<td>14</td>
</tr>
<tr>
<td>Zinc (mg)</td>
<td>10</td>
</tr>
<tr>
<td>Copper (mg)</td>
<td>1</td>
</tr>
<tr>
<td>Manganese (mg)</td>
<td>2</td>
</tr>
<tr>
<td>Fluoride (mg)</td>
<td>3.5</td>
</tr>
<tr>
<td>Selenium (μg)</td>
<td>55</td>
</tr>
<tr>
<td>Chromium (μg)</td>
<td>40</td>
</tr>
<tr>
<td>Molybdenum (μg)</td>
<td>50</td>
</tr>
<tr>
<td>Iodine (μg)</td>
<td>150</td>
</tr>
</tbody>
</table>

2. Significant amount of vitamins and minerals

As a rule, the following values should be taken into consideration in deciding what constitutes a significant amount:

— 15 % of the nutrient reference values specified in point 1 supplied by 100 g or 100 ml in the case of products other than beverages,

— 7.5 % of the nutrient reference values specified in point 1 supplied by 100 ml in the case of beverages, or,

— 15 % of the nutrient reference values specified in point 1 per portion if the package contains only a single portion,

PART B — REFERENCE INTAKES FOR ENERGY AND SELECTED NUTRIENTS OTHER THAN VITAMINS AND MINERALS (ADULTS)

<table>
<thead>
<tr>
<th>Energy or nutrient</th>
<th>Reference intake</th>
</tr>
</thead>
<tbody>
<tr>
<td>Energy</td>
<td>8 400 kJ/2 000 kcal</td>
</tr>
<tr>
<td>Total fat</td>
<td>70 g</td>
</tr>
<tr>
<td>Saturates</td>
<td>20 g</td>
</tr>
<tr>
<td>Carbohydrate</td>
<td>260 g</td>
</tr>
<tr>
<td>Sugars</td>
<td>90 g</td>
</tr>
<tr>
<td>Protein</td>
<td>50 g</td>
</tr>
<tr>
<td>Salt</td>
<td>6 g</td>
</tr>
</tbody>
</table>
## ANNEX XIV

### CONVERSION FACTORS

**CONVERSION FACTORS FOR THE CALCULATION OF ENERGY**

The energy value to be declared shall be calculated using the following conversion factors:

<table>
<thead>
<tr>
<th>Component</th>
<th>Conversion Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>carbohydrate (except polyols)</td>
<td>17 kJ/g — 4 kcal/g</td>
</tr>
<tr>
<td>polyols</td>
<td>10 kJ/g — 2.4 kcal/g</td>
</tr>
<tr>
<td>protein</td>
<td>17 kJ/g — 4 kcal/g</td>
</tr>
<tr>
<td>fat</td>
<td>37 kJ/g — 9 kcal/g</td>
</tr>
<tr>
<td>salatrim</td>
<td>25 kJ/g — 6 kcal/g</td>
</tr>
<tr>
<td>alcohol (ethanol)</td>
<td>29 kJ/g — 7 kcal/g</td>
</tr>
<tr>
<td>organic acid</td>
<td>13 kJ/g — 3 kcal/g</td>
</tr>
<tr>
<td>fibre</td>
<td>8 kJ/g — 2 kcal/g</td>
</tr>
<tr>
<td>erythritol</td>
<td>0 kJ/g — 0 kcal/g</td>
</tr>
</tbody>
</table>
**ANNEX XV**

**EXPRESSION AND PRESENTATION OF NUTRITION DECLARATION**

The units of measurement to be used in the nutrition declaration for energy (kilojoules (kJ) and kilocalories (kcal)) and mass (grams (g), milligrams (mg) or micrograms (μg)) and the order of presentation of the information, as appropriate, shall be the following:

<table>
<thead>
<tr>
<th></th>
<th>energy</th>
<th>kJ/kcal</th>
</tr>
</thead>
<tbody>
<tr>
<td>fat</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>of which</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— saturates</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>— mono-unsaturates</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>— polyunsaturates</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>carbohydrate</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>of which</td>
<td></td>
<td></td>
</tr>
<tr>
<td>— sugars</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>— polyols</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>— starch</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>fibre</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>protein</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>salt</td>
<td>g</td>
<td></td>
</tr>
<tr>
<td>vitamins and minerals</td>
<td>the units specified in point 1 of Part A of Annex XIII</td>
<td></td>
</tr>
</tbody>
</table>
DIRECTIVES

DIRECTIVE 2011/83/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 25 October 2011
(Text with EEA relevance)

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),

Having regard to the opinion of the Committee of the
Regions (2),

Acting in accordance with the ordinary legislative procedure (3),

Whereas:

protect the consumer in respect of contracts negotiated
away from business premises (4) and Directive 97/7/EC of
the European Parliament and of the Council of 20 May
1997 on the protection of consumers in respect of
distance contracts (5) lay down a number of contractual
rights for consumers.

(2) Those Directives have been reviewed in the light of
experience with a view to simplifying and updating the
applicable rules, removing inconsistencies and closing
unwanted gaps in the rules. That review has shown
that it is appropriate to replace those two Directives by
a single Directive. This Directive should therefore lay
down standard rules for the common aspects of
distance and off-premises contracts, moving away from
the minimum harmonisation approach in the former
Directives whilst allowing Member States to maintain
or adopt national rules in relation to certain aspects.

(3) Article 169(1) and point (a) of Article 169(2) of the
Treaty on the Functioning of the European Union
(TFEU) provide that the Union is to contribute to the
attainment of a high level of consumer protection
through the measures adopted pursuant to Article 114
thereof.

(4) In accordance with Article 26(2) TFEU, the internal
market is to comprise an area without internal frontiers
in which the free movement of goods and services and
freedom of establishment are ensured. The harmonisation
of certain aspects of consumer distance and off-premises
contracts is necessary for the promotion of a real
consumer internal market striking the right balance
between a high level of consumer protection and the
competitiveness of enterprises, while ensuring respect
for the principle of subsidiarity.

(5) The cross-border potential of distance selling, which
should be one of the main tangible results of the
internal market, is not fully exploited. Compared with
the significant growth of domestic distance sales over
the last few years, the growth in cross-border distance
sales has been limited. This discrepancy is particularly
significant for Internet sales for which the potential for
further growth is high. The cross-border potential of
contracts negotiated away from business premises
(direct selling) is constrained by a number of factors
including the different national consumer protection
rules imposed upon the industry. Compared with the
growth of domestic direct selling over the last few
years, in particular in the services sector, for instance
utilities, the number of consumers using this channel
for cross-border purchases has remained flat. Responding
to increased business opportunities in many Member
States, small and medium-sized enterprises (including
individual traders) or agents of direct selling companies

(3) Position of the European Parliament of 23 June 2011 (not yet
published in the Official Journal) and decision of the Council of
10 October 2011.
should be more inclined to seek business opportunities in other Member States, in particular in border regions. Therefore the full harmonisation of consumer information and the right of withdrawal in distance and off-premises contracts will contribute to a high level of consumer protection and a better functioning of the business-to-consumer internal market.

(6) Certain disparities create significant internal market barriers affecting traders and consumers. Those disparities increase compliance costs to traders wishing to engage in the cross-border sale of goods or provision of services. Disproportionate fragmentation also undermines consumer confidence in the internal market.

(7) Full harmonisation of some key regulatory aspects should considerably increase legal certainty for both consumers and traders. Both consumers and traders should be able to rely on a single regulatory framework based on clearly defined legal concepts regulating certain aspects of business-to-consumer contracts across the Union. The effect of such harmonisation should be to eliminate the barriers stemming from the fragmentation of the rules and to complete the internal market in this area. Those barriers can only be eliminated by establishing uniform rules at Union level. Furthermore consumers should enjoy a high common level of protection across the Union.

(8) The regulatory aspects to be harmonised should only concern contracts concluded between traders and consumers. Therefore, this Directive should not affect national law in the area of contracts relating to employment, contracts relating to succession rights, contracts relating to family law and contracts relating to the incorporation and organisation of companies or partnership agreements.

(9) This Directive establishes rules on information to be provided for distance contracts, off-premises contracts and contracts other than distance and off-premises contracts. This Directive also regulates the right of withdrawal for distance and off-premises contracts and harmonises certain provisions dealing with the performance and some other aspects of business-to-consumer contracts.

(10) This Directive should be without prejudice to 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) (1).

(11) This Directive should be without prejudice to Union provisions relating to specific sectors, such as medicinal products for human use, medical devices, privacy and electronic communications, patients’ rights in cross-border healthcare, food labelling and the internal market for electricity and natural gas.

(12) The information requirements provided for in this Directive should complete the information requirements of Directive 2006/123/EC of the European Parliament and of the Council of 12 December 2006 on services in the internal market (2) and Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce) (3). Member States should retain the possibility to impose additional information requirements applicable to service providers established in their territory.

(13) Member States should remain competent, in accordance with Union law, to apply the provisions of this Directive to areas not falling within its scope. Member States may therefore maintain or introduce national legislation corresponding to the provisions of this Directive, or certain of its provisions, in relation to contracts that fall outside the scope of this Directive. For instance, Member States may decide to extend the application of the rules of this Directive to legal persons or to natural persons who are not consumers within the meaning of this Directive, such as non-governmental organisations, start-ups or small and medium-sized enterprises. Similarly, Member States may apply the provisions of this Directive to contracts that are not distance contracts within the meaning of this Directive, for example because they are not concluded under an organised distance sales or service-provision scheme. Moreover, Member States may also maintain or introduce national provisions on issues not specifically addressed in this Directive, such as additional rules concerning sales contracts, including in relation to the delivery of goods, or requirements for the provision of information during the existence of a contract.

(14) This Directive should not affect national law in the area of contract law for contract law aspects that are not regulated by this Directive. Therefore, this Directive should be without prejudice to national law regulating for instance the conclusion or the validity of a contract (for instance in the case of lack of consent). Similarly, this Directive should not affect national law in relation to the general contractual legal remedies, the rules on public economic order, for instance rules on excessive or exorbitant prices, and the rules on unethical legal transactions.

(15) This Directive should not harmonise language requirements applicable to consumer contracts. Therefore, Member States may maintain or introduce in their national law language requirements regarding contractual information and contractual terms.

(16) This Directive should not affect national laws on legal representation such as the rules relating to the person who is acting in the name of the trader or on his behalf (such as an agent or a trustee). Member States should remain competent in this area. This Directive should apply to all traders, whether public or private.

(17) The definition of consumer should cover natural persons who are acting outside their trade, business, craft or profession. However, in the case of dual purpose contracts, where the contract is concluded for purposes partly within and partly outside the person's trade and the trade purpose is so limited as not to be predominant in the overall context of the contract, that person should also be considered as a consumer.

(18) This Directive does not affect the freedom of Member States to define, in conformity with Union law, what they consider to be services of general economic interest, how those services should be organised and financed, in compliance with State aid rules, and which specific obligations they should be subject to.

(19) Digital content means data which are produced and supplied in digital form, such as computer programs, applications, games, music, videos or texts, irrespective of whether they are accessed through downloading or streaming, from a tangible medium or through any other means. Contracts for the supply of digital content should fall within the scope of this Directive. If digital content is supplied on a tangible medium, such as a CD or a DVD, it should be considered as goods within the meaning of this Directive. Similarly to contracts for the supply of water, gas or electricity, where they are not put up for sale in a limited volume or set quantity, or of district heating, contracts for digital content which is not supplied on a tangible medium should be classified, for the purpose of this Directive, neither as sales contracts nor as service contracts. For such contracts, the consumer should have a right of withdrawal unless he has consented to the beginning of the performance of the contract during the withdrawal period and has acknowledged that he will consequently lose the right to withdraw from the contract. In addition to the general information requirements, the trader should inform the consumer about the functionality and the relevant interoperability of digital content. The notion of functionality should refer to the ways in which digital content can be used, for instance for the tracking of consumer behaviour; it should also refer to the absence or presence of any technical restrictions such as protection via Digital Rights Management or region coding. The notion of relevant interoperability is meant to describe the information regarding the standard hardware and software environment with which the digital content is compatible, for instance the operating system, the necessary version and certain hardware features. The Commission should examine the need for further harmonisation of provisions in respect of digital content and submit, if necessary, a legislative proposal for addressing this matter.

(20) The definition of distance contract should cover all cases where a contract is concluded between the trader and the consumer under an organised distance sales or service-provision scheme, with the exclusive use of one or more means of distance communication (such as mail order, Internet, telephone or fax) up to and including the time at which the contract is concluded. That definition should also cover situations where the consumer visits the business premises merely for the purpose of gathering information about the goods or services and subsequently negotiates and concludes the contract at a distance. By contrast, a contract which is negotiated at the business premises of the trader and finally concluded by means of distance communication should not be considered a distance contract. Neither should a contract initiated by means of distance communication, but finally concluded at the business premises of the trader be considered a distance contract. Similarly, the concept of distance contract should not include reservations made by a consumer through a means of distance communications to request the provision of a service from a professional, such as in the case of a consumer phoning to request an appointment with a hairdresser. The notion of an organised distance sales or service-provision scheme should include those schemes offered by a third party other than the trader but used by the trader, such as an online platform. It should not, however, cover cases where websites merely offer information on the trader, his goods and/or services and his contact details.

(21) An off-premises contract should be defined as a contract concluded with the simultaneous physical presence of the trader and the consumer, in a place which is not the business premises of the trader, for example at the consumer's home or workplace. In an off-premises context, the consumer may be under potential psychological pressure or may be confronted with an element of surprise, irrespective of whether or not the consumer has solicited the trader's visit. The definition of an off-premises contract should also include situations where the consumer is personally and individually addressed in an off-premises context but the contract is concluded immediately afterwards on the business premises of the trader or through a means of distance communication. The definition of an off-premises contract should not cover situations in which the
Business premises should include premises in whatever form (such as shops, stalls or lorries) which serve as a permanent or usual place of business for the trader. Market stalls and fair stands should be treated as business premises if they fulfil this condition. Retail premises where the trader carries out his activity on a seasonal basis, for instance during the tourist season at a ski or beach resort, should be considered as business premises as the trader carries out his activity in those premises on a usual basis. Spaces accessible to the public, such as streets, shopping malls, beaches, sports facilities and public transport, which the trader uses on an exceptional basis for his business activities as well as private homes or workplaces should not be regarded as business premises. The business premises of a person acting in the name or on behalf of the trader as defined in this Directive should be considered as business premises within the meaning of this Directive.

Durable media should enable the consumer to store the information for as long as it is necessary for him to protect his interests stemming from his relationship with the trader. Such media should include in particular paper, USB sticks, CD-ROMs, DVDs, memory cards or the hard disks of computers as well as e-mails.

A public auction implies that traders and consumers attend or are given the possibility to attend the auction in person. The goods or services are offered by the trader to the consumer through a bidding procedure authorised by law in some Member States, to offer goods or services at public sale. The successful bidder is bound to purchase the goods or services. The use of online platforms for auction purposes which are at the disposal of consumers and traders should not be considered as a public auction within the meaning of this Directive.

Contracts related to district heating should be covered by this Directive, similarly to the contracts for the supply of water, gas or electricity. District heating refers to the supply of heat, inter alia, in the form of steam or hot water, from a central source of production through a transmission and distribution system to multiple buildings, for the purpose of heating.

Contracts related to the transfer of immovable property or of rights in immovable property or to the creation or acquisition of such immovable property or rights, contracts for the construction of new buildings or the substantial conversion of existing buildings as well as contracts for the rental of accommodation for residential purposes are already subject to a number of specific requirements in national legislation. Those contracts include for instance sales of immovable property still to be developed and hire-purchase. The provisions of this Directive are not appropriate to those contracts, which should be therefore excluded from its scope. A substantial conversion is a conversion comparable to the construction of a new building, for example where only the façade of an old building is retained. Service contracts in particular those related to the construction of annexes to buildings (for example a garage or a veranda) and those related to repair and renovation of buildings other than substantial conversion, should be included in the scope of this Directive, as well as contracts related to the services of a real estate agent and those related to the rental of accommodation for non-residential purposes.

Transport services cover passenger transport and transport of goods. Passenger transport should be excluded from the scope of this Directive as it is already subject to other Union legislation or, in the case of public transport and taxis, to regulation at national level. However, the provisions of this Directive protecting consumers against excessive fees for the use of means of payment or against hidden costs should apply also to passenger transport contracts. In relation to transport of goods and car rental which are services, consumers should benefit from the protection afforded by this Directive, with the exception of the right of withdrawal.

In order to avoid administrative burden being placed on traders, Member States may decide not to apply this Directive where goods or services of a minor value are sold off-premises. The monetary threshold should be established at a sufficiently low level as to exclude only purchases of small significance. Member States should be allowed to define this value in their national legislation provided that it does not exceed EUR 50. Where two or more contracts with related subjects are concluded at the same time by the consumer, the total cost thereof should be taken into account for the purpose of applying this threshold.
(29) Social services have fundamentally distinct features that are reflected in sector-specific legislation, partially at Union level and partially at national level. Social services include, on the one hand, services for particularly disadvantaged or low income persons as well as services for persons and families in need of assistance in carrying out routine, everyday tasks and, on the other hand, services for all people who have a special need for assistance, support, protection or encouragement in a specific life phase. Social services cover, inter alia, services for children and youth, assistance services for families, single parents and older persons, and services for migrants. Social services cover both short-term and long-term care services, for instance services provided by home care services or provided in assisted living facilities and residential homes or housing (‘nursing homes’). Social services include not only those provided by the State at a national, regional or local level by providers mandated by the State or by charities recognised by the State but also those provided by private operators. The provisions of this Directive are not appropriate to social services which should be therefore excluded from its scope.

(30) Healthcare requires special regulations because of its technical complexity, its importance as a service of general interest as well as its extensive public funding. Healthcare is defined in Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients’ rights in cross-border healthcare (1) as ‘health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices’. Health professional is defined in that Directive as a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (2) or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in point (a) of Article 3(1) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment. The provisions of this Directive are not appropriate to healthcare which should be therefore excluded from its scope.

(31) Gambling should be excluded from the scope of this Directive. Gambling activities are those which involve wagering at stake with pecuniary value in games of chance, including lotteries, gambling in casinos and betting transactions. Member States should be able to adopt other, including more stringent, consumer protection measures in relation to such activities.

(32) The existing Union legislation, inter alia, relating to consumer financial services, package travel and timeshare contains numerous rules on consumer protection. For this reason, this Directive should not apply to contracts in those areas. With regard to financial services, Member States should be encouraged to draw inspiration from existing Union legislation in that area when legislating in areas not regulated at Union level, in such a way that a level playing field for all consumers and all contracts relating to financial services is ensured.

(33) The trader should be obliged to inform the consumer in advance of any arrangement resulting in the consumer paying a deposit to the trader, including an arrangement whereby an amount is blocked on the consumer’s credit or debit card.

(34) The trader should give the consumer clear and comprehensible information before the consumer is bound by a distance or off-premises contract, a contract other than a distance or an off-premises contract, or any corresponding offer. In providing that information, the trader should take into account the specific needs of consumers who are particularly vulnerable because of their mental, physical or psychological infirmity, age or credulity in a way which the trader could reasonably be expected to foresee. However, taking into account such specific needs should not lead to different levels of consumer protection.

(35) The information to be provided by the trader to the consumer should be mandatory and should not be altered. Nevertheless, the contracting parties should be able to expressly agree to change the content of the contract subsequently concluded, for instance the arrangements for delivery.

(36) In the case of distance contracts, the information requirements should be adapted to take into account the technical constraints of certain media, such as the restrictions on the number of characters on certain mobile telephone screens or the time constraint on television sales spots. In such cases the trader should comply with a minimum set of information requirements and refer the consumer to another source of information, for instance by providing a toll free telephone number or a hypertext link to a webpage of the trader where the relevant information is directly available and easily accessible. As to the requirement to inform the consumer of the cost of returning goods which by their nature cannot normally be returned by post, it will be considered to have been met, for example, if the trader specifies one carrier (for instance the one he assigned for the delivery of the good) and one price concerning the cost of returning the goods. Where the
Trading websites should indicate clearly and legibly at the point of order that the withdrawal period expires after 14 days from the moment at which the consumer acquires physical possession of the goods. When goods are delivered in multiple lots or pieces, the withdrawal period should expire after 14 days from the day on which the consumer acquires physical possession of the last lot or piece.

Since in the case of distance sales, the consumer is not able to see the goods before concluding the contract, he should have a right of withdrawal. For the same reason, the consumer should be allowed to test and inspect the goods he has bought to the extent necessary to establish the nature, characteristics and the functioning of the goods. Concerning off-premises contracts, the consumer should have the right of withdrawal because of the potential surprise element and/or psychological pressure. Withdrawal from the contract should terminate the obligation of the contracting parties to perform the contract.

It is important to ensure for distance contracts concluded through websites that the consumer is able to fully read and understand the main elements of the contract before placing his order. To that end, provision should be made in this Directive for those elements to be displayed in the close vicinity of the confirmation requested for placing the order. It is also important to ensure that, in such situations, the consumer is able to determine the moment at which he assumes the obligation to pay the trader. Therefore, the consumer’s attention should specifically be drawn, through an unambiguous formulation, to the fact that placing the order entails the obligation to pay the trader.

The current varying lengths of the withdrawal periods both between the Member States and for distance and off-premises contracts cause legal uncertainty and compliance costs. The same withdrawal period should apply to all distance and off-premises contracts. In the case of service contracts, the withdrawal period should expire after 14 days from the conclusion of the contract. In the case of sales contracts, the withdrawal period should expire after 14 days from the day on which the consumer or a third party other than the carrier and indicated by the consumer, acquires physical possession of the goods. Where multiple goods are ordered by the consumer in one order but are delivered separately, the withdrawal period should expire after 14 days from the day on which the consumer acquires physical possession of the last lot or piece.

In order to ensure legal certainty, it is appropriate that Council Regulation (EEC, Euratom) No 1182/71 of 3 June 1971 determining the rules applicable to periods, dates and time limits (1) should apply to the calculation of the periods contained in this Directive. Therefore, all periods contained in this Directive should be understood to be expressed in calendar days. Where a period expressed in days is to be calculated from the moment at which an event occurs or an action takes place, the day during which that event occurs or that action takes place should not be considered as falling within the period in question.

The provisions relating to the right of withdrawal should be without prejudice to the Member States’ laws and regulations governing the termination or unenforceability of a contract or the possibility for the consumer to fulfil his contractual obligations before the time determined in the contract.

If the trader has not adequately informed the consumer prior to the conclusion of a distance or off-premises contract, the withdrawal period should be extended. However, in order to ensure legal certainty as regards the length of the withdrawal period, a 12-month limitation period should be introduced.

Differences in the ways in which the right of withdrawal is exercised in the Member States have caused costs for traders selling cross-border. The introduction of a harmonised model withdrawal form that the consumer may use should simplify the withdrawal process and bring legal certainty. For these reasons, Member States should refrain from adding any presentational requirements to the Union-wide model form relating for example to the font size. However, the consumer should remain free to withdraw in his own words, provided that his statement setting out his decision to withdraw from the contract to the trader is unequivocal. A letter, a telephone call or returning the goods with a clear statement could meet this requirement, but the burden of proof of having withdrawn within the time limits fixed in the Directive should be on the consumer. For this reason, it is in the interest of the consumer to make use of a durable medium when communicating his withdrawal to the trader.

As experience shows that many consumers and traders prefer to communicate via the trader’s website, there should be a possibility for the trader to give the consumer the option of filling in a web-based withdrawal form. In this case the trader should provide an acknowledgement of receipt for instance by e-mail without delay.

In the event that the consumer withdraws from the contract, the trader should reimburse all payments received from the consumer, including those covering the expenses borne by the trader to deliver goods to the consumer. The reimbursement should not be made by voucher unless the consumer has used vouchers for the initial transaction or has expressly accepted them. If the consumer expressly chooses a certain type of delivery (for instance 24-hour express delivery), although the trader had offered a common and generally acceptable type of delivery which would have incurred lower delivery costs, the consumer should bear the difference in costs between these two types of delivery.

Some consumers exercise their right of withdrawal after having used the goods to an extent more than necessary to establish the nature, characteristics and the functioning of the goods. In this case the consumer should not lose the right to withdraw but should be liable for any diminished value of the goods. In order to establish the nature, characteristics and functioning of the goods, the consumer should only handle and inspect them in the same manner as he would be allowed to do in a shop. For example, the consumer should only try on a garment and should not be allowed to wear it. Consequently, the consumer should handle and inspect the goods with due care during the withdrawal period. The obligations of the consumer in the event of withdrawal should not discourage the consumer from exercising his right of withdrawal.

The consumer should be required to send back the goods not later than 14 days after having informed the trader about his decision to withdraw from the contract. In situations where the trader or the consumer does not fulfil the obligations relating to the exercise of the right of withdrawal, penalties provided for by national legislation in accordance with this Directive should apply as well as contract law provisions.

Certain exceptions from the right of withdrawal should exist, both for distance and off-premises contracts. A right of withdrawal could be inappropriate for example given the nature of particular goods or services. That is the case for example with wine supplied a long time after the conclusion of a contract of a speculative nature where the value is dependent on fluctuations in the market (‘vin en primeur’). The right of withdrawal should neither apply to goods made to the consumer’s specifications or which are clearly personalised such as tailor-made curtains, nor to the supply of fuel, for example, which is a good, by nature inseparably mixed with other items after delivery. The granting of a right of withdrawal to the consumer could also be inappropriate in the case of certain services where the conclusion of the contract implies the setting aside of capacity which, if a right of withdrawal were exercised, the trader may find difficult to fill. This would for example be the case where reservations are made at hotels or concerning holiday cottages or cultural or sporting events.

On the one hand, the consumer should benefit from his right of withdrawal even in case he has asked for the provision of services before the end of the withdrawal period. On the other hand, if the consumer exercises his right of withdrawal, the trader should be assured to be adequately paid for the service he has provided. The calculation of the proportionate amount should be based on the price agreed in the contract unless the consumer demonstrates that that total price is itself disproportionate, in which case the amount to be paid shall be calculated on the basis of the market value of the service provided. The market value should be defined by comparing the price of an equivalent service performed by other traders at the time of the conclusion of the contract. Therefore the consumer should request the performance of services before the end of the withdrawal period by making this request expressly and, in the case of off-premises contracts, on a durable medium. Similarly, the trader should inform the consumer on a durable medium of any obligation to pay the proportionate costs for the services already provided. For contracts having as their object both goods and services, the rules provided for in this Directive on the return of goods should apply to the goods aspects and the compensation regime for services should apply to the services aspects.

The main difficulties encountered by consumers and one of the main sources of disputes with traders concern delivery of goods, including goods getting lost or damaged during transport and late or partial delivery. Therefore it is appropriate to clarify and harmonise the national rules as to when delivery should occur. The place and modalities of delivery and the rules concerning the determination of the conditions for the transfer of the ownership of the goods and the moment at which such transfer takes place, should remain subject to national law and therefore should not be affected by this Directive. The rules on delivery laid down in this Directive should include the possibility for the consumer to allow a third party to acquire on his behalf the physical possession or control of the goods. The consumer should be considered to have control of the goods where he or a third party indicated by the consumer has access to the goods to use them as an owner, or the ability to resell the goods (for example, when he has received the keys or possession of the ownership documents).
In the context of sales contracts, the delivery of goods can take place in various ways, either immediately or at a later date. If the parties have not agreed on a specific delivery date, the trader should deliver the goods as soon as possible, but in any event not later than 30 days from the day of the conclusion of the contract. The rules regarding late delivery should also take into account goods to be manufactured or acquired specially for the consumer which cannot be reused by the trader without considerable loss. Therefore, a rule which grants an additional reasonable period of time to the trader in certain circumstances should be provided for in this Directive. When the trader has failed to deliver the goods within the period of time agreed with the consumer, before the consumer can terminate the contract, the consumer should call upon the trader to make the delivery within a reasonable additional period of time and be entitled to terminate the contract if the trader fails to deliver the goods even within that additional period of time. However, this rule should not apply when the trader has refused to deliver the goods in an unequivocal statement. Neither should it apply in certain circumstances where the delivery period is essential such as, for example, in the case of a wedding dress which should be delivered before the wedding. Nor should it apply in circumstances where the consumer informs the trader that delivery on a specified date is essential. For this purpose, the consumer may use the trader’s contact details given in accordance with this Directive. In these specific cases, if the trader fails to deliver the goods on time, the consumer should be entitled to terminate the contract immediately after the expiry of the delivery period initially agreed. This Directive should be without prejudice to national provisions on the way the consumer should notify the trader of his will to terminate the contract.

In addition to the consumer’s right to terminate the contract where the trader has failed to fulfill his obligations to deliver the goods in accordance with this Directive, the consumer may, in accordance with the applicable national law, have recourse to other remedies, such as granting the trader an additional period of time for delivery, enforcing the performance of the contract, withholding payment, and seeking damages.

In accordance with Article 52(3) of Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market (1), Member States should be able to prohibit or limit traders’ right to request charges from consumers taking into account the need to encourage competition and promote the use of efficient payment instruments. In any event, traders should be prohibited from charging consumers fees that exceed the cost borne by the trader for the use of a certain means of payment.

Where the goods are dispatched by the trader to the consumer, disputes may arise, in the event of loss or damage, as to the moment at which the transfer of risk takes place. Therefore this Directive should provide that the consumer be protected against any risk of loss of or damage to the goods occurring before he has acquired the physical possession of the goods. The consumer should be protected during a transport arranged or carried out by the trader, even where the consumer has chosen a particular delivery method from a range of options offered by the trader. However, that provision should not apply to contracts where it is up to the consumer to take delivery of the goods himself or to ask a carrier to take delivery. Regarding the moment of the transfer of the risk, a consumer should be considered to have acquired the physical possession of the goods when he has received them.

Persons or organisations regarded under national law as having a legitimate interest in protecting consumer contractual rights should be afforded the right to initiate proceedings, either before a court or before an administrative authority which is competent to decide upon complaints or to initiate appropriate legal proceedings.

It is necessary that Member States lay down penalties for infringements of this Directive and ensure that they are enforced. The penalties should be effective, proportionate and dissuasive.

The consumer should not be deprived of the protection granted by this Directive. Where the law applicable to the contract is that of a third country, Regulation (EC) No 593/2008 should apply, in order to determine whether the consumer retains the protection granted by this Directive.

The Commission, following consultation with the Member States and stakeholders, should look into the most appropriate way to ensure that all consumers are made aware of their rights at the point of sale.

Since inertia selling, which consists of unsolicited supply of goods or provision of services to consumers, is prohibited by Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market (‘Unfair Commercial Practices Directive’) (2) but no contractual remedy is provided therein, it is necessary to introduce in this Directive the contractual remedy of exempting the consumer from the obligation to provide any consideration for such unsolicited supply or provision.


It is appropriate for the Commission to review this Directive if some barriers to the internal market are identified. In its review, the Commission should pay particular attention to the possibilities granted to Member States to maintain or introduce specific national provisions including in certain areas of Council Directive 93/13/EEC of 5 April 1993 on unfair terms in consumer contracts (2) and Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees (3). That review could lead to a Commission proposal to amend this Directive; that proposal may include amendments to other consumer protection legislation reflecting the Commission’s Consumer Policy Strategy commitment to review the Union acquis in order to achieve a high, common level of consumer protection.

Directives 93/13/EEC and 1999/44/EC should be amended to require Member States to inform the Commission about the adoption of specific national provisions in certain areas.

Directives 85/577/EEC and 97/7/EC should be repealed.

Since the objective of this Directive, namely, through the achievement of a high level of consumer protection, to contribute to the proper functioning of the internal market, 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 Directive does not go beyond what is necessary in order to achieve that objective.

This Directive respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union.

In accordance with point 34 of the Interinstitutional agreement on better law-making (4), Member States are encouraged to draw up, for themselves and in the interests of the Union, their own tables, which will, as far as possible, illustrate the correlation between this Directive and the transposition measures, and to make them public.

CHAPTER I

SUBJECT MATTER, DEFINITIONS AND SCOPE

Article 1

Subject matter

The purpose of this Directive is, through the achievement of a high level of consumer protection, to contribute to the proper functioning of the internal market by approximating certain aspects of the laws, regulations and administrative provisions of the Member States concerning contracts concluded between consumers and traders.

Article 2

Definitions

For the purpose of this Directive, the following definitions shall apply:

(1) ‘consumer’ means any natural person who, in contracts covered by this Directive, is acting for purposes which are outside his trade, business, craft or profession;

(2) ‘trader’ means any natural person or any legal person, irrespective of whether privately or publicly owned, who is acting, including through any other person acting in his name or on his behalf, for purposes relating to his trade, business, craft or profession in relation to contracts covered by this Directive;

(3) ‘goods’ means any tangible movable items, with the exception of items sold by way of execution or otherwise by authority of law; water, gas and electricity shall be considered as goods within the meaning of this Directive where they are put up for sale in a limited volume or a set quantity;

(4) ‘goods made to the consumer’s specifications’ means non-prefabricated goods made on the basis of an individual choice of or decision by the consumer;

(5) ‘sales contract’ means any contract under which the trader transfers or undertakes to transfer the ownership of goods to the consumer and the consumer pays or undertakes to pay the price thereof, including any contract having as its object both goods and services;

(6) ‘service contract’ means any contract other than a sales contract under which the trader supplies or undertakes to supply a service to the consumer and the consumer pays or undertakes to pay the price thereof;

(7) ‘distance contract’ means any contract concluded between the trader and the consumer under an organised distance sales or service-provision scheme without the simultaneous physical presence of the trader and the consumer, with the exclusive use of one or more means of distance communication up to and including the time at which the contract is concluded;

(8) ‘off-premises contract’ means any contract between the trader and the consumer:

(a) concluded in the simultaneous physical presence of the trader and the consumer, in a place which is not the business premises of the trader;

(b) for which an offer was made by the consumer in the same circumstances as referred to in point (a);

(c) concluded on the business premises of the trader or through any means of distance communication immediately after the consumer was personally and individually addressed in a place which is not the business premises of the trader in the simultaneous physical presence of the trader and the consumer; or

(d) concluded during an excursion organised by the trader with the aim or effect of promoting and selling goods or services to the consumer;

(9) ‘business premises’ means:

(a) any immovable retail premises where the trader carries out his activity on a permanent basis; or

(b) any movable retail premises where the trader carries out his activity on a usual basis;

(10) ‘durable medium’ means any instrument which enables the consumer or the trader to store information addressed personally to him in a way accessible for future reference for a period of time adequate for the purposes of the information and which allows the unchanged reproduction of the information stored;

(11) ‘digital content’ means data which are produced and supplied in digital form;

(12) ‘financial service’ means any service of a banking, credit, insurance, personal pension, investment or payment nature;

(13) ‘public auction’ means a method of sale where goods or services are offered by the trader to consumers, who attend or are given the possibility to attend the auction in person, through a transparent, competitive bidding procedure run by an auctioneer and where the successful bidder is bound to purchase the goods or services;

(14) ‘commercial guarantee’ means any undertaking by the trader or a producer (the guarantor) to the consumer, in addition to his legal obligation relating to the guarantee of conformity, to reimburse the price paid or to replace, repair or service goods in any way if they do not meet the specifications or any other requirements not related to conformity set out in the guarantee statement or in the relevant advertising available at the time of, or before the conclusion of the contract;

(15) ‘ancillary contract’ means a contract by which the consumer acquires goods or services related to a distance contract or an off-premises contract and where those goods are supplied or those services are provided by the trader or by a third party on the basis of an arrangement between that third party and the trader.

Article 3

Scope

1. This Directive shall apply, under the conditions and to the extent set out in its provisions, to any contract concluded between a trader and a consumer. It shall also apply to contracts for the supply of water, gas, electricity or district heating, including by public providers, to the extent that these commodities are provided on a contractual basis.

2. If any provision of this Directive conflicts with a provision of another Union act governing specific sectors, the provision of that other Union act shall prevail and shall apply to those specific sectors.

3. This Directive shall not apply to contracts:

(a) for social services, including social housing, childcare and support of families and persons permanently or temporarily in need, including long-term care;

(b) for healthcare as defined in point (a) of Article 3 of Directive 2011/24/EU, whether or not they are provided via healthcare facilities;

(c) for gambling, which involves wagering a stake with pecuniary value in games of chance, including lotteries, casino games and betting transactions;
(d) for financial services;

(e) for the creation, acquisition or transfer of immovable property or of rights in immovable property;

(f) for the construction of new buildings, the substantial conversion of existing buildings and for rental of accommodation for residential purposes;

(g) which fall within the scope of Council Directive 90/314/EEC of 13 June 1990 on package travel, package holidays and package tours (1);

(h) which fall within the scope of Directive 2008/122/EC of the European Parliament and of the Council of 14 January 2009 on the protection of consumers in respect of certain aspects of timeshare, long-term holiday product, resale and exchange contracts (2);

(i) which, in accordance with the laws of Member States, are established by a public office-holder who has a statutory obligation to be independent and impartial and who must ensure, by providing comprehensive legal information, that the consumer only concludes the contract on the basis of careful legal consideration and with knowledge of its legal scope;

(j) for the supply of foodstuffs, beverages or other goods intended for current consumption in the household, and which are physically supplied by a trader on frequent and regular rounds to the consumer's home, residence or workplace;

(k) for passenger transport services, with the exception of Article 8(2) and Articles 19 and 22;

(l) concluded by means of automatic vending machines or automated commercial premises;

(m) concluded with telecommunications operators through public payphones for their use or concluded for the use of one single connection by telephone, Internet or fax established by a consumer.

4. Member States may decide not to apply this Directive or not to maintain or introduce corresponding national provisions to off-premises contracts for which the payment to be made by the consumer does not exceed EUR 50. Member States may define a lower value in their national legislation.

5. This Directive shall not affect national general contract law such as the rules on the validity, formation or effect of a contract, in so far as general contract law aspects are not regulated in this Directive.

6. This Directive shall not prevent traders from offering consumers contractual arrangements which go beyond the protection provided for in this Directive.

Article 4
Level of harmonisation

Member States shall not maintain or introduce, in their national law, provisions diverging from those laid down in this Directive, including more or less stringent provisions to ensure a different level of consumer protection, unless otherwise provided for in this Directive.

CHAPTER II
CONSUMER INFORMATION FOR CONTRACTS OTHER THAN DISTANCE OR OFF-PREMISES CONTRACTS

Article 5
Information requirements for contracts other than distance or off-premises contracts

1. Before the consumer is bound by a contract other than a distance or an off-premises contract, or any corresponding offer, the trader shall provide the consumer with the following information in a clear and comprehensible manner, if that information is not already apparent from the context:

(a) the main characteristics of the goods or services, to the extent appropriate to the medium and to the goods or services;

(b) the identity of the trader, such as his trading name, the geographical address at which he is established and his telephone number;

(c) the total price of the goods or services inclusive of taxes, or where the nature of the goods or services is such that the price cannot reasonably be calculated in advance, the manner in which the price is to be calculated, as well as, where applicable, all additional freight, delivery or postal charges or, where those charges cannot reasonably be calculated in advance, the fact that such additional charges may be payable;

(d) where applicable, the arrangements for payment, delivery, performance, the time by which the trader undertakes to deliver the goods or to perform the service, and the trader's complaint handling policy;

(e) in addition to a reminder of the existence of a legal guarantee of conformity for goods, the existence and the conditions of after-sales services and commercial guarantees, where applicable;

(f) the duration of the contract, where applicable, or, if the contract is of indeterminate duration or is to be extended automatically, the conditions for terminating the contract;

(g) where applicable, the functionality, including applicable technical protection measures, of digital content;

(h) where applicable, any relevant interoperability of digital content with hardware and software that the trader is aware of or can reasonably be expected to have been aware of.

2. Paragraph 1 shall also apply to contracts for the supply of water, gas or electricity, where they are not put up for sale in a limited volume or set quantity, of district heating or of digital content which is not supplied on a tangible medium.

3. Member States shall not be required to apply paragraph 1 to contracts which involve day-to-day transactions and which are performed immediately at the time of their conclusion.

4. Member States may adopt or maintain additional pre-contractual information requirements for contracts to which this Article applies.

CHAPTER III
CONSUMER INFORMATION AND RIGHT OF WITHDRAWAL FOR DISTANCE AND OFF-PREMISES CONTRACTS

Article 6
Information requirements for distance and off-premises contracts

1. Before the consumer is bound by a distance or off-premises contract, or any corresponding offer, the trader shall provide the consumer with the following information in a clear and comprehensible manner:

(a) the main characteristics of the goods or services, to the extent appropriate to the medium and to the goods or services;

(b) the identity of the trader, such as his trading name;

(c) the geographical address at which the trader is established and the trader's telephone number, fax number and e-mail address, where available, to enable the consumer to contact the trader quickly and communicate with him efficiently and, where applicable, the geographical address and identity of the trader on whose behalf he is acting;

(d) if different from the address provided in accordance with point (c), the geographical address of the place of business of the trader, and, where applicable, that of the trader on whose behalf he is acting, where the consumer can address any complaints;

(e) the total price of the goods or services inclusive of taxes, or where the nature of the goods or services is such that the price cannot reasonably be calculated in advance, the manner in which the price is to be calculated, as well as, where applicable, all additional freight, delivery or postal charges and any other costs or, where those charges cannot reasonably be calculated in advance, the fact that such additional charges may be payable. In the case of a contract of indeterminate duration or a contract containing a subscription, the total price shall include the total costs per billing period. Where such contracts are charged at a fixed rate, the total price shall also mean the total monthly costs. Where the total costs cannot be reasonably calculated in advance, the manner in which the price is to be calculated shall be provided;

(f) the cost of using the means of distance communication for the conclusion of the contract where that cost is calculated other than at the basic rate;

(g) the arrangements for payment, delivery, performance, the time by which the trader undertakes to deliver the goods or to perform the services and, where applicable, the trader's complaint handling policy;

(h) where a right of withdrawal exists, the conditions, time limit and procedures for exercising that right in accordance with Article 11(1), as well as the model withdrawal form set out in Annex I(B);

(i) where applicable, that the consumer will have to bear the cost of returning the goods in case of withdrawal and, for distance contracts, if the goods, by their nature, cannot normally be returned by post, the cost of returning the goods;

(j) that, if the consumer exercises the right of withdrawal after having made a request in accordance with Article 7(3) or Article 8(8), the consumer shall be liable to pay the trader reasonable costs in accordance with Article 14(3);

(k) where a right of withdrawal is not provided for in accordance with Article 16, the information that the consumer will not benefit from a right of withdrawal or, where applicable, the circumstances under which the consumer loses his right of withdrawal;
(f) a reminder of the existence of a legal guarantee of conformity for goods;

(m) where applicable, the existence and the conditions of after sale customer assistance, after-sales services and commercial guarantees;

(n) the existence of relevant codes of conduct, as defined in point (f) of Article 2 of Directive 2005/29/EC, and how copies of them can be obtained, where applicable;

(o) the duration of the contract, where applicable, or, if the contract is of indeterminate duration or is to be extended automatically, the conditions for terminating the contract;

(p) where applicable, the minimum duration of the consumer's obligations under the contract;

(q) where applicable, the existence and the conditions of deposits or other financial guarantees to be paid or provided by the consumer at the request of the trader;

(r) where applicable, the functionality, including applicable technical protection measures, of digital content;

(s) where applicable, any relevant interoperability of digital content with hardware and software that the trader is aware of or can reasonably be expected to have been aware of;

(t) where applicable, the possibility of having recourse to an out-of-court complaint and redress mechanism, to which the trader is subject, and the methods for having access to it.

2. Paragraph 1 shall also apply to contracts for the supply of water, gas or electricity, where they are not put up for sale in a limited volume or set quantity, of district heating or of digital content which is not supplied on a tangible medium.

3. In the case of a public auction, the information referred to in points (b), (c) and (d) of paragraph 1 may be replaced by the equivalent details for the auctioneer.

4. The information referred to in points (h), (i) and (j) of paragraph 1 may be provided by means of the model instructions on withdrawal set out in Annex I(A). The trader shall have fulfilled the information requirements laid down in points (h), (i) and (j) of paragraph 1 if he has supplied these instructions to the consumer, correctly filled in.

5. The information referred to in paragraph 1 shall form an integral part of the distance or off-premises contract and shall not be altered unless the contracting parties expressly agree otherwise.

6. If the trader has not complied with the information requirements on additional charges or other costs as referred to in point (e) of paragraph 1, or on the costs of returning the goods as referred to in point (i) of paragraph 1, the consumer shall not bear those charges or costs.

7. Member States may maintain or introduce in their national law language requirements regarding the contractual information, so as to ensure that such information is easily understood by the consumer.

8. The information requirements laid down in this Directive are in addition to information requirements contained in Directive 2006/123/EC and Directive 2000/31/EC and do not prevent Member States from imposing additional information requirements in accordance with those Directives.

Without prejudice to the first subparagraph, if a provision of Directive 2006/123/EC or Directive 2000/31/EC on the content and the manner in which the information is to be provided conflicts with a provision of this Directive, the provision of this Directive shall prevail.

9. As regards compliance with the information requirements laid down in this Chapter, the burden of proof shall be on the trader.

Article 7

Formal requirements for off-premises contracts

1. With respect to off-premises contracts, the trader shall give the information provided for in Article 6(1) to the consumer on paper or, if the consumer agrees, on another durable medium. That information shall be legible and in plain, intelligible language.

2. The trader shall provide the consumer with a copy of the signed contract or the confirmation of the contract on paper or, if the consumer agrees, on another durable medium, including, where applicable, the confirmation of the consumer's prior express consent and acknowledgement in accordance with point (m) of Article 16.

3. Where a consumer wants the performance of services or the supply of water, gas or electricity, where they are not put up for sale in a limited volume or set quantity, or of district heating to begin during the withdrawal period provided for in Article 9(2), the trader shall require that the consumer makes such an express request on a durable medium.
4. With respect to off-premises contracts where the consumer has explicitly requested the services of the trader for the purpose of carrying out repairs or maintenance for which the trader and the consumer immediately perform their contractual obligations and where the payment to be made by the consumer does not exceed EUR 200:

(a) the trader shall provide the consumer with the information referred to in points (b) and (c) of Article 6(1) and information about the price or the manner in which the price is to be calculated together with an estimate of the total price, on paper or, if the consumer agrees, on another durable medium. The trader shall provide the information referred to in points (a), (h) and (k) of Article 6(1), but may choose not to provide it on paper or another durable medium if the consumer expressly agrees;

(b) the confirmation of the contract provided in accordance with paragraph 2 of this Article shall contain the information provided for in Article 6(1).

Member States may decide not to apply this paragraph.

5. Member States shall not impose any further formal pre-contractual information requirements for the fulfilment of the information obligations laid down in this Directive.

Article 8

Formal requirements for distance contracts

1. With respect to distance contracts, the trader shall give the information provided for in Article 6(1) or make that information available to the consumer in a way appropriate to the means of distance communication used in plain and intelligible language. In so far as that information is provided on a durable medium, it shall be legible.

2. If a distance contract to be concluded by electronic means places the consumer under an obligation to pay, the trader shall make the consumer aware in a clear and prominent manner, and directly before the consumer places his order, of the information provided for in points (a), (e), (o) and (p) of Article 6(1).

The trader shall ensure that the consumer, when placing his order, explicitly acknowledges that the order implies an obligation to pay. If placing an order entails activating a button or a similar function, the button or similar function shall be labelled in an easily legible manner only with the words 'order with obligation to pay' or a corresponding unambiguous formulation indicating that placing the order entails an obligation to pay the trader. If the trader has not complied with this subparagraph, the consumer shall not be bound by the contract or order.

3. Trading websites shall indicate clearly and legibly at the latest at the beginning of the ordering process whether any delivery restrictions apply and which means of payment are accepted.

4. If the contract is concluded through a means of distance communication which allows limited space or time to display the information, the trader shall provide, on that particular means prior to the conclusion of such a contract, at least the pre-contractual information regarding the main characteristics of the goods or services, the identity of the trader, the total price, the right of withdrawal, the duration of the contract and, if the contract is of indeterminate duration, the conditions for terminating the contract, as referred to in points (a), (b), (e), (h) and (o) of Article 6(1). The other information referred to in Article 6(1) shall be provided by the trader to the consumer in an appropriate way in accordance with paragraph 1 of this Article.

5. Without prejudice to paragraph 4, if the trader makes a telephone call to the consumer with a view to concluding a distance contract, he shall, at the beginning of the conversation with the consumer, disclose his identity and, where applicable, the identity of the person on whose behalf he makes that call, and the commercial purpose of the call.

6. Where a distance contract is to be concluded by telephone, Member States may provide that the trader has to confirm the offer to the consumer who is bound only once he has signed the offer or has sent his written consent. Member States may also provide that such confirmations have to be made on a durable medium.

7. The trader shall provide the consumer with the confirmation of the contract concluded, on a durable medium within a reasonable time after the conclusion of the distance contract, and at the latest at the time of the delivery of the goods or before the performance of the service begins. That confirmation shall include:

(a) all the information referred to in Article 6(1) unless the trader has already provided that information to the consumer on a durable medium prior to the conclusion of the distance contract; and

(b) where applicable, the confirmation of the consumer’s prior express consent and acknowledgment in accordance with point (m) of Article 16.

8. Where a consumer wants the performance of services, or the supply of water, gas or electricity, where they are not put up for sale in a limited volume or set quantity, or of district heating, to begin during the withdrawal period provided for in Article 9(2), the trader shall require that the consumer make an express request.
9. This Article shall be without prejudice to the provisions on the conclusion of e-contracts and the placing of e-orders set out in Articles 9 and 11 of Directive 2000/31/EC.

10. Member States shall not impose any further formal pre-contractual information requirements for the fulfilment of the information obligations laid down in this Directive.

Article 9

Right of withdrawal

1. Save where the exceptions provided for in Article 16 apply, the consumer shall have a period of 14 days to withdraw from a distance or off-premises contract, without giving any reason, and without incurring any costs other than those provided for in Article 13(2) and Article 14.

2. Without prejudice to Article 10, the withdrawal period referred to in paragraph 1 of this Article shall expire after 14 days from:

(a) in the case of service contracts, the day of the conclusion of the contract;

(b) in the case of sales contracts, the day on which the consumer or a third party other than the carrier and indicated by the consumer acquires physical possession of the goods or:

(i) in the case of multiple goods ordered by the consumer in one order and delivered separately, the day on which the consumer or a third party other than the carrier and indicated by the consumer acquires physical possession of the last good;

(ii) in the case of delivery of a good consisting of multiple lots or pieces, the day on which the consumer or a third party other than the carrier and indicated by the consumer acquires physical possession of the last lot or piece;

(iii) in the case of contracts for regular delivery of goods during defined period of time, the day on which the consumer or a third party other than the carrier and indicated by the consumer acquires physical possession of the first good;

(c) in the case of contracts for the supply of water, gas or electricity, where they are not put up for sale in a limited volume or set quantity, of district heating or of digital content which is not supplied on a tangible medium, the day of the conclusion of the contract.

3. The Member States shall not prohibit the contracting parties from performing their contractual obligations during the withdrawal period. Nevertheless, in the case of off-premises contracts, Member States may maintain existing national legislation prohibiting the trader from collecting the payment from the consumer during the given period after the conclusion of the contract.

Article 10

Omission of information on the right of withdrawal

1. If the trader has not provided the consumer with the information on the right of withdrawal as required by point (h) of Article 6(1), the withdrawal period shall expire 12 months from the end of the initial withdrawal period, as determined in accordance with Article 9(2).

2. If the trader has provided the consumer with the information provided for in paragraph 1 of this Article within 12 months from the day referred to in Article 9(2), the withdrawal period shall expire 14 days after the day upon which the consumer receives that information.

Article 11

Exercise of the right of withdrawal

1. Before the expiry of the withdrawal period, the consumer shall inform the trader of his decision to withdraw from the contract. For this purpose, the consumer may either:

(a) use the model withdrawal form as set out in Annex I(B); or

(b) make any other unequivocal statement setting out his decision to withdraw from the contract.

Member States shall not provide for any formal requirements applicable to the model withdrawal form other than those set out in Annex I(B).

2. The consumer shall have exercised his right of withdrawal within the withdrawal period referred to in Article 9(2) and Article 10 if the communication concerning the exercise of the right of withdrawal is sent by the consumer before that period has expired.

3. The trader may, in addition to the possibilities referred to in paragraph 1, give the option to the consumer to electronically fill in and submit either the model withdrawal form set out in Annex I(B) or any other unequivocal statement on the trader’s website. In those cases the trader shall communicate to the consumer an acknowledgement of receipt of such a withdrawal on a durable medium without delay.

4. The burden of proof of exercising the right of withdrawal in accordance with this Article shall be on the consumer.
Article 12

Effects of withdrawal
The exercise of the right of withdrawal shall terminate the obligations of the parties:

(a) to perform the distance or off-premises contract; or

(b) to conclude the distance or off-premises contract, in cases where an offer was made by the consumer.

Article 13

Obligations of the trader in the event of withdrawal

1. The trader shall reimburse all payments received from the consumer, including, if applicable, the costs of delivery without undue delay and in any event not later than 14 days from the day on which he is informed of the consumer's decision to withdraw from the contract in accordance with Article 11.

The trader shall carry out the reimbursement referred to in the first subparagraph using the same means of payment as the consumer used for the initial transaction, unless the consumer has expressly agreed otherwise and provided that the consumer does not incur any fees as a result of such reimbursement.

2. Notwithstanding paragraph 1, the trader shall not be required to reimburse the supplementary costs, if the consumer has expressly opted for a type of delivery other than the least expensive type of standard delivery offered by the trader.

3. Unless the trader has offered to collect the goods himself, with regard to sales contracts, the trader may withhold the reimbursement until he has received the goods back, or until the consumer has supplied evidence of having sent back the goods, whichever is the earliest.

Article 14

Obligations of the consumer in the event of withdrawal

1. Unless the trader has offered to collect the goods himself, the consumer shall send back the goods or hand them over to the trader or to a person authorised by the trader to receive the goods, without undue delay and in any event not later than 14 days from the day on which he has communicated his decision to withdraw from the contract to the trader in accordance with Article 11. The deadline shall be met if the consumer sends back the goods before the period of 14 days has expired.

The consumer shall only bear the direct cost of returning the goods unless the trader has agreed to bear them or the trader failed to inform the consumer that the consumer has to bear them.

In the case of off-premises contracts where the goods have been delivered to the consumer's home at the time of the conclusion of the contract, the trader shall at his own expense collect the goods if, by their nature, those goods cannot normally be returned by post.

2. The consumer shall only be liable for any diminished value of the goods resulting from the handling of the goods other than what is necessary to establish the nature, characteristics and functioning of the goods. The consumer shall in any event not be liable for diminished value of the goods where the trader has failed to provide notice of the right of withdrawal in accordance with point (h) of Article 6(1).

3. Where a consumer exercises the right of withdrawal after having made a request in accordance with Article 7(3) or Article 8(8), the consumer shall pay to the trader an amount which is in proportion to what has been provided until the time the consumer has informed the trader of the exercise of the right of withdrawal, in comparison with the full coverage of the contract. The proportionate amount to be paid by the consumer to the trader shall be calculated on the basis of the total price agreed in the contract. If the total price is excessive, the proportionate amount shall be calculated on the basis of the market value of what has been provided.

4. The consumer shall bear no cost for:

(a) the performance of services or the supply of water, gas or electricity, where they are not put up for sale in a limited volume or set quantity, or of district heating, in full or in part, during the withdrawal period, where:

(i) the trader has failed to provide information in accordance with points (h) or (j) of Article 6(1); or

(ii) the consumer has not expressly requested performance to begin during the withdrawal period in accordance with Article 7(3) and Article 8(8); or

(b) the supply, in full or in part, of digital content which is not supplied on a tangible medium where:

(i) the consumer has not given his prior express consent to the beginning of the performance before the end of the 14-day period referred to in Article 9;

(ii) the consumer has not acknowledged that he loses his right of withdrawal when giving his consent; or

(iii) the trader has failed to provide confirmation in accordance with Article 7(2) or Article 8(7).
5. Except as provided for in Article 13(2) and in this Article, the consumer shall not incur any liability as a consequence of the exercise of the right of withdrawal.

**Article 15**

Effects of the exercise of the right of withdrawal on ancillary contracts

1. Without prejudice to Article 15 of Directive 2008/48/EC of the European Parliament and of the Council of 23 April 2008 on credit agreements for consumers (1), if the consumer exercises his right of withdrawal from a distance or an off-premises contract in accordance with Articles 9 to 14 of this Directive, any ancillary contracts shall be automatically terminated, without any costs for the consumer, except as provided for in Article 13(2) and in Article 14 of this Directive.

2. The Member States shall lay down detailed rules on the termination of such contracts.

**Article 16**

Exceptions from the right of withdrawal

Member States shall not provide for the right of withdrawal set out in Articles 9 to 15 in respect of distance and off-premises contracts as regards the following:

(a) service contracts after the service has been fully performed if the performance has begun with the consumer’s prior express consent, and with the acknowledgement that he will lose his right of withdrawal once the contract has been fully performed by the trader;

(b) the supply of goods or services for which the price is dependent on fluctuations in the financial market which cannot be controlled by the trader and which may occur within the withdrawal period;

(c) the supply of goods made to the consumer’s specifications or clearly personalised;

(d) the supply of goods which are liable to deteriorate or expire rapidly;

(e) the supply of sealed goods which are not suitable for return due to health protection or hygiene reasons and were unsealed after delivery;

(f) the supply of goods which are, after delivery, according to their nature, inseparably mixed with other items;

(g) the supply of alcoholic beverages, the price of which has been agreed upon at the time of the conclusion of the sales contract, the delivery of which can only take place after 30 days and the actual value of which is dependent on fluctuations in the market which cannot be controlled by the trader;

(h) contracts where the consumer has specifically requested a visit from the trader for the purpose of carrying out urgent repairs or maintenance. If, on the occasion of such visit, the trader provides services in addition to those specifically requested by the consumer or goods other than replacement parts necessarily used in carrying out the repairs, the right of withdrawal shall apply to those additional services or goods;

(i) the supply of sealed audio or sealed video recordings or sealed computer software which were unsealed after delivery;

(j) the supply of a newspaper, periodical or magazine with the exception of subscription contracts for the supply of such publications;

(k) contracts concluded at a public auction;

(l) the provision of accommodation other than for residential purpose, transport of goods, car rental services, catering or services related to leisure activities if the contract provides for a specific date or period of performance;

(m) the supply of digital content which is not supplied on a tangible medium if the performance has begun with the consumer’s prior express consent and his acknowledgment that he thereby loses his right of withdrawal.

**CHAPTER IV**

**OTHER CONSUMER RIGHTS**

**Article 17**

Scope

1. Articles 18 and 20 shall apply to sales contracts. Those Articles shall not apply to contracts for the supply of water, gas or electricity, where they are not put up for sale in a limited volume or set quantity, of district heating or the supply of digital content which is not supplied on a tangible medium.

2. Articles 19, 21 and 22 shall apply to sales and service contracts and to contracts for the supply of water, gas, electricity, district heating or digital content.

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Article 18

Delivery

1. Unless the parties have agreed otherwise on the time of delivery, the trader shall deliver the goods by transferring the physical possession or control of the goods to the consumer without undue delay, but not later than 30 days from the conclusion of the contract.

2. Where the trader has failed to fulfil his obligation to deliver the goods at the time agreed upon with the consumer or within the time limit set out in paragraph 1, the consumer shall call upon him to make the delivery within an additional period of time appropriate to the circumstances. If the trader fails to deliver the goods within that additional period of time, the consumer shall be entitled to terminate the contract.

The first subparagraph shall not be applicable to sales contracts where the trader has refused to deliver the goods or where delivery within the agreed delivery period is essential taking into account all the circumstances attending the conclusion of the contract or where the consumer informs the trader, prior to the conclusion of the contract, that delivery by or on a specified date is essential. In those cases, if the trader fails to deliver the goods at the time agreed upon with the consumer or within the time limit set out in paragraph 1, the consumer shall be entitled to terminate the contract immediately.

3. Upon termination of the contract, the trader shall, without undue delay, reimburse all sums paid under the contract.

4. In addition to the termination of the contract in accordance with paragraph 2, the consumer may have recourse to other remedies provided for by national law.

Article 19

Fees for the use of means of payment

Member States shall prohibit traders from charging consumers, in respect of the use of a given means of payment, fees that exceed the cost borne by the trader for the use of such means.

Article 20

Passing of risk

In contracts where the trader dispatches the goods to the consumer, the risk of loss of or damage to the goods shall pass to the consumer when he or a third party indicated by the consumer and other than the carrier has acquired the physical possession of the goods. However, the risk shall pass to the consumer upon delivery to the carrier if the carrier was commissioned by the consumer to carry the goods and that choice was not offered by the trader, without prejudice to the rights of the consumer against the carrier.

Article 21

Communication by telephone

Member States shall ensure that where the trader operates a telephone line for the purpose of contacting him by telephone in relation to the contract concluded, the consumer, when contacting the trader is not bound to pay more than the basic rate.

The first subparagraph shall be without prejudice to the right of telecommunication services providers to charge for such calls.

Article 22

Additional payments

Before the consumer is bound by the contract or offer, the trader shall seek the express consent of the consumer to any extra payment in addition to the remuneration agreed upon for the trader’s main contractual obligation. If the trader has not obtained the consumer’s express consent but has inferred it by using default options which the consumer is required to reject in order to avoid the additional payment, the consumer shall be entitled to reimbursement of this payment.

CHAPTER V

GENERAL PROVISIONS

Article 23

Enforcement

1. Member States shall ensure that adequate and effective means exist to ensure compliance with this Directive.

2. The means referred to in paragraph 1 shall include provisions whereby one or more of the following bodies, as determined by national law, may take action under national law before the courts or before the competent administrative bodies to ensure that the national provisions transposing this Directive are applied:

(a) public bodies or their representatives;

(b) consumer organisations having a legitimate interest in protecting consumers;

(c) professional organisations having a legitimate interest in acting.

Article 24

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.
2. Member States shall notify those provisions to the Commission by 13 December 2013 and shall notify it without delay of any subsequent amendment affecting them.

**Article 25**

**Imperative nature of the Directive**

If the law applicable to the contract is the law of a Member State, consumers may not waive the rights conferred on them by the national measures transposing this Directive. Any contractual terms which directly or indirectly waive or restrict the rights resulting from this Directive shall not be binding on the consumer.

**Article 26**

**Information**

Member States shall take appropriate measures to inform consumers and traders of the national provisions transposing this Directive and shall, where appropriate, encourage traders and code owners as defined in point (g) of Article 2 of Directive 2005/29/EC, to inform consumers of their codes of conduct.

**Article 27**

**Inertia selling**

The consumer shall be exempted from the obligation to provide any consideration in cases of unsolicited supply of goods, water, gas, electricity, district heating or digital content or unsolicited provision of services, prohibited by Article 5(5) and point 29 of Annex I to Directive 2005/29/EC. In such cases, the absence of a response from the consumer following such an unsolicited supply or provision shall not constitute consent.

**Article 28**

**Transposition**

1. Member States shall adopt and publish, by 13 December 2013, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of these measures in the form of documents. The Commission shall make use of these documents for the purposes of the report referred to in Article 30.

They shall apply those measures from 13 June 2014.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. The provisions of this Directive shall apply to contracts concluded after 13 June 2014.

**Article 29**

**Reporting requirements**

1. Where a Member State makes use of any of the regulatory choices referred to in Article 3(4), Article 6(7), Article 6(8), Article 7(4), Article 8(6) and Article 9(3), it shall inform the Commission thereof by 13 December 2013, as well as of any subsequent changes.

2. The Commission shall ensure that the information referred to in paragraph 1 is easily accessible to consumers and traders, inter alia, on a dedicated website.

3. The Commission shall forward the information referred to in paragraph 1 to the other Member States and the European Parliament. The Commission shall consult stakeholders on that information.

**Article 30**

**Reporting by the Commission and review**

By 13 December 2016, the Commission shall submit a report on the application of this Directive to the European Parliament and the Council. That report shall include in particular an evaluation of the provisions of this Directive regarding digital content including the right of withdrawal. The report shall be accompanied, where necessary, by legislative proposals to adapt this Directive to developments in the field of consumer rights.

**CHAPTER VI**

**FINAL PROVISIONS**

**Article 31**

**Repeals**


References to the repealed Directives shall be construed as references to this Directive and shall be read in accordance with the correlation table set out in Annex II.

Article 32

Amendment to Directive 93/13/EEC

In Directive 93/13/EEC, the following Article is inserted:

‘Article 8a

1. Where a Member State adopts provisions in accordance with Article 8, it shall inform the Commission thereof, as well as of any subsequent changes, in particular where those provisions:

— extend the unfairness assessment to individually negotiated contractual terms or to the adequacy of the price or remuneration; or,

— contain lists of contractual terms which shall be considered as unfair,

2. The Commission shall ensure that the information referred to in paragraph 1 is easily accessible to consumers and traders, inter alia, on a dedicated website.

3. The Commission shall forward the information referred to in paragraph 1 to the other Member States and the European Parliament. The Commission shall consult stakeholders on that information.’

Article 33

Amendment to Directive 1999/44/EC

In Directive 1999/44/EC, the following Article is inserted:

‘Article 8a

Reporting requirements

1. Where, in accordance with Article 8(2), a Member State adopts more stringent consumer protection provisions than those provided for in Article 5(1) to (3) and in Article 7(1), it shall inform the Commission thereof, as well as of any subsequent changes.

2. The Commission shall ensure that the information referred to in paragraph 1 is easily accessible to consumers and traders, inter alia, on a dedicated website.

3. The Commission shall forward the information referred to in paragraph 1 to the other Member States and the European Parliament. The Commission shall consult stakeholders on that information.’

Article 34

Entry into force

This Directive shall enter into force on the 20th day following its publication in the Official Journal of the European Union.

Article 35

Addressees

This Directive is addressed to the Member States.

Done at Strasbourg, 25 October 2011.

For the European Parliament

The President

J. BUZEK

For the Council

The President

M. DOWGIELEWICZ
ANNEX I

Information concerning the exercise of the right of withdrawal

A. Model instructions on withdrawal

Right of withdrawal

You have the right to withdraw from this contract within 14 days without giving any reason.

The withdrawal period will expire after 14 days from the day [1].

To exercise the right of withdrawal, you must inform us (2) of your decision to withdraw from this contract by an unequivocal statement (e.g. a letter sent by post, fax or e-mail). You may use the attached model withdrawal form, but it is not obligatory. [3]

To meet the withdrawal deadline, it is sufficient for you to send your communication concerning your exercise of the right of withdrawal before the withdrawal period has expired.

Effects of withdrawal

If you withdraw from this contract, we shall reimburse to you all payments received from you, including the costs of delivery (with the exception of the supplementary costs resulting from your choice of a type of delivery other than the least expensive type of standard delivery offered by us), without undue delay and in any event not later than 14 days from the day on which we are informed about your decision to withdraw from this contract. We will carry out such reimbursement using the same means of payment as you used for the initial transaction, unless you have expressly agreed otherwise; in any event, you will not incur any fees as a result of such reimbursement. [4]

Instructions for completion:

1. Insert one of the following texts between inverted commas:

   (a) in the case of a service contract or a contract for the supply of water, gas or electricity, where they are not put up for sale in a limited volume or set quantity, of district heating or of digital content which is not supplied on a tangible medium: 'of the conclusion of the contract.';

   (b) in the case of a sales contract: 'on which you acquire, or a third party other than the carrier and indicated by you acquires, physical possession of the goods.';

   (c) in the case of a contract relating to multiple goods ordered by the consumer in one order and delivered separately: 'on which you acquire, or a third party other than the carrier and indicated by you acquires, physical possession of the last good.';

   (d) in the case of a contract relating to delivery of a good consisting of multiple lots or pieces: 'on which you acquire, or a third party other than the carrier and indicated by you acquires, physical possession of the last lot or piece.';

   (e) in the case of a contract for regular delivery of goods during a defined period of time: 'on which you acquire, or a third party other than the carrier and indicated by you acquires, physical possession of the first good.'.

2. Insert your name, geographical address and, where available, your telephone number, fax number and e-mail address.

3. If you give the option to the consumer to electronically fill in and submit information about his withdrawal from the contract on your website, insert the following: 'You can also electronically fill in and submit the model withdrawal form or any other unequivocal statement on our website [insert Internet address]. If you use this option, we will communicate to you an acknowledgement of receipt of such a withdrawal on a durable medium (e.g. by e-mail) without delay.'.

4. In the case of sales contracts in which you have not offered to collect the goods in the event of withdrawal insert the following: 'We may withhold reimbursement until we have received the goods back or you have supplied evidence of having sent back the goods, whichever is the earliest.'.
5. If the consumer has received goods in connection with the contract:

(a) insert:

— ‘We will collect the goods.; or,

— ‘You shall send back the goods or hand them over to us or … [insert the name and geographical address, where applicable, of the person authorised by you to receive the goods], without undue delay and in any event not later than 14 days from the day on which you communicate your withdrawal from this contract to us. The deadline is met if you send back the goods before the period of 14 days has expired.’

(b) insert:

— ‘We will bear the cost of returning the goods.’,

— ‘You will have to bear the direct cost of returning the goods.’,

— If, in a distance contract, you do not offer to bear the cost of returning the goods and the goods, by their nature, cannot normally be returned by post: ‘You will have to bear the direct cost of returning the goods. The cost is estimated at a maximum of approximately ... EUR [insert the amount]; or if the cost of returning the goods cannot reasonably be calculated in advance: ‘You will have to bear the direct cost of returning the goods. The cost is estimated at a maximum of approximately ... EUR [insert the amount]; or

— If, in an off-premises contract, the goods, by their nature, cannot normally be returned by post and have been delivered to the consumer’s home at the time of the conclusion of the contract: ‘We will collect the goods at our own expense.; and,

(c) insert ‘You are only liable for any diminished value of the goods resulting from the handling other than what is necessary to establish the nature, characteristics and functioning of the goods.’

6. In the case of a contract for the provision of services or the supply of water, gas or electricity, where they are not put up for sale in a limited volume or set quantity, or of district heating, insert the following: ‘If you requested to begin the performance of services or the supply of water/gas/electricity/district heating [delete where inapplicable] during the withdrawal period, you shall pay us an amount which is in proportion to what has been provided until you have communicated us your withdrawal from this contract, in comparison with the full coverage of the contract.’.

B. Model withdrawal form

(complete and return this form only if you wish to withdraw from the contract)

— To [here the trader’s name, geographical address and, where available, his fax number and e-mail address are to be inserted by the trader]:

— I/We (*) hereby give notice that I/We (*) withdraw from my/our (*) contract of sale of the following goods (*)/for the provision of the following service (*).

— Ordered on (*)/received on (*).

— Name of consumer(s),

— Address of consumer(s),

— Signature of consumer(s) (only if this form is notified on paper).

— Date

(*) Delete as appropriate.
## ANNEX II

### Correlation table

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To be construed as a reference to

Paragraphs 2 and 11

This Directive

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